Development of a Core Outcome Set for Person-Centred Outcomes in End-of-Life Care in Critical Care (PEACE-COS)

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Abstract

***Background*:** Critical care end-of-life research employs a diverse range of outcomes, including clinical, composite, observer and proxy-reported. However, there is a lack of agreement on *'what'* to measure in these studies, with limited emphasis on person-centred outcomes. Furthermore, outcomes are inconsistently reported, limiting the synthesis of evidence and the comparability of study findings.

***Aim*:** To develop a core outcome set (COS) for research evaluating end-of-life care (EoLC) in critical care.

Methods: Following established COS methodology, a four-stage study was undertaken. A systematic review (Stage One) and a qualitative interview and focus group study (Stage Two) identified a long list of potential outcomes for consideration in the COS. An international two-round modified e-Delphi study (Stage Three) was conducted, where panellists (patient/family representatives, health professionals, and researchers) rated the importance of outcomes for inclusion on a 9-point Likert scale. Consensus for inclusion was defined *a priori*. Framework analysis was employed to systematically organise and interpret qualitative comments. An international consensus meeting was held with key stakeholders to reach a final consensus on the outcomes for inclusion and to ratify the COS (Stage Four).

***Participants*:** Sixteen health professionals participated in Stage Two. Eighty-four panel members from ten countries across five continents participated in Stage Three. Six patient/family representatives attended a pre-consensus meeting, and 14 stakeholders attended the consensus meeting (Stage Four).

Results: Stage One identified 114 unique outcomes with Stage Two identifying 175 outcomes. Panellists rated 93 outcomes in Round One and 69 outcomes in Round Two. Consensus was achieved on the inclusion of 27 outcomes. Reasons an outcome was considered either critical or not critical for inclusion were attributed to 14 themes. Ten themes and 29 subthemes emerged from the reasons provided for score alterations between rounds, with the most common reasons being *'human consequences'* and *'importance'*. Six outcomes were ratified for inclusion in the final COS: pain, respiratory distress, delirium, dignity, quality of death and dying, and quality of communication.

Conclusion: This is the first study to develop a COS for EoLC in critical care. It has the potential to reduce future research waste by standardising outcome selection, reducing heterogeneity in study reporting, facilitating the comparability of findings, and improving research quality.

Public Researcher Partners Contribution: Study design, public-facing study documents, participant engagement resources, and presentation of findings.

Dedications



Dedicated to my parents, Mary and Dave, for their unconditional support and encouragement through the ups and downs and everything in between. They made innumerable sacrifices to enable me to complete my PhD journey and believed in me throughout. To Jessie, my phenomenal Guide Dog, who patiently walked beside me through every stage, guiding me to conferences while providing continual reassurance and unwavering support both at home and at work.

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Abbreviations

Abbreviation	Full Name
AOS	Airway Obstruction Scale
APACHE II	Acute Physiology and Chronic Health Evaluation II
APACHE III	Acute Physiology and Chronic Health Evaluation III
BEAQ	Brief Experiential Avoidance Questionnaire
BPS	Behavioural Pain Scale score
CAESAR	Care Assessment of the Experience of Relatives scale
CCFSS	Critical Care Family Satisfaction Survey
CENTRAL	Cochrane Central Register of Controlled Trials
CEQUEL	Caregiver Evaluation of the Quality of End-of-Life Scales
CEQUEL-Revised	Caregiver Evaluation of the Quality of End-of-Life Scales - Revised
ClinRO	Clinician-reported outcome
COMET	Core Outcome Measures in Effectiveness Trials
COSMIC	Caregiver Self-Efficacy in the ICU Scale
COSSTAD	Core Outcome Set Standards for Development
COS-STAR	Core Outcome Set Standards for Reporting
CSACD	Collaboration and Satisfaction about Care Decisions Scale
DASS	Depression Anxiety Stress Scales
DCS	Decision Conflict Scale
DRS	Decisional Regret Scale
DTS	Distress Tolerance Scale
DTS-Revised	Distress Tolerance Scale revised version
EEW	Evaluation of the Experience of Withdrawal
EoL	End-of-Life
EoLC	End-of-Life Care
FDMSS	Family Decision-Making Self-efficacy Scale: Unconscious Patient Scenario
FMWBQ	Family member well-being
FOLLOS	Fear of Losing Loved Ones Scale
FS-ICU-24	The Family Satisfaction in the Intensive Care Unit scale
FS-ICU-35	The Family Satisfaction in the Intensive Care Unit scale
GAD-7	Generalised Anxiety Disorder-7
GRADE	Grading of Recommendations, Assessment, Development and Evaluations

GRIPP 2	Guidance for Reporting Involvement of Patients and the Public
HADS	Hospital anxiety and depression scale
ICG	Inventory of Complicated Grief
ICNARC	Intensive Care National Audit and Research Centre
ICU	Intensive Care Unit
ICUQODD	Quality of Dying and Death in the ICU instrument
IES	Impact of Event Scale
IES-R	Impact of Event Scale-Revised
JSS	Job Strain Score
KADL	Katz Activities of Daily Living
LMIC	Low/middle-income country
LST	Life sustaining treatment
MBI	Maslach Burnout Inventory
MISS-21	Rapport subscale of the medical interview satisfaction scale
mNGT	Modified Nominal Group Technique
MOMENT	Management of Otitis Media with Effusion in Cleft Palate Scoring System
NACEL	National Audit of Care at the End of Life
NEST	Needs; Existential concerns; Symptoms; and Therapeutic interaction scale
NEST - Adapted	Adapted needs of social nature, existential concerns, symptoms, and therapeutic interaction scale
NGT	Nominal Group Technique
OMERACT	Outcome Measures for Rheumatology Clinical Trials
OMI	Outcome Measurement Instrument
PCCS	Patient-Centeredness of Care Scale
PICOC	Population, Intervention, Comparison, Outcome, Context
PTSD PCL-C	Post-Traumatic Stress Disorder Checklist Civilian Version
PDEQ	Peritraumatic Dissociative Experiences Questionnaire
PDI ICU	Peritraumatic Distress Inventory ICU Version
PDI modified	Peritraumatic Distress Inventory
PG-12	Prolonged Grief 12
PG-12 Carer Version	Prolonged Grief Disorder Carer Version
PG-13	Prolonged Grief-13 questionnaire
PHQ-8	The Patient Health Questionnaire depression scale
PHQ-9	Patient Health Questionnaire-9

POMS-SF	Profile of mood states short form
PPC modified	Patient perception of patient centredness scale, modified for use by surrogate
PREM	Patient-reported experience measure
PRO	Patient-reported outcome
PROM	Patient-reported outcome measure
PROSPERO	International Prospective Register of Systematic Reviews
ProxRO	Proxy-reported outcome
PTSS	Post-Traumatic Stress Syndrome inventory
QEOLC-10	Quality of End-of-Life Care–10 instrument
QOC	Quality of Communication questionnaire
QODD	Quality of Dying and Death questionnaire
QODD-1	Quality of death and dying-1 scale
QoL2	Quality of Life scale for terminal cancer patients
RCT	Randomised Controlled Trial
RDOS	Respiratory Distress Observation Scale
SF-36	Health Survey Short Form-36
SSDM	Satisfaction on Shared Decision-Making scale
STAI-Y Trait	State Trait Anxiety Questionnaire—Trait Scale
vNGT	Virtual Nominal Group Technique
WHO ICTRP	World Health Organisation International Clinical Trials Registry Platform

Table of contents

Abstract i
Dedications ii
Acknowledgements ii
Abbreviations iii
Table of contents vi
List of tables xii
List of figures xiv
List of appendices xvi
Publications and presentations xviii
Initials of researchers involved in thesis research xx

Chapter 1: Introduction and Background 1
1.1 Critical care 1
1.2 End-of-Life Care 2
1.3 Person-centred 4
1.4 Interventions in EoL 5
1.5 Outcome selection and type 6
1.6 The problem of outcomes in Critical Care research 9
1.7 Core outcome sets (COS) 10
1.7.1 Aim 11
1.7.2 Objectives 11
1.8 Conclusion 12
1.9 Next chapter 12

Chapter 2: Methods 13
2.1 Research Paradigms and Standpoints 13
2.1.1 Positivism 14
2.1.2 Post-positivism 14
2.1.3 Constructivism 15
2.1.4 Critical theory paradigm 15
2.1.5 Pragmatism 16
2.1.6 Application to the PEACE-COS study 17
2.1.7 Researcher positionality 18

2.2 COS methodology 20
2.2.1 OMERACT (Outcome Measures for Rheumatology Clinical Trials) 20
2.2.2 COMET (Core Outcome Measures in Effectiveness Trials) 21
2.3 COS development standards 23
2.3.1 Define 23
2.3.2 Check 24
2.3.3 Develop 25
2.3.4 COS stakeholder involvement 25
2.3.5 Determine 30
2.3.6 COS consensus process 37
2.3.7 PEACE-COS Stage Three 50
2.3.8 PEACE-COS Stage Four 53
2.4 Ethical and regulatory considerations 53
2.5 Next chapter 54

Chapter 3: A systematic review to inform the development of a core outcome set for end-of-life care in critical care 55
3.1 Abstract 55
3.2 Introduction 56
3.2.1 Rationale 56
3.2.2 Objectives 57
3.3 Methods 57
3.3.1 Eligibility criteria 57
3.3.2 Information sources 58
3.3.3 Search strategy 59
3.3.4 Selection process 61
3.4 Data Extraction 65
3.4.1 Methodological quality 66
3.4.2 Data synthesis 68
3.5 Results 68
3.5.1 Study selection 68
3.5.2 Study characteristics 69
3.5.3 Intervention type 71
3.5.4 Outcomes 72
3.5.5 Outcome data source 75
3.5.6 Outcome frequency 78

3.5.7 Outcome Measurement Instruments (OMIs) 80
3.5.8 Database registration 83
3.5.9 Study quality 83
3.6 Discussion 85
3.6.1 Strengths and limitations 87
3.7 Conclusion 88
3.8 Next chapter 89

Chapter 4: What outcomes are important in EoLC research in critical care? A qualitative study of EoLC experience 90
4.1 Abstract 90
4.2 Introduction 90
4.3 Background 91
4.4 Study design 92
4.4.1 Aims 92
4.4.2 Theoretical framework 92
4.5 Participant selection and setting 92
4.5.1 Sampling 93
4.5.2 Methods of approach 94
4.5.3 Study timelines 95
4.6 Ethical considerations 99
4.6.1 Participant support 99
4.6.2 Researcher support 99
4.6.3 Ethical approval 100
4.7 Data collection methods 100
4.7.1 Topic guide 101
4.7.2 Audio-visual recording 102
4.8 Analysis and finding 103
4.8.1 Data analysis 103
4.8.2 Research team, rigour and reflexivity 108
4.9 Findings 111
4.9.1 Care satisfaction 112
4.9.2 Communication 114
4.9.3 Decision making 118
4.9.4 Impact on family 122
4.9.5 Patient and family centred 126

4.9.6 Professional competency 130
4.9.7 Staff burden 134
4.9.8 Resource use 139
4.9.9 Outcomes used 141
4.10 Discussion 142
4.11 Strengths 145
4.12 Limitations 145
4.13 Conclusion 147
4.14 Next chapter 147

Chapter 5: An International eDelphi study 148
5.1 Abstract 148
5.2 Introduction 149
5.3 Methods 149
5.3.1 Research question 149
5.3.2 The modified eDelphi technique 149
5.4 Stakeholder panel 150
5.4.1 Group size 154
5.5 Ethical considerations 156
5.5.1 Consent 156
5.5.2 Study setting 156
5.6 Questionnaire development 157
5.7 Data collection methods 160
5.7.1 Data validation 161
5.7.2 Pilot 164
5.8 Round One 164
5.8.1 Scoring 165
5.9 Round Two 166
5.10 Data analysis 169
5.10.1 Quantitative data analysis 169
5.10.2 Qualitative data analysis 170
5.10.3 Reflexivity 176
5.10.4 Attrition analysis 176
5.11 Results 176
5.11.1 Participant characteristics 180
5.11.2 Round One 182

5.11.3 Round One outcomes suggested 191
5.11.4 Round One free text comments 191
5.11.5 Description themes 193
5.11.6 Critical for inclusion themes 196
5.11.7 Not critical for inclusion themes 197
5.12 Round Two 199
5.12.1 Participant characteristics 199
5.12.2 Round Two consensus 201
5.12.3 Scoring changes 208
5.12.4 Critical and not critical for inclusion themes 212
5.12.5 Attrition analysis 212
5.13 Discussion 214
5.14 Strengths 217
5.15 Limitations 217
5.16 Conclusion 218
5.17 Next chapter 219

Chapter 6: An International Consensus Meeting 220
6.1 Abstract 220
6.2 Introduction 220
6.3 Methods 221
6.3.1 Aims 221
6.3.2 Study design 221
6.3.3 Sample identification 221
6.3.4 Ethical approval and consent 222
6.3.5 Steering committee consultation 222
6.3.6 Pilot 224
6.3.7 Consensus meeting structure 224
6.3.8 Qualitative data analysis 231
6.4 Results 232
6.4.1 Pre-consensus meeting 232
6.4.2 Consensus meeting 235
6.4.3 Participant characteristics 236
6.4.4 Coding frameworks 240
6.4.5 Final outcomes included 252
6.5 Discussion 256

6.5.1 Main findings 256
6.5.2 Strengths and limitations 259
6.6 Conclusion 261

Chapter 7: Discussion 262
7.1 Introduction 262
7.2 Summary of findings 262
7.3 Implications and impact 264
7.3.1 Stage One 264
7.3.2 Stage Two 265
7.3.3 Stage Three 265
7.3.4 Stage Four 266
7.4 Strengths 268
7.4.1 Methodological peer review and rigour 268
7.4.2 Mixed-methods approach 268
7.4.3 Inclusive accessible design 269
7.4.4 Public research partners 270
7.4.5 Pre-consensus meeting 270
7.5 Limitations 270
7.5.1 Recruitment challenges 270
7.5.2 Consideration of proxies 271
7.5.3 Consideration of critical illness survivors 272
7.5.4 Linguistics 273
7.5.5 Steering committee composition and independence 273
7.5.6 Inclusion of Low-Middle Income Countries 273
7.6 Dissemination 274
7.7 Future work 275
7.8 Conclusion 277

References 278

Appendices 319

List of tables

Table 2.1 Example of defining a broad and narrow scope 23
Table 2.2 PEACE-COS COS-STAD scope 24
Table 2.3 PEACE-COS COS-STAD stakeholder involvement 27
Table 2.4 Critical care COS Delphi panel sizes 41
Table 2.5 Critical care COS Delphi timings 48
Table 2.6 PEACE-COS COS-STAD eDelphi consensus 49
Table 2.7 PEACE-COS COS-STAD eDelphi stakeholder involvement 51

Table 3.1 Bibliographic database coverage 59
Table 3.2 Interpretation of K statistic 62
Table 3.3 Title and abstract screening agreement and interrater reliability 63
Table 3.4 Full text screening agreement and interrater reliability 65
Table 3.5 Study characteristics 71
Table 3.6 Study Interventions 72
Table 3.7 Outcomes classified according to the COMET taxonomy 74
Table 3.8 Outcome source 77
Table 3.9 Outcomes defined 78
Table 3.10 Top twenty outcomes per outcome 79
Table 3.11 Outcome Measurement Instrument 81
Table 3.12 Study-specific OMI 83
Table 3.13 Assessment of MOMENT criteria 84

Table 4.1 Professional characteristics 98
Table 4.2 Extract of pain outcomes codebook 105

Table 5.1 Stakeholder inclusion criteria 155
Table 5.2 Outcome reduction for Round One 159
Table 5.3 Outcomes modified for Round One 160
Table 5.4 Consensus definition 169
Table 5.5 Round One stakeholder progress 178
Table 5.6 Completion times of those who completed Round One 179
Table 5.7 Round One participant characteristics, according to free-text comments 181
Table 5.8 Round One outcomes per stakeholder group 184

Table 5.9 Round Two participant characteristics, according to free-text comments 200
Table 5.10 Round Two rating by stakeholder group 203
Table 5.11 Round Two number of rating changes 208
Table 5.12 Round Two: number of rating changes within categories 209
Table 5.13 Round Two: number of rating changes across consensus threshold 209
Table 5.14 Free-text comments reason for score change 211

Table 6.1 Outcomes for consensus meeting 223
Table 6.2 Pre-consensus meeting results 234
Table 6.3 Characteristics of participants across the consensus process 237
Table 6.4 Final consensus meeting voting 238
Table 6.5 Reasons for core 242
Table 6.6 Core framework matrix per outcome 243
Table 6.7 Reason non-core 246
Table 6.8 Non-core framework matrix per outcome 247
Table 6.9 Outcome descriptions 256

Table 7.1 Outcome Measurement Instruments 276

List of figures

Figure 1.1 End-of-life trajectory....3
Figure 1.2 Types of outcomes in critical care....7

Figure 2.1 PEACE-COS schematic....18
Figure 2.2 The OMERACT COS development process....21
Figure 2.3 The COMET COS development process....22
Figure 2.4 PEACE-COS Public research partner involvement....29

Figure 3.1 Author contact process....64
Figure 3.2 MOMENT criteria....67
Figure 3.3 Prisma flow diagram....70
Figure 3.4 Unique outcome generation process....73
Figure 3.5 Themes....75
Figure 3.6 Risk of bias assessment for randomised controlled trials....85
Figure 3.7 Risk of bias assessment for non-randomised studies....85

Figure 4.1 Recruitment timelines....95
Figure 4.2 Recruitment numbers by method....97
Figure 4.3 Sample topic guide....102
Figure 4.4 Stage Two qualitative data collection, coding and analysis process....104
Figure 4.5 Coding example of the outcome pain....106
Figure 4.6 Case classifications created in NVivo....107
Figure 4.7 Stage Two memos example....109
Figure 4.8 Stage Two reflective journal....110
Figure 4.9 Diagrammatic representation of the eight outcome themes....111

Figure 5.1 Sample identification and recruitment process....151
Figure 5.2 Cognitive theory of multimedia learning....153
Figure 5.3 Round One outcome generation....158
Figure 5.4 Example of stop logic employed....161
Figure 5.5 Example of how screening questions are presented depending on branching logic related to stakeholder group....163
Figure 5.6 Example of Round One free-text box....166

Figure 5.7 Example of Round Two outcome within the Mortality domain.....167
Figure 5.8 Example of changes to Round Two outcome and description 168
Figure 5.9 Framework analysis process 171
Figure 5.10 Outcome Framework for Metabolic and Nutrition Outcomes 173
Figure 5.11 Nausea and vomiting outcome matrix.....175
Figure 5.12 Round One QR engagement 177
Figure 5.13 Round One participant location by continent 180
Figure 5.14 Round One consensus infographic.....183
Figure 5.15 Round One comment themes 192
Figure 5.16 Round One description themes and subthemes 195
Figure 5.17 Round Two participant location by continent 199
Figure 5.18 Round Two consensus infographic.....202
Figure 5.19 Thematic scheme of reasons for score change 210
Figure 5.20 Participant flow 213

Figure 6.1 Overview of the modified nominal group technique process.....225
Figure 6.2 Pre-consensus meeting survival outcome 227
Figure 6.3 Consensus meeting survival outcome 229
Figure 6.4 Example of consensus meeting voting 230
Figure 6.5 Pre-consensus meeting results.....233
Figure 6.6 Consensus meeting attendance by stakeholder group 236
Figure 6.7 Thematic scheme of reasons for core or non-core 241
Figure 6.8 Euler diagram of core and non-core themes and subthemes 251
Figure 6.9 Identification and selection of outcomes 252
Figure 6.10 Final COS 253

Figure 7.1 Summary of findings 263

List of appendices

Appendix 1 The hybrid emic-etic positionality 319
Appendix 2 Public researcher partners 320
Appendix 3 Steering committee 320
Appendix 4 HRA approvals 321
Appendix 5 University of Hertfordshire approvals 330
Appendix 6 Medline initial search 332
Appendix 7 PRESS (2015) Guideline evidence-based checklist 333
Appendix 8 Final Medline search 335
Appendix 9 Database search strategies 336
Appendix 10 Data extraction form fields 346
Appendix 11 Included studies 357
Appendix 12 Supplementary study data sources 360
Appendix 13 All outcomes extracted 361
Appendix 14 Unique outcomes 381
Appendix 15 Outcome assessment timing 400
Appendix 16 Quality assessment MOMENT score 412
Appendix 17 CASP quality assessment 413
Appendix 18 Cochrane risk of bias tool 414
Appendix 19 ROBINS-I tool 414
Appendix 20 Stage Two NHS family members recruitment flow chart 415
Appendix 21 Stage Two Health professionals recruitment flow chart 415
Appendix 22 Stage Two participant booklet and consent form example 416
Appendix 23 Stage Two poster example 425
Appendix 24 Stage Two social media assets 426
Appendix 25 Stage Two Non-NHS family member recruitment flow chart 427
Appendix 26 Management of distressed participants protocol 428
Appendix 27 Stage Two researcher safety protocol 429
Appendix 28 Transcriber distress protocol 430
Appendix 29 Data information flow protocol 431
Appendix 30 Theme care satisfaction coding 432
Appendix 31 Theme communication coding 433
Appendix 32 Theme decision-making coding 434
Appendix 33 Theme impact on family coding 435

Appendix 34 Theme patient and family centred coding 436
Appendix 35 Theme professional competency coding 437
Appendix 36 Theme staff burden coding 438
Appendix 37 Theme resource use coding 439
Appendix 38 Theme care satisfaction supplementary outcome quotes 440
Appendix 39 Theme communication supplementary outcome quotes 446
Appendix 40 Theme decision making supplementary outcome quotes 451
Appendix 41 Theme impact on family supplementary outcome quotes 459
Appendix 42 Theme patient and family centred supplementary outcome quotes 463
Appendix 43 Theme professional competency supplementary outcome quotes 469
Appendix 44 Theme staff burden supplementary outcome quotes 473
Appendix 45 Theme resource use supplementary outcome quotes 477
Appendix 46 Stage Three participant information sheet 479
Appendix 47 Stage Three social media adverts 484
Appendix 48 Stage Three recruitment poster example 485
Appendix 49 Stage Three screening questionnaire 486
Appendix 50 Stage Three e-Consent form 487
Appendix 51 Stage Three demographics questionnaire 488
Appendix 52 Round One instructions 489
Appendix 53 Public Involvement in Research group (PIRg) in eDelphi study 490
Appendix 54 Stage Three organisations approached 492
Appendix 55 Round One no consensus outcomes amended 494
Appendix 56 Round One outcomes proposed actions 506
Appendix 57 Round One description exemplar quotes 514
Appendix 58 Round One reasons critical for inclusion exemplar quotes 519
Appendix 59 Round One reasons not critical for inclusion exemplar quotes 523
Appendix 60 Round Two reasons for score change exemplar quotes 526
Appendix 61 Round Two reasons critical for inclusion exemplar quotes 532
Appendix 62 Round Two reasons not critical for inclusion exemplar quotes 536
Appendix 63 Stage Four consent form 539
Appendix 64 Stage Four demographics form 540
Appendix 65 Consensus meeting participant pack 541
Appendix 66 Reasons for core 543
Appendix 67 Reasons for non-core 546

Publications and presentations

Book chapter

Pattison, N., & Humphreys, S. (2025). Withdrawal of Treatment and End- of- Life Care for the Critically Ill Patient. In Bench, S., Credland, N., & Hill, C. (Eds.), *Critical Care Manual of Clinical Nursing Procedures* (2nd ed., pp. 622–660). Wiley-Blackwell.

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Humphreys, S. (2024b). End-of-life outcomes of importance to healthcare professionals in critical care. *Vision and Voices, University of Hertfordshire Post Graduate Research Conference*.

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Guidelines

Humphreys, S., Dawe, E., & Cosgrove, J. (2026). Care at the end-of-life. In *Guidelines for the Provision of Intensive Care Services (GPICS)* (3rd ed., pp. 145-146). The Faculty of Intensive Care Medicine. https://ficm.ac.uk/sites/ficm/files/documents/2026-02/GPICS%20V3%202026%200.1_1.pdf

Publications

Humphreys, S., Pattison, N., Godbold, R., Lone, N., Scott, R., & Lomas, J. (2021). *Development of a core outcome set for person-centred outcomes in end-of-life care in critical care*. COMET Initiative. https://comet-initiative.org/Studies/Details/1970

Humphreys, S., Pattison, N., Godbold, R., Scott, R., & Harris, D. (2022). *A systematic review to inform the development of a core outcome set for person-centred outcome measures in end-of-life care in adult critical care research (PEACE-COS-SR)*. International Prospective Register of Systematic Reviews. https://www.crd.york.ac.uk/PROSPERO/view/CRD42022344709

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Chapter 1: Introduction and Background

1.1 Critical care

Critical care, also known as Intensive care, is an evolving, multidisciplinary and interprofessional speciality found in both low/middle-income and high-income countries, focusing on the management of patients experiencing or at risk of acute, life-threatening organ dysfunction (Leach, 2026; Singer et al., 2025; Urdent, 2026). A broad range of advanced organ support technologies are employed, often simultaneously targeting respiratory, cardiovascular, neurological and renal systems to support the function of failing organs with the overarching aim to maintain physiologic stability and prevent further deterioration while the underlying condition is treated (Marshall et al., 2017). The diverse spectrum of aetiologies treated means critical care is not an absolute concept, but a continuum of changing processes and care systems relative to each patient and the health care system within which it is provided (Bench et al., 2025). The heterogeneity of diagnosis, disease severity and patient demographics requires a structured approach (Barton et al., 2026).

Although critical care can be delivered in a number of locations across a hospital environment, care is predominantly provided in a purpose-designed Critical Care or Intensive Care Unit (ICU) characterised by continuous patient physiologic monitoring, a high nurse-to-patient ratio and immediate access to advanced organ support (Marshall et al., 2017; Singer et al., 2025). Unit configurations, specific monitoring and the definition of a critical care bed vary internationally, influenced by regulatory requirements, economic factors and resource availability. A substantial proportion of countries, however, have established accreditation frameworks and staffing structures providing a clear distinction between critical care and ward care, ranging from staff with experience in critical care to formal specialists with critical care training (College of Intensive Care Medicine, 2016; Critical Care Society of Southern Africa, 2022; Hamilton et al., 2025; Waydhas et al., 2023). Critical care units can be general or specialist (Singer et al., 2025). International surveys and consensus guidelines demonstrate that general units are the most common model internationally, providing care across a heterogeneous case mix (Marshall et al., 2017; Schell et al., 2025; Vincent, et al., 2014). Whilst specialist units are delineated by organ support, surgical subspeciality or patient age group. Specialist examples include, but are not limited to, burns, cardiac, neuro, trauma, and paediatric units.

1.2 End-of-Life Care

Despite diagnostic and therapeutic advances in critical care medicine and organisational care that support and prolong life, many patients admitted to critical care deteriorate and die (Efstathiou & Clifford, 2011; Sprung et al., 2019). Historically, epidemiological studies have consistently demonstrated relatively high mortality rates in intensive care units, varying globally between 20-35% (Mercadante et al., 2018; Orban et al., 2017; Sultan et al., 2019; Vincent et al., 2014) and increasing up to 84.6% in Asia, Europe and North America during the first wave of the COVID-19 pandemic (Armstrong et al., 2020). Recent data indicates that 25,363 (12.5%) of patients admitted to general adult critical care units in England, Wales and Northern Ireland die in critical care, with variations according to patient case mix, and a further 4,109 (4.1%) die prior to acute hospital discharge (ICNARC, 2024). Providing end-of-life care (EoLC) for patients is therefore a prominent and integral component of contemporary critical care, yet observational studies indicate significant variation in EoLC within and between countries (Sprung et al., 2019; Sprung et al., 2013; Yaguchi et al., 2005).

Within literature, the term EoLC is frequently used interchangeably and occasionally synonymously with palliative, terminal and comfort care (Abu-Ghori et al., 2016; Pattison & Humphreys, 2025; Riegel et al., 2021), yet key differences exist. Palliative care transcends the continuum of a patient's life-limiting illness, focusing on improving quality of life through the prevention and alleviation of symptoms (Krau, 2016), whilst EoLC pertains to the last phases of life, describing a state of irreversible progressive decline (Myatra et al., 2014; Pattison & Humphreys, 2025) (**Figure 1.1**). Although there is ambiguity in how comfort care is defined, it is regularly perceived as relieving patients from discomfort, recognising that contexts are physical, psychospiritual, social, and environmental (Olausson et al., 2019). End-of-life care is, therefore, a complex, multifactorial phenomenon that presents significant definitional and operational challenges spanning medical, legal, ethical and cultural domains. Despite the term being frequently used in both literature and clinical practice, no internationally accepted definition of EoLC in critical care exists (Vincent, 2009).

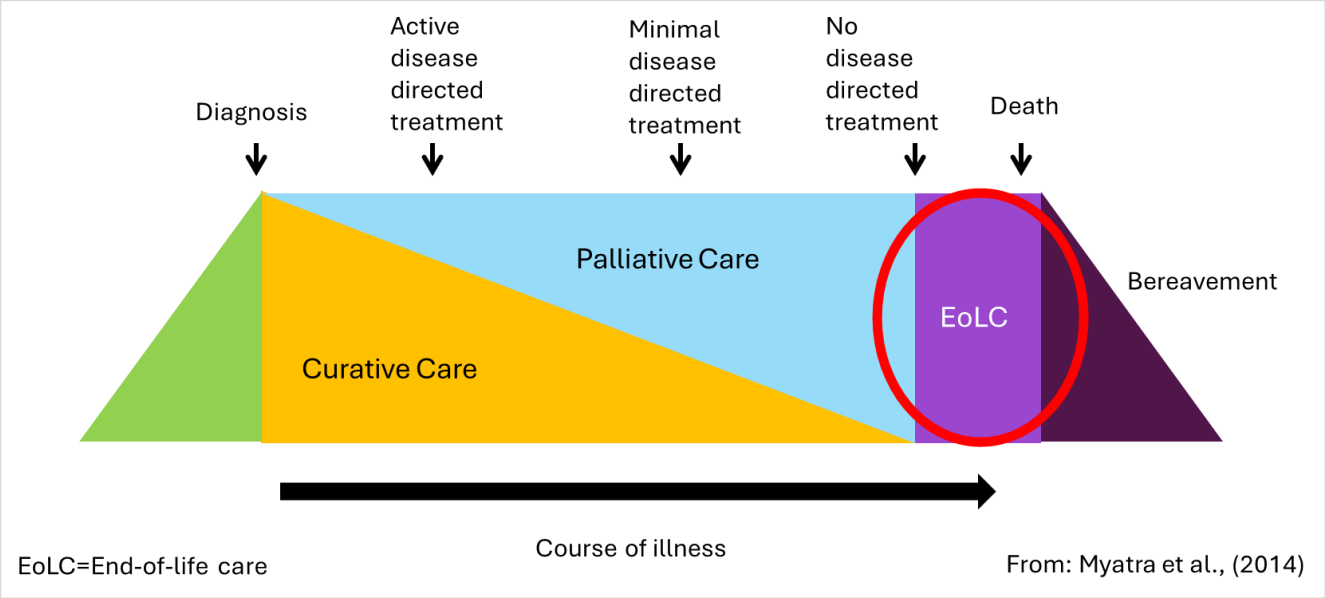


Figure 1.1 End-of-life trajectory

A systematic review of EoL concepts and definitions found inconsistent temporal boundaries, with definitions ranging from the last hours of life to the final 12 months (Hui et al., 2014). No consensus was evident on the prognostic time frame within which EoL should be formally defined, with authors postulating the limitation to *'patients with months or less of expected survival'* (Hui et al., 2014, p. 87). Applying a specific time-frame is problematic in critical care. Internationally prognostic models such as the Acute Physiologic and Chronic Health Evaluation (APACHE II and III) score, and the Simplified Acute Physiology Score (SAPS) are used to predict in-hospital mortality rates, yet they are dependent on static variables recorded within the initial 24 hours of admission, not reflective of the rapidly fluctuating illness trajectories of critically ill patients that can follow this period (Zheng et al., 2025). Furthermore, these scores are based on a population of critically ill patients as opposed to an individual patient, where they may not be wholly accurate (Pattison & Humphreys, 2025).

Recent conceptual shifts in the international understanding of EoL are leading to definitions that move away from fixed prognostic time frames toward estimated time frames informed by predictive models (Schüttengruber et al., 2022). In critical care, this distinction is crucial, shifting the focus from population-level to individual-level estimates that acknowledge the uncertainty and variability of EoL trajectories. Sakaki & Nakamura. (2023) conceptualise EoLC in critical care as short-term, highly intensive and technologically mediated, occurring when death is imminent rather than anticipated over

weeks or months. Family engagement is espoused as central, recognising that patients are frequently unable to articulate their preferences, goals or needs (Sakaki & Nakamura, 2023). End-of-life predictions and subsequent EoL decisions are therefore multifaceted, patient, family and context-specific, dependent on tacit knowledge and professional experience (Flannery et al., 2016), and influenced by religion, culture and geographical location (Chakraborty et al., 2017; Hartog et al., 2022; Schefold et al., 2023). EoL practices are consequently highly variable, not only across international and regional settings but also between individual ICUs and between individual intensivists (Guidet et al., 2018; Kapoor et al., 2023; Mark et al., 2015).

Within critical care, death can be dichotomised as anticipated or unexpected (Pattison & Humphreys, 2025). Anticipated deaths can be defined as those occurring following a decision to withhold or withdraw life-sustaining treatment, whilst unexpected deaths may occur despite receiving life-sustaining measures following events such as cardiac arrest, refractory shock or intractable multiorgan failure and where EoL decisions are unlikely to have been made or initiated (Efstathiou et al., 2020; Orban et al., 2017). Within European ICUs, over 80% of deaths are anticipated deaths (Sprung et al., 2019) where achieving the therapeutic goal is unattainable, or the therapeutic treatment burden is perceived to exceed its anticipated clinical gains (Tanaka Gutiez et al., 2023). It is this subset of critical care EoL patients who are the focus of this study.

1.3 Person-centred

Enshrined in EoLC is the notion of person-centredness, which places the patient, their family and health professionals at the centre of care. Founded on the cancer care paradigm (Kearns et al., 2017; Luckett, 2017; Mularski et al., 2007), EoLC is a complex multifactorial phenomenon. Historically, critical care has been dominated by biomedical frameworks with epistemological roots in positivism and paternalistic approaches, driven by organisational efficiency (Rattray & Mckenna, 2012). Person-centredness, however, represents a paradigm shift away from such reductionist premises towards an equal approach, placing patients and their families at the heart of care decisions and dialogue (Andersson, 2021). Whilst it is central to UK health policy (Health and Social Care Act, 2012) and internationally acknowledged as a component of high-quality healthcare (Giusti et al., 2020; World Health Organisation, 2016), variation is evident in how the concept is interpreted in practice, reflecting a divergence between its theoretical constructs and

practical application (Byrne et al., 2020). International reviews demonstrate terminological heterogeneity is prevalent, with ‘personalised’, ‘patient-centred’, ‘people-centred’ and ‘person-centred’ employed (de Silva, 2014; Giusti et al., 2020; Rossiter et al., 2020). The World Health Organisation (2016) emphasises that care is coordinated around people’s comprehensive needs, respecting their preferences and values through a therapeutic partnership between the patient, their family, community and health professionals. In contrast, McCormack & McCance (2017) conceptualise person-centredness as arising from an approach to practice based on helpful relationships rather than care activities.

Demonstrating that EoLC is not only safe and effective but also person-centred presents challenges. Ambiguity over the meaning of the term, coupled with uncertainty about the optimal methods for assessing person-centred outcomes, has hindered conceptual and empirical development (Giusti et al., 2020). Person-centredness, therefore, remains a complex, evolving concept, articulated in a variety of ways and grounded in a range of philosophical and theoretical frameworks. An exploratory qualitative critical care study found that contextual, professional, and attitudinal factors influenced the degree to which person-centred care operated, concluding further research is needed into the perceived effectiveness of interventions in EoLC and bereavement (Walker & Deacon, 2016).

1.4 Interventions in EoL

Interventions in EoL in critical care are poorly articulated and understood. Nurses perform a pivotal role in instituting EoLC and may, in some areas, even lead withdrawal of treatment at EoL (Pattison & Humphreys, 2025). A plethora of studies have focused on the nurse’s experience in providing EoLC (Efstathiou & Clifford, 2011; Efstathiou & Walker, 2014; Vanderspank-Wright et al., 2018). However, there is a paucity of research studies, particularly from the UK, on the impact of EoL interventions from an efficacy or experiential perspective. Heyland et al., (2017) suggested that this may be partly attributed to the lack of validated quality indicators and outcomes that can be used to measure EoL, coupled with limited healthcare policies to guide contemporary practice. Whilst a range of EoL critical care guidelines have been developed within Europe and the UK, outcome heterogeneity remains (Humphreys et al., 2026; Kesecioglu et al., 2024; Pattison & Humphreys, 2025). Furthermore, as the trajectory of care shifts from curative to EoL in critical care, different outcome measures are required.

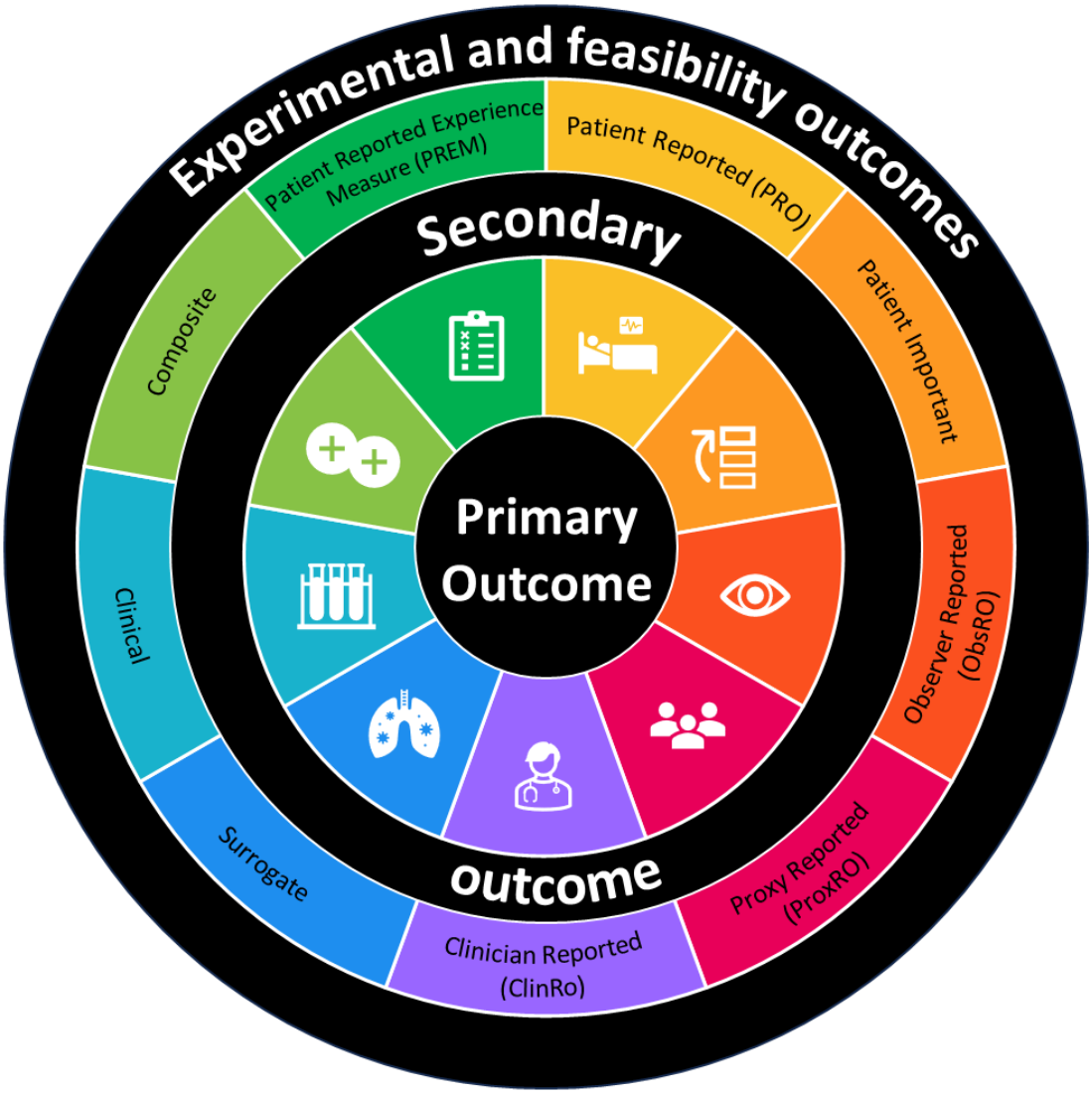
1.5 Outcome selection and type

In research, an outcome refers to a measurable or observable endpoint that reflects the effect of an intervention, condition or process over time, evaluated at a specified time point (Hackshaw, 2024). The extent to which a study contributes to knowledge is contingent on the outcome selected, which determines what effects are detected, how they are interpreted and how meaningful the findings are (Leach et al., 2022). Selecting an appropriate outcome is therefore fundamental to conducting EoL research. The chosen outcome must correlate with the intervention of interest, effectively capture change and minimise potential bias whilst taking into consideration the acceptability and financial implications and relevance to stakeholders impacted by the findings (Chacko et al., 2025; Walker et al., 2024). Furthermore, an outcome must be clearly defined and reproducible to allow comparison across populations, intervention groups and studies (Williamson et al., 2017).

Outcomes are categorised hierarchically, as either primary or secondary. Defined *a priori* to prevent selective reporting, the primary outcome is core, used to determine the sample size needed to detect a statistically significant difference and answer the research question (Leach et al., 2022). In contrast, secondary outcomes may be related to the primary outcome but are considered less important, providing a broader understanding of the intervention's effects (e.g., efficacy or adverse effects) or the study context, rather than confirming the study hypothesis (Menon et al., 2024). Researchers may also employ experimental, exploratory and feasibility outcomes. Similar to primary and secondary outcomes, each serves a distinct role; however, experimental, exploratory, and feasibility outcomes are not inherently hierarchical, rather they are descriptive and, depending on study design, may be primary or secondary (Hackshaw, 2024). Experimental outcomes are predominantly employed to determine intervention efficiency with the aim of establishing causal relationships, whereas exploratory outcomes inform hypothesis generation and intervention design by identifying patterns and emerging themes (Hackshaw, 2024). Feasibility outcomes are distinct from the aforementioned outcomes in that they do not measure efficacy, but the practicality of implementing an intervention in real-world conditions (Leach et al., 2022). Consequently, feasibility outcomes focus on recruitment rates, adherence and acceptability measures (Hackshaw, 2024).

In critical care research, an extensive range of outcomes can be used to capture patient complexity and care delivery (**Figure 1.2**) (Chacko et al., 2025). Clinical outcomes, such as ICU mortality, provide objective, quantifiable measures of a patient's health or survival and have historically dominated studies (Hackshaw, 2024) yet fail to capture patient, family or staff experience. Surrogate outcomes are indirect measures, such as laboratory or clinical exam findings that substitute for clinical outcomes where direct outcomes are too complex, costly or unethical to achieve (Hackshaw, 2024). Frequently chosen to improve study efficiency, surrogate outcomes are, however, controversial and can be subject to the 'surrogate paradox' where an intervention improves the surrogate while simultaneously exerting a harmful or negative effect on the outcome (Ciani et al., 2022; Manyara et al., 2024; Vanderweele, 2013).

Figure 1.2 Types of outcomes in critical care



Composite outcomes aggregate two or more outcomes into a single outcome and are increasingly employed in both prospective and retrospective critical care research due to their ability to enhance statistical power and precision while reducing sample size (Marella et al., 2025). Limitations are evident as the effects across composite components can be inconsistent; consequently, composite outcomes must be interpreted with caution (Hackshaw, 2024). Despite the CONSORT-outcomes extension requirement for all composite components to be reported (Butcher et al., 2022), a systematic review of composite outcomes in high-impact critical care randomised controlled trials found only 65% of trials reported all individual components, with only 52.6% of the trials acknowledging the outcomes as composite (Walker et al., 2024). Furthermore, definition challenges are also evident. Marella et al. (2025) found ventilator-free days to be the most commonly reported composite primary outcome, yet definitions were variable and measured over a wide range of timeframes, compounding study comparability.

Outcomes can also be categorised by data source. Patient-reported outcomes (PROs) are reported directly by patients regarding their health status or quality of life, while patient-reported outcome measures (PROMs) are the instruments used to measure PROs (Higgins et al., 2022). In contrast to PROMS, patient-reported experience measures (PREMs) capture patients' experiences during the research study period or in relation to the study's intervention focus and are predominantly used in survivorship critical care research (Hibbert et al., 2026). Conversely, the use of PROs and PREMS presents distinct methodological challenges in EoL in critical care. Mechanical ventilation, sedation, and delirium, coupled with the physiological process of dying, reduce a significant proportion of patients' mental capacity, rendering self-reporting infeasible (Pattison & Humphreys, 2025) or unreliable (Roydhouse et al., 2022). Furthermore, if a patient dies, neither PROMS nor PREMs can be retrospectively completed as the report must originate directly from the patient without any intermediate interpretation, potentially leading to missing or incomplete data (Snowdon et al., 2023).

Proxy-reported (ProxRO), clinician-reported (ClinRO), and observer-reported outcomes (ObsRO) may be employed where PROs and PREMs are unobtainable or to mitigate missing data (Roydhouse et al., 2022). A proxy reports an outcome on behalf of a patient (Oldenburger et al., 2023). Although commonly performed by a family member/caregiver, health professionals can also be proxies (Roydhouse et al., 2022). Clinician-reported

outcomes are differentiated from ProxROs as they are underpinned by professional judgment and interpretation (Leach et al., 2022). In contrast, ObsRO exclusively focus on what is observable, and can be reported from a family member or caregiver perspective, negating the need for professional expertise (Roydhouse et al., 2022).

When determining which outcomes to measure, it is increasingly advocated that priority should be given to the perceived importance of the outcomes to patients, reflecting a paradigm shift towards person-centredness (Dinglas et al., 2020). Conversely, Gaudry et al. (2017) found that randomised-controlled trials conducted in critical care rarely selected patient-important outcomes as primary outcomes with Walker et al. (2024) finding that only 7% of trials using a composite outcome consisted solely of patient-important outcomes. Through the adoption of consensus methodology, patient-important outcomes are starting to become established in critical care survivorship research operationalised through long-term functional status, cognitive and psychological well-being and health-related quality of life (Connolly et al., 2024). However, systematic reviews demonstrate that EoL interventions lag behind other areas of critical care research, with outcomes frequently assessed using ClinRO that are poorly aligned with patient or family perceived importance, and their perspectives remain under-reported in interventional research, limiting the study's relevance and effectiveness (Chen et al., 2020).

1.6 The problem of outcomes in Critical Care research

Among patients, health professionals, and researchers, there is currently a lack of consensus as to which outcome measures should be collected and reported in studies in EoLC in critical care. Consequently, health professionals, policymakers and researchers may make arbitrary decisions as to which outcome to use and the outcome chosen may not reflect those of the patient or their family. This absence of a systematic approach impedes both current and future research and the cumulative development of the evidence base for EoLC. If studies are to be comparable, results need to be consistently reported (Leow et al., 2021). The problem is further compounded by the divergent outcome definitions, outcome types and instruments which capture different dimensions and constructs of EoLC (Oczkowski et al., 2016; Suwardianto et al., 2025). Previous work has focused on staff satisfaction, palliative rather than EoLC interventions or included patients outside a critical care unit (Aslakson & Bridges, 2013; Takahashi et al., 2024). Aslakson & Bridges. (2013) investigated palliative care interventions in intensive care patients, finding

that outcome measures were heterogeneous, with studies subject to multiple biases and underpowered. Similarly, Metaxa et al., (2021) concluded that outcome measures were heterogeneous and stratified between decedents and survivors in some studies. The stratification of research findings between decedents and survivors also presents challenges, as patients who die differ in illness severity and the timing of the interventions they received (Dinglas et al., 2020). Furthermore, analysing outcomes separately or restricting analysis to survivors risks selection bias, rendering associations between interventions and outcomes imprecise or misleading. While Chen et al. (2020) explored EoLC in ICU from the family perspective, family outcomes and interventions were found to be ineffective, incongruent with families' needs and perceptions and heterogeneous. This heterogeneity in interventions and outcomes, coupled with a lack of consensus on which outcome is the most appropriate, renders interpretation and comparison of findings difficult, potentially contributing to research waste (Connolly et al., 2018; Dinglas et al., 2020). In addition, the absence of reliable person-centred outcome measures has compounded the advancement of EoLC research in critical care (Curtis et al., 2016).

1.7 Core outcome sets (COS)

Core outcome sets (COS) are an agreed minimum standardised set of outcomes on *'what'* should be measured and reported in a specific clinical area or condition (Williamson et al., 2017). Driven by consensus, COS are a method of reducing heterogeneity between studies, bias of outcome selection and research waste by allowing meaningful interpretation and comparison, facilitating meta-analysis (Dinglas et al., 2020). They capture aspects that are of most importance to key stakeholders, which crucially include patients and their families to ensure that the outcomes are personally and clinically relevant for the individuals involved (Williamson et al., 2012). Researchers, however, are not restricted to only the outcomes contained in the COS. There is an expectation that additional outcomes may be measured and reported to capture study-specific events, intervention mechanisms or contextual factors (Beaton et al., 2021; Williamson et al., 2017).

In contrast to a COS, a core outcome measurement set (COMS) addresses *'how'* the outcomes identified in a COS should be measured. COMS extend standardisation beyond a COS by specifying instruments, scales, tools or methods operationalising each outcome domain included in the COS (Boers et al., 2014). Consequently, a hierarchical sequential

relationship exists. A COS must precede a COM as *'what'* must be established and agreed prior to the selection and validation of appropriate outcome measurement instruments (OMIs) (Beaton et al., 2021; Williamson et al., 2017).

Where a COS for the condition or intervention under investigation exists, its use is strongly recommended by both the World Health Organisation and the UK's National Institute for Health Care Research (Hughes et al., 2019; World Health Organisation, 2024). Furthermore, all COS outcomes should be reported in full (Beaton et al., 2021; Williamson et al., 2017), an assertion that is underpinned by the COS-Standard Reporting statement (Kirkham et al., 2016). Critical care research has seen a marked increase in the development and formal registration of both COS and COMS, with 39 COSs and 10 associated COMSs developed with 21 in development (Gorst et al., 2025). Currently, no COS has been developed for EoLC within the critical care context. Previously suggested outcome measures appear arbitrary, while traditional outcomes utilised in critical care, such as length of stay, mortality, and organ dysfunction, have limited value in EoLC. They focus on system measures rather than outcomes important to patients and their families, overlooking relational, ethical and existential dimensions. This presents a critical gap in the evidence base and progression of EoLC in critical care. Without person-centred outcomes, EoLC risks being clinically effective but experientially poor. Aligning outcome measures with patient, family and staff priorities in EoL critical care research is therefore required if outcomes are to be person-centred, which emphasises value-based care, partnership and individual preferences (McCormack & McCance, 2017).

1.7.1 Aim

The aim of the PEACE-COS study was to generate international consensus opinion and use key stakeholders' experience (patient/family representatives, health professionals and researchers) to inform the development of a person-centred core outcome set for EoL care in critical care research.

1.7.2 Objectives

- To identify a list of person-centred outcomes and associated outcome measurement instruments (OMIs) reported in studies of EoLC within critical care through a systematic review.

- To explore what family members of critical care decedents and health professionals consider important in EoLC in critical care, which outcomes they feel should be assessed, and why.
- To define and achieve international consensus on the draft COS using a modified e-Delphi study with patients/family representatives, health professionals and researchers.
- To agree and ratify the COS through an international consensus meeting using a modified nominal group technique.

1.8 Conclusion

Chapter one has provided a brief overview of EoLC in critical care, introducing the terminology and concepts employed throughout the study. It has highlighted the current challenges with outcome selection. Disparities are evident in outcome definition, selection, measurement and reporting which constrains the evidence base of EoL research. The development of a COS is proposed as a solution.

1.9 Next chapter

The next chapter presents the methodological approach the PEACE-COS study employed to develop the COS.

Chapter 2: Methods

This chapter explores paradigmatic standpoints within the context of the PEACE-COS study. The conceptual and methodological frameworks for COS development are discussed. Grounded theory methodology, its philosophical evolution, and its relevance to the PEACE-COS study are presented.

2.1 Research Paradigms and Standpoints

Comprised of abstract ideas and concepts, research paradigms provide a conceptual framework to guide the research process, reflecting the researchers' underlying philosophical position about the world according to epistemological, ontological and axiological assumptions (Brown & Dueñas, 2020; Creswell & Plano Clark, 2018; Tashakkori et al., 2021). An in-depth understanding is essential as each paradigm embraces different assumptions influencing methodological decisions and rigor.

Derived from Geek aetiology, epistemology is concerned with the study and nature of knowledge, whilst ontology pertains to the nature of reality and axiology, the nature of values and judgments (Creswell & Plano Clark, 2018; Silverman, 2017). Since each paradigm has different epistemological and ontological assumptions, the philosophical foundations of each paradigm cannot be empirically demonstrated, and all assumptions are conjectured (Scotland, 2012). Opinions differ as to which assumption researchers should consider first. Guba and Lincoln (1994) suggest that researchers should consider their ontological assumptions first and that assumptions are interrelated, an assertion widely supported across a range of specialities (Grix, 2002; Hays, 2002). Conversely, Crotty (1998) asserts that researchers have the flexibility to consider their epistemological, ontological, or methodological assumptions in any order. Neither of these stances, however, considers axiology in any depth and Brown & Dueñas, (2020) propose that healthcare research should commence by examining axiological assumptions. Irrespective of the starting point, the central tenet of all approaches is that the paradigmatic stance should be prospectively recognised and transparent.

A number of paradigms have been proposed yet the actual number remains ambiguous as classifications continue to evolve. Guba & Lincoln, (1994) classified research paradigms into four dominant paradigms: Positivism, Post-positivism, Critical Theory and

Constructivism. Tashakkori & Teddlie, (1998) subsequently proposed a Pragmatic paradigm, arguing for methodological pluralism.

2.1.1 Positivism

Historically, healthcare research has been dominated by the positivist research paradigm (Broom & Willis, 2007; Brown & Dueñas, 2020) which maintains that knowledge is objective, gained only through variables which can be measured or observed through quantitative means (Ghiara, 2020). From an axiology perspective, it is questionable if this objectivity is truly congruent with the concept of person-centredness and the development of a COS in EoLC in critical care. Positivism discards the importance of the research participant's subjective experience or values (Park et al., 2020), core tenets in COS development (Biggane et al., 2018; Kirkham et al., 2017; Williamson et al., 2012, 2017). Ontologically, positivists assume a position of realism, the notion that reality exists independent of the researcher's thoughts and beliefs (Creswell & Plano Clark, 2018). Relying on hypothetical deductive logic, pure positivism involves experimental methodologies searching for cause-and-effect relationships to predict or control the study phenomena (Park et al., 2020). In the positivist paradigm, the person receiving EoLC is viewed solely as a physical/mechanistic entity (Allsop, 2019). Yet person-centredness extends beyond physical entities, incorporating the emotional, social, and spiritual needs of the individual receiving EoLC, as well as those of their family and healthcare professionals.

Underpinned by the law of inferential statistics, large sample sizes are considered important, with positivists valuing generalisable inferences and universality (Scotland, 2012; Tashakkori et al., 2021). Whilst this nomothetic approach facilitates the replication of research findings and the validity of results (Park et al., 2020), the explicit emphasis on universal generalities makes it challenging to apply research findings to complex real-world situations such as EoLC.

2.1.2 Post-positivism

Post-positivism emerged from positivism and differs from an axiology perspective, acknowledging that prior knowledge, values, and views influence how a researcher sets questions, designs experiments, and interprets results (Tashakkori et al., 2021; Young & Ryan, 2020). This disparity extends to ontological assumptions where post-positivists

assume a position of critical realism, considering reality imperfect, and that truth is probable rather than absolute (Kivunja & Kuyini, 2017).

Congruent with positivism, a hypothetico-deductive approach is advocated where physical, psychological, and behavioural phenomena are reduced to quantifiable entities that can be tested (Routledge, 2007; Tashakkori et al., 2021). Knowledge, however, is perceived to be progressive, providing descriptions and explanations in an attempt to enhance the theoretical and predictive understanding of phenomena (Young & Ryan, 2020). Post-positivism acknowledges the complexity of human phenomena rejecting the notion of absolute predictability, universality, and universal laws. Causality is considered recursive and complex (Forbes et al., 1999; Routledge, 2007), allowing for observational and experimental approaches to develop a nuanced understanding of the phenomenon (Young & Ryan, 2020). The patient receiving EoLC is therefore perceived as a distinct entity with generalisations context-dependent.

2.1.3 Constructivism

Contrasting to both positivism and post-positivism, constructivism assumes a balanced axiology, considering values are existential emerging in the context of the lived experience and thus value-bound (Guba & Lincoln, 1994; Tashakkori et al., 2021). The central endeavour is to understand the individual's experience and social phenomenon from the individual's perspective (Okesina, 2020). Epistemology is therefore considered subjective; the researcher engages in an interactive process to socially construct knowledge through language or dialogue (Ugwu et al., 2021). Within the constructivist paradigm, EoLC can only be comprehended from the perspective of individuals directly involved. A relativist ontology is assumed to advocate the existence of multiple realities in any phenomenon (Bergman et al., 2012; Okesina, 2020). Constructivism is therefore congruent with person-centredness, as it socially constructs outcomes that are individually interpreted, respecting the unique experiences of each participant.

2.1.4 Critical theory paradigm

Similar to constructivism, critical theory centres around the subjective reality of lived experiences; however, the specific foci on power, inequality, oppression, and social position in phenomena differentiate the paradigms, with critical theory having a historical realism ontology. Aiming for social transformation, critical theory can be viewed as an

overarching paradigm for Marxism, postmodernism, feminism, antiracism, and anticolonialism (Asghar, 2013; Paradis et al., 2020). The axiological assumption is normative; with utopian ideologies (Scotland, 2012) which may not be attainable in a critical care setting. Whilst contemporary studies of EoLC identify power differentials between patients, family members, healthcare professionals, and policymakers (Hauschildt, 2022), a central tenet of COS development is the inclusion of all key stakeholders as participants in the research process (Kirkham et al., 2019; Williamson et al., 2017). The critical paradigm fails to recognise that such stakeholders have diverging and dynamic preferences with diverse levels of conscientisation, classifying all participants to a specific marginalised group and superimposing homogeneous concepts of identity (Scotland, 2012).

2.1.5 Pragmatism

Axiologically, pragmatism values practical consequences and the usefulness of ideas or actions, proposing that the value of an idea is intrinsically linked to its ability to solve problems and produce beneficial outcomes (Gillespie et al., 2024). Values are fluid, objective, subjective or both but context-dependent (Deeb et al., 2024). This consequentialist ethic is linked to its ontological stance, rejecting rigid metaphysical dualities and contending that reality is relational, dynamic, and pluralistic (Creswell & Plano Clark, 2018). In this context, the reality of EoLC is not fixed or independent of human action but created through individual experience and inquiry. Pluralism is intentionally embraced, facilitating methodological diversity and allowing for the complexity of EoLC to be explored in granular detail.

Epistemologically, pragmatism posits a fallibilist approach, recognising that expert judgements may be incomplete and consensus does not guarantee correctness (Deeb et al., 2024; Gillespie et al., 2024). Beliefs require testing through empirical inquiry, where their validity is determined by practical application. Truth is, therefore, contingent and provisional, developed through an ongoing process. Knowledge is never considered absolute but perpetually subject to revision and enhancement (Kaushik & Walsh, 2019). This epistemology standpoint resonates with some tenets of person-centredness and COS methodology. Researchers are urged to explore the inclusion of supplementary outcomes beyond those delineated in the COS to achieve study-specific aims, whilst developers are

periodically encouraged to review outcomes to ensure alignment with contemporary practice and evolving priorities (Gargon et al., 2019; Williamson et al., 2017).

Pragmatism supports the assertion that theories can be both contextual and generalisable (Shannon-Baker, 2016) yet it is questionable if a COS on EoLC in critical care could be transferable to another situation, such as EoLC in the community. The fallibilist epistemology conflicts with the COS requirement for reproducible outcomes. Furthermore, the pragmatist standpoint of 'what works' (Rorty, 1982) could create a relativistic approach to outcome selection, undermining the consistency, comparability and rigour that PEACE-COS aims to increase (Williamson et al., 2012).

2.1.6 Application to the PEACE-COS study

Comprised of a series of stages, COS development involves an iterative research process in which outcomes are continually evaluated against what matters to stakeholders within their specific context (Beaton et al., 2021; Williamson et al., 2017). Within the PEACE-COS study, four sequential stages were conducted (**Figure 2.1)**, with each stage designed to answer a specific question. Employing a single-paradigm approach risks an outcome set that fails to capture the complex multidimensional nature of EoLC in critical care. Conversely, paradigmatic pluralism risks incommensurability of epistemological and ontological assumptions, creating practical and conceptual challenges (Guba & Lincoln, 1994). Instead, sequential paradigmatic engagement occurred across the COS development stages, leveraging each paradigm's strengths while mitigating its limitations.

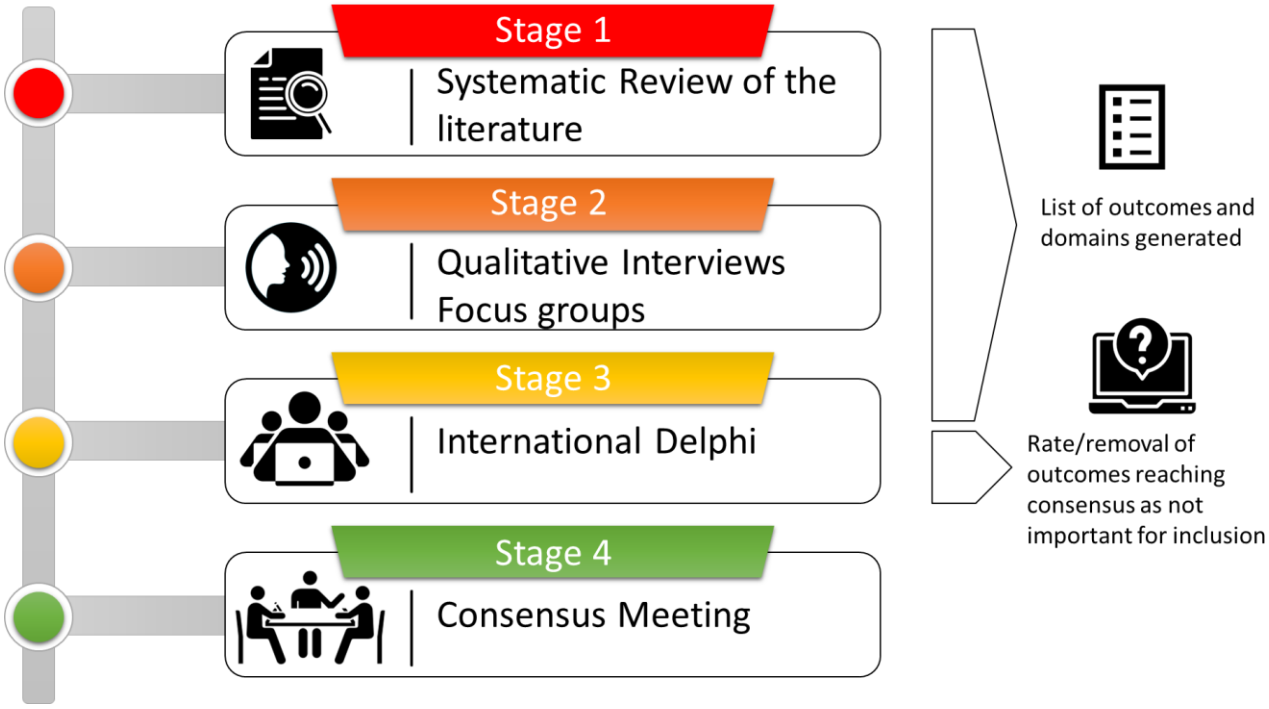


Figure 2.1 PEACE-COS schematic

Stage One employed a post-positivist paradigm to aggregate existing outcomes from the literature, while Stage Two used a constructivist paradigm with a qualitative approach to identify and explore core constructs in EoLC in critical care, recognising outcomes as subjectively meaningful. A quantitative post-positivist Delphi phase followed, whereby the significance and reliability of the constructs were statistically tested. Each stage was afforded equal status (Creamer, 2022; Creamer & Tech, 2021) based on the premise that each paradigm offers a valid way of identifying and understanding the constructs in EoLC in critical care. Finally, an integration synthesis or 'mixing' of the qualitative and quantitative phases through the pragmatist paradigm was employed to enhance the study design, blending research traditions to provide a richer insight into the phenomena being studied. In this context, mixing paradigms is viewed as a complementary choice as opposed to competing methodologies (Rocco et al., 2003). Multiple perspectives were intentionally engaged, in an attempt to understand the complexity of person-centred EoL outcomes whilst respectfully valuing disparities (Greene, 2007).

2.1.7 Researcher positionality

Positionality and reflexivity constitute interrelated concepts that require researchers to explicitly acknowledge and critically examine their positioning within the research context and its influence upon the research process (Holmes, 2020). Historically confined to

qualitative research and critical theory paradigms, there is increasing recognition that positionality and reflexivity can be employed across all research paradigms, including mixed-methods research to promote transparency, rigour, and ethical integrity (Tashakkori et al., 2021; Wilson et al., 2022). Conversely, explicit positionality and reflexivity statements appear uncommon and ill-defined in COS development. During this COS development, only one Critical Care COS reported positionality considerations in relation to a qualitative component, using the Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines (Connolly et al., 2024; Tong et al., 2007). Furthermore, a methodological review of Delphi reporting found that epistemological foundations were rarely articulated or reflected on (Spranger et al., 2022). The absence of positionality statements in COS development could reflect the historical dominance of positivist epistemologies, coupled with the lack of explicit reporting requirements, word limit constraints and journal requirements to prioritise methods, results and clinical implications over methodological reflectivity. Yet omitting positionality and associated contextual information deprives COS stakeholders and reviewers of the opportunity to assess power dynamics, potential biases, and alternative interpretations arising from differently positioned researchers (Beck, 2024).

Positionality statements enable researchers to articulate how their identity and personal experiences affected the research phenomenon, the research participants, and the research methodology (Holmes, 2020). Identity within positionality encompasses social and professional dimensions, recognising that researchers occupy multiple, intersecting dimensions that simultaneously influence their researcher lens (Goundar, 2025; Holmes, 2020). Social identity includes ascribed and achieved characteristics such as ethnicity, race, gender, age, sexual orientation, disability status, socioeconomic background, language, religion, and lived experiences of health, illness, or marginalisation (Yip, 2024). In contrast, professional identity encompasses occupational role, disciplinary/academic background and the author's relationship within communities (Holmes, 2020; Wilson et al., 2022). Tensions arose when deciding which aspects of identity to disclose in this positionality section. No clear consensus guidelines exist on the breadth or depth of disclosure required, leaving researchers to decide which dimensions are relevant to the specific research context (Holmes, 2020).

The researcher identifies as a female, white, English-speaking clinical academic holding positions within the NHS as a critical care specialist research nurse and within academia as a PhD student and visiting speaker. Working clinically simultaneously brings together professional and speciality-specific knowledge, which abstractly influenced the development of the COS. Person-centredness is integral to contemporary nursing practice (McCormack, 2022), and the researcher has previous experience in providing and initiating EoLC in critical care, the research phenomenon of interest. Procedural and nomenclature familiarity was therefore evident; however, this is within the confines of the UK, and significant international variation in EoLC must be recognised. Being recognised as a clinical peer, nurse, or academic facilitated trust with some stakeholders, whilst introducing power imbalances and privileges for others. As such, the researcher acknowledges the fluidity of positionality throughout the COS development, bringing both an insider (emic) and an outsider (etic) lens to the study (Tashakkori et al., 2021) to achieve a deeper and more equitable understanding of outcomes important in EoLC in critical care, thereby creating an impactful and meaningful COS (**Appendix 1**).

2.2 COS methodology

Despite its clear advantages, COS development methodology faces significant challenges due to the lack of a “gold standard” approach, leading to variability in the relevance, validity and generalisability of core outcomes across different healthcare contexts. Limited empirical evidence is available concerning which methods are most efficient, with the Outcome Measures in Rheumatology Clinical Trials (OMERACT) or Core Outcome Measures in Effectiveness Trials (COMET) initiatives most frequently used. Whilst both initiatives aim to improve the consistency and relevance of outcomes in clinical research, they differ in scope and focus, with COMET reporting a simultaneous increase in COS developed for both research and routine care (Gargon et al., 2021).

2.2.1 OMERACT (Outcome Measures for Rheumatology Clinical Trials)

Founded in 1992, the original focus of OMERACT was on improving outcome measures in rheumatology through three clinimetric concepts of truth (measuring content, face and construct validity), discrimination (reliability and sensitivity to change) and feasibility (practicability and interpretability) (Tugwell et al., 2007). This narrow focus initially failed to adequately address ‘what’ to measure or capture the patient perspective in the COS development process, considered integral to contemporary COS. OMERACT’s iterative

data-driven consensus process has, however, significantly evolved since its inception into six stages (**Figure 2.2**), with patient involvement now central to each stage of the process and guidelines provided on 'what' to measure (Beaton, et al., 2021).

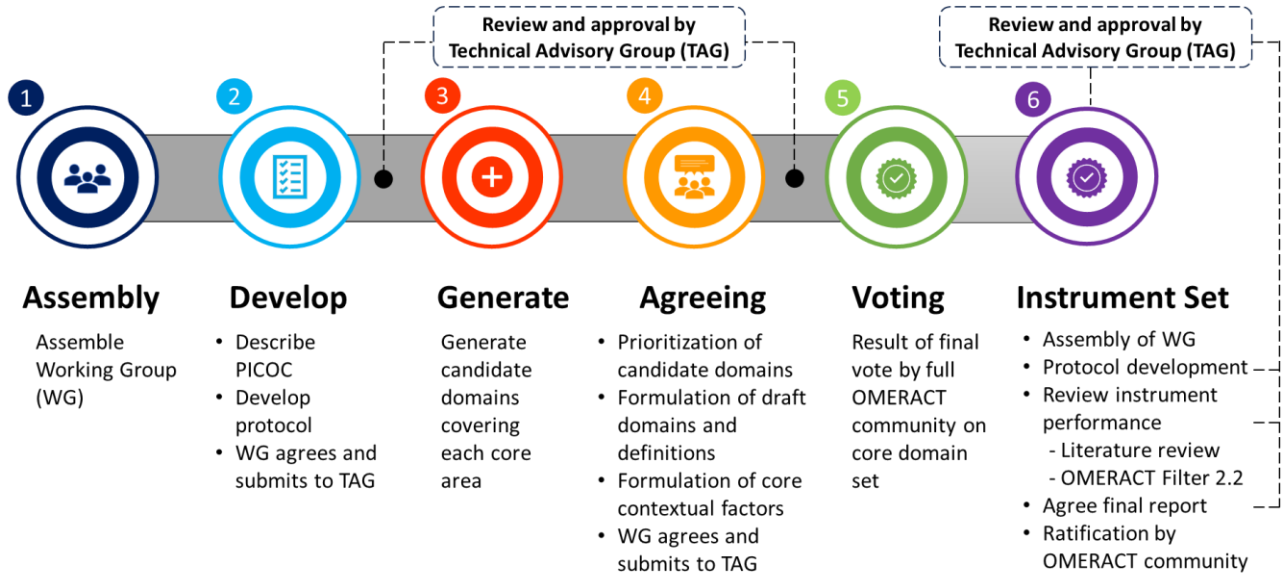


Figure 2.2 The OMERACT COS development process

2.2.2 COMET (Core Outcome Measures in Effectiveness Trials)

Established in 2010, the COMET Initiative aims to improve the quality and consistency of health research by developing and promoting the use of COS. Similar to OMERACT a sequential five-stage process is proposed (**Figure 2.3**) differentiating between 'what' and 'how to measure' in the latter stage (Williamson et al., 2017). Whilst OMERACT recommends that either a scoping or systematic review should primarily be conducted to identify outcomes (Beaton, et al., 2021) COMET advocates that researchers commence with a systematic review (Williamson et al., 2017). No specific qualitative methods are espoused within COMET methodology. Instead, researchers are encouraged to consider the methodological merits and analytical orientations of a range of approaches to identify an approach congruent with the COS aims, with interviews or focus groups used most frequently for data collection (Williamson et al., 2017). This general framework provides a broader scope than OMERACT.

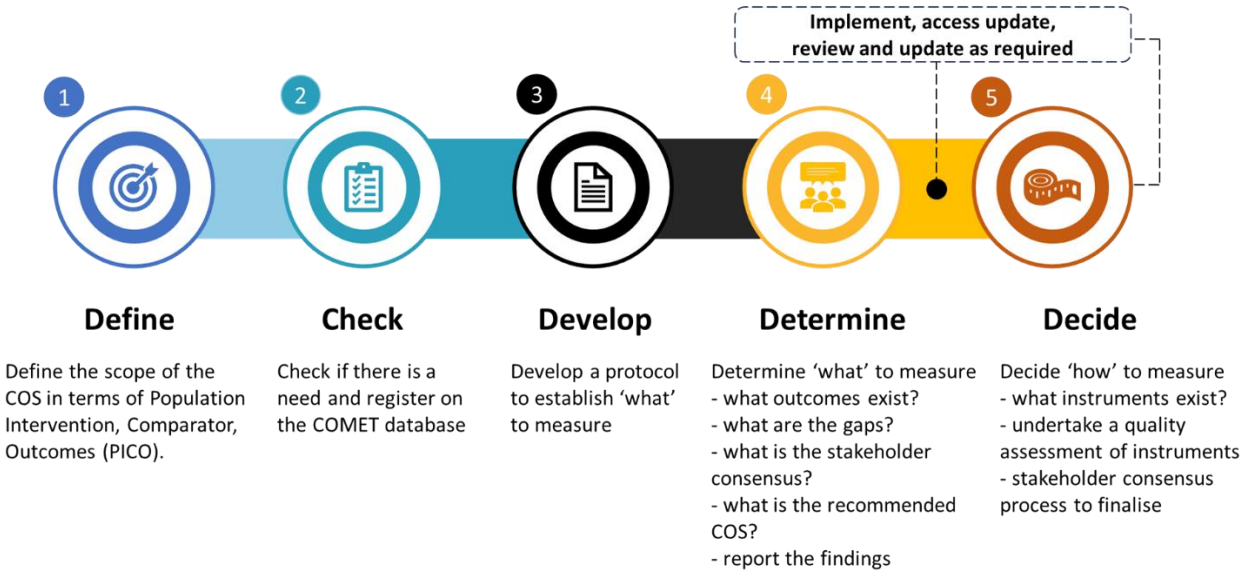


Figure 2.3 The COMET COS development process

Although COMET and OMERACT present a sequential process, OMERACT is punctuated by a Technical Advisory Group (TAG) that must review and approve each stage, necessitating the need to establish, convene, and maintain two distinct groups. By their own admission, OMERACT consider their COS development process long compared to COMET, with OMERACT COS taking up to 6 years to be developed (Beaton, et al., 2021; Tugwell et al., 2007). Given the time and financial constraints of the PhD, a proportional pragmatic mixed methods study design was adopted following the first four stages of the COMET COS development process (**Figure 2.3**) (Williamson et al., 2012, 2017), Recommendations for the Conducting and REporting of DElphi Studies (CREDES) (Jünger et al., 2017) and Core Outcome Set-STAndardised Protocol Items (COS-STAP) statement (Kirkham et al., 2017). The study focused on *'what'* should be measured, *'how'* and *'when'* the proposed outcomes included in the COS should be measured is beyond the scope of this study and will form the basis of post-doctoral work. The methodological considerations of the four stages of COS development will be explored, followed by their application to the study.

2.3 COS development standards

To enhance the development of the COS, this study has been developed in line with the 11 minimum standards for Core Outcome Set Standards for Development (COS-STAD) (Kirkham et al., 2019). Applicable to all COS for research and clinical care, the COS-STAD recommendations focus on three domains: i) defining the COS scope, ii) stakeholder involvement, and iii) a transparent consensus process (Kirkham et al., 2017). How outcomes should be defined or measured is not within the remit of the COS-STAD.

2.3.1 Define

Defining the COS scope is fundamental in determining which outcomes should be considered for inclusion, providing a focus for the development and reducing the ambiguity of purpose while allowing potential users to determine the relevance of the COS to their research. (Williamson et al., 2017). Kirkham et al., (2017) posit four components should define the scope: i) research or practice settings in which the COS is to be utilised, ii) health condition, iii) population, and iv) interventions, yet no recommendations are provided on whether the scope should be narrow or broad. Instead, careful consideration should be given to each component, with each clearly specified. **Table 2.1** illustrates narrow and broad examples within the critical care context. Broad COS provide inclusiveness, generalisability and efficiency, but may lack precision. Narrow COS provide precision, but limit comparability, increasing outcome proliferation risk. Transparency is, therefore, essential if COS developers are to balance generalisability and relevance.

Table 2.1 Example of defining a broad and narrow scope

Scope component	Narrow example	Broad example
Setting	Research	Research and clinical practice
Health condition	End-of-life	Palliative
Population	Burns critical care patients	All critical care patients
Intervention	Neuromodulator to reduce itch	All interventions: Structured family meetings, communication bundles, family support, early referral to palliative care team

PEACE-COS scope

2.3.1.1.1 Setting

Designed for international applicability, a core outcome set was developed for all research trials and clinical studies evaluating EoLC in critical care. It could potentially be employed to evaluate clinical guidelines, EoLC pathways, and educational programmes for health professionals (Dodd et al., 2020).

2.3.1.1.2 Health condition and population

As presented in **Chapter One 1.2**, the health condition applicable to the COS is end-of-life, at risk of dying, with the population being adult patients (≥18 years of age) in critical care. Paediatric and neonatal patients were not included as COS are under development in these areas (Fink et al., 2020; Gallagher et al., 2023) with outcomes and outcome measurement instruments (OMIs) anticipated to differ.

2.3.1.1.3 Intervention

The COS covers all interventions (individual or multidisciplinary) initiated during the EoLC period and delivered to critically ill patients or their families within critical care (**Table 2.2**).

Table 2.2 PEACE-COS COS-STAD scope

COS-STAD Standard	Methodology	PEACE-COS Study
1	Setting	All research trials and clinical studies evaluating EoLC in critical care
2	Health condition(s)	EoL in critical illness
3	Population	Adult patients (≥18 years of age) in critical care receiving EoLC at risk of dying
4	Intervention	All EoL interventions (individual or multi-disciplinary) initiated in the EoLC period delivered to critically ill patients or their families within critical care

2.3.2 Check

Confirming that no current or registered COS exists prior to commencing the development of a COS is essential to mitigate duplication and research waste, unnecessary participant burden and ensure an efficient use of resources (Williamson et al., 2017). Details of the

study were prospectively registered on the COMET initiative database (Humphreys et al., 2021a), a free-to-access, unrestricted public repository of ongoing, planned and completed COS studies. No other similar critical care COS were located on the COMET repository prior to commencing the study.

2.3.3 Develop

A study protocol was developed *a priori*, defining the study aim and objectives, methodology, data collection processes and planned analyses. It was presented for external peer review at the UK Critical Care Research Group Conference (UKCCRG) (Humphreys et al., 2023).

2.3.4 COS stakeholder involvement

Stakeholder involvement in COS development is vital to ensure that the outcomes selected are relevant and meaningful to those who will use or be affected by the COS. A diverse array of key stakeholders should be considered, such as health service users, regulators, policymakers, researchers, healthcare practitioners and members of the public (Williamson et al., 2017). Determining which stakeholder group to include, and in which capacity, depends on the COS scope, methodology, and practical feasibility. However, central to all COS development is the inclusion of a minimum of three stakeholder groups: researchers, healthcare professionals and patients or their representatives (Kirkham et al., 2017).

Researchers

Empirical evidence suggests that involving trialists as stakeholders correlates with increased utilisation of a COS (Bellucci et al., 2021). Trialists, however, represent a specific subset of researchers whose primary focus is on evaluating the effectiveness of interventions. In contrast, researchers work across multiple study designs, providing broader expertise and an additional lens to facilitate the conceptual clarity of proposed outcomes whilst ensuring that the COS is pragmatically implementable across diverse study designs. Including researchers facilitates the alignment of outcomes with study/trial design requirements, minimising research waste and complements health professionals' focus on clinical relevance by strengthening scientific feasibility and rigour (Williamson et al., 2017). Researchers (both individuals and those representing research organisations) were therefore included in this COS development to ensure that the selected outcomes

are robust, transferable, and sustainable, strengthening the COS long-term impact. Their methodological and practical expertise facilitated an understanding of whether proposed outcomes are measurable, reliable and sensitive to change across different EoLC study designs, mitigating the risk of selecting outcomes that are impractical or incongruent with research practices. Further details are provided in **Chapter 5:** and **Chapter 6:**.

Health professionals

To address the complex, multifaceted needs of patients and their families during EoLC a multidisciplinary team approach is advocated (Pattison & Humphreys, 2025). Each member brings distinct professional and experiential knowledge, shaping their epistemological and ontological standpoints and outcome selection. For example, physicians may prioritise objective, measurable outcomes grounded in positivist assumptions, while nurses may prioritise subjective experiences underpinned by a constructivist understanding of EoL. Such divergent perspectives can lead to disparities in how outcomes are valued, defined and operationalised. Integrating such diversity through including a broad range of health professionals as stakeholders is therefore imperative to ensure that the COS is conceptually inclusive and relevant across multidisciplinary teams. All experienced healthcare professionals (including members of the multidisciplinary team and spiritual leaders) were approached for inclusion in this COS development.

Patient/patient representatives

Patient participation is considered integral to COS development (Williamson et al., 2017) and aligns person-centred care principles within the research process. Including patients' diverse experiences enhances the legitimacy and acceptability of the COS among the communities they affect. A COS developed without patient participation risks including outcomes that are irrelevant or clinically meaningless to those affected by the COS.

Capturing the patients' perspective is, however, challenging within critical care as only a limited number of patients can articulate their views. Furthermore, when consideration is being given to withholding or withdrawing life-sustaining treatment and moving to EoLC, a large proportion of critical care patients lack the mental capacity to make decisions concerning their care due to the fact they are sedated, dying or too critically ill (Pattison & Humphreys, 2025). Excluding patients from COS development risks perpetuating paternalistic research paradigms rather than active participants, which COMET explicitly

posits (Williamson et al., 2017). When direct participation is unfeasible, proxy or surrogate decision-makers may be used as stakeholders, preventing exclusion bias of vulnerable or under represented populations (Williamson et al., 2017). Proxies can include family members, informal caregivers or healthcare professionals closely involved in the patient's care (Dagne et al., 2025). Puntillo et al., (2012) found family members showed moderate-to-strong concordance with ICU patients for six symptoms (pain, shortness of breath, restlessness, anxiety, sadness, and fear), with intraclass correlation coefficients (ICCs) ≥0.35. Clinicians (both physicians and nurses) were less accurate; only moderate concordance was evident with physicians for three symptoms, while nurses failed to achieve ICCS ≥0.35 for any symptom (Puntillo et al., 2012). It is therefore essential to include the families of critical care decedents to offer insights into the quality of EoLC and inform future core outcome measures, while acknowledging that proxy-patient agreement varies across different outcome domains. **Table 2.3** summarises stakeholder involvement.

Table 2.3 PEACE-COS COS-STAD stakeholder involvement

Standard	Methodology	PEACE-COS Study
5	Those who will use the COS in research	Researchers and healthcare professionals interested in EoLC in critical care
6	Healthcare professionals with experience of patients with the condition	All experienced healthcare professionals (including all members of the multi-disciplinary team) with at least 1 year postgraduate experience, in the provision of EoLC in critical care.
7	Patients with the condition or their representatives	Family members with direct experience of an adult (>18 years) family member dying in critical care within the last 10 years and have recollection of the EoL process or had a family member receive EoLC in critical care within the last 10 years and have recollection of the EoLC process

Public research partners (PRP)

Working with people and communities is fundamental to all research (NIHR, 2024) and paramount to COS development as outcomes need to resonate with both their needs and preferences. Empirical evidence demonstrates that such involvement improves research design, quality and impact (Modigh et al., 2021) yet terminology is inconsistent, creating

ambiguity. A variety of terms are used depending on the research context, such as public and patient involvement (PPI) or patient and public involvement and engagement (PPIE) where public is considered to mean patients, service user and carers (NIHR, 2024). Such nomenclature is further compounded within COS development, with COMET preferring the term ‘public research partners’ while OMERAC use ‘patient research partners’ (Williamson et al., 2017). For the purpose of this study, public research partners (PRP) are used, congruent with the COMET methodology.

Previous critical care COS have included public research partners on Study Advisory Groups (SAG) or steering committees (Connolly et al., 2018; Kjær et al., 2022) however, others have only included patients/patient representatives as stakeholder participants (Johnston et al., 2023; Viau-Lapointe et al., 2018). In contrast to stakeholder participation, working with public research partners involves actively working with researchers on research priorities, design, conduct, and interpretation (NIHR, 2024), thereby transforming traditional research paradigms from studies conducted ‘on’ to studies conducted ‘with’. This paradigm shift recognises the unique experiential knowledge that people with experience of the relevant condition possess, aligning with COS recommendations (Williamson et al., 2017) and the theoretical underpinning of pragmatic approaches (Allemang et al., 2022). Rather than using a singular group, the researcher worked with a range of public research partners across the research cycle (**Appendix 2**), increasing the breadth and depth of insights to generate more meaningful research (**Figure 2.4**). Further details are provided within each chapter in line with the GRIPP 2 recommendations (Staniszewska et al., 2017), and involvement will continue within the dissemination, implementation and evaluation stages of the COS.

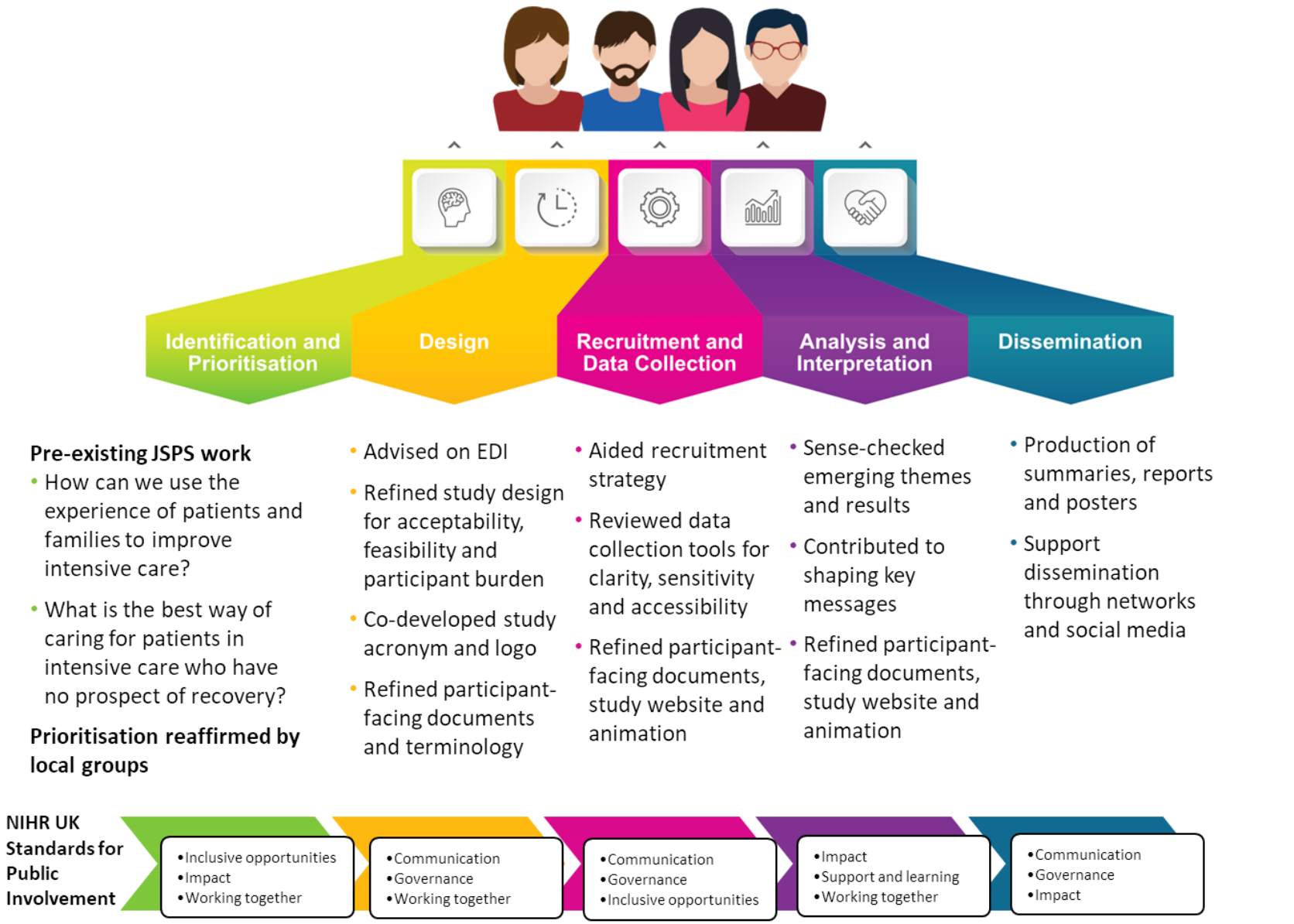


Figure 2.4 PEACE-COS Public research partner involvement

COS steering committee

A study steering committee was also established, comprising of diverse expertise in critical care, EoLC, research ethics, information management and one patient and public representative (**Appendix 3**) underpinned by the COMET Checklist for Public Research (COMET PoPPIE Working Group, 2016). Although all resided in the UK at the time of the study, members had previously resided and worked in different countries, reflecting diverse geographical and cultural backgrounds. An independent person was also appointed to facilitate communication and interaction between potential participants, but was not part of the steering committee.

2.3.5 Determine

Outcome identification for inclusion

Before prioritising outcomes for inclusion in a COS, it is essential to identify a long-list of potential outcomes. Contingent on resource availability, a range of strategies have been proposed to generate a comprehensive and inclusive list: systematic reviews of published studies, reviews of qualitative research, clinical trial registries and interviews or focus groups with key stakeholders (Williamson et al., 2017).

2.3.5.1.1 Systematic reviews of research literature

Underpinned by a transparent methodological technique, systematic reviews are an established type of synthesis research for identifying existing knowledge and advancing knowledge synthesis in a specific domain (Moosapour et al., 2021). Rigorously conducted, they enable researchers to address a specific question, summarising and integrating existing literature so that future research and clinical decisions can be maximally informed. In the context of COS development, systematic reviews represent the starting point for identifying existing knowledge about outcomes. Here, the aim is to identify all potentially relevant outcomes from published studies/trial registries and, where feasible, ongoing studies (Beaton et al., 2021; Williamson et al., 2017). Careful consideration of the systematic scope is required to balance study relevance without unnecessary data collection (Williamson et al., 2017). Whilst a rigorous scope ensures all potentially relevant outcomes are captured, reducing selection bias and enhancing the credibility and trustworthiness of the COS (Kirkham et al., 2016), the scope must be feasible within the time constraints and resources available.

Conversely, there is no recommended time period over which a systematic review should be conducted (Williamson et al., 2017) with critical care COS developers adopting different approaches. Rose et al., (2020) limited the time period and language yet provided limited or no explanation or justification, potentially introducing bias and undermining systematic review validity. Time period limitations may exclude foundational research or evolving outcome measures, while excluding qualitative research may lead to an incomplete picture of outcomes of importance. Other critical care COS developers have limited searches to include only randomised controlled trials (RCTs) (Gaudry et al., 2017) yet non-randomised studies provide valuable outcomes that can complement RCTs, capturing real-world patient-centred outcomes that can differ in focus or composition (Saldanha et al., 2022). Given the comparatively smaller and heterogeneous evidence base of RCTs in EoLC, a systematic review must be rigorous enough to capture a broad range of outcomes, necessitating the inclusion of both RCTs and non-randomised studies, while remaining feasible within time constraints. Without such an approach, there is the potential that outcomes could be either be missed or included in a COS that are not representative of the EoL critical care literature.

2.3.5.1.2 PEACE-COS Stage One

A systematic review identified and summarised all potentially relevant outcomes from existing research literature conducted according to a predefined protocol registered on the International Prospective Register of Systematic Reviews (PROSPERO) (Humphreys et al., 2022). In summary, the systematic review sought to identify outcomes reported in quantitative intervention studies in EoLC in critical care and themes in qualitative studies to form a unique preliminary list of outcomes for review. The list was refined in subsequent stages of the study. The systematic review is reported using Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Liberati, et al., 2009) and to PRISMA protocols (PRISMA-P) (Shamseer, et al., 2015). Detailed methodology is presented in **Chapter Three 3.3 and 3.4** to identify a long list of potential outcomes.

2.3.5.1.3 Filling the gaps in existing knowledge

Historically, there has been minimal patient and public involvement in determining which outcomes are measured and used in research (Williamson et al., 2017). The outcomes captured in the systematic review are likely to reflect researchers' opinions, potentially overlooking outcomes that patients, their families and health professionals consider

important. Previous COS have highlighted the need to articulate patients' priorities as these may not be congruent with those of healthcare professionals (Beaton et al., 2021). Qualitative interviews or focus groups with key stakeholders are established data collection methods used to identify and fill gaps in existing knowledge within COS development, with the data collection method guided by the COS scope and qualitative expertise (Beaton et al., 2021; Williamson et al., 2017).

Encapsulated within the confines of a dyadic relationship, individual interviews can facilitate in-depth explorations of personal experiences of EoLC, enabling the researcher to develop a nuanced understanding of outcomes of importance. Such approaches have been demonstrated to be effective in sensitive research topics such as critical care bereavement (Bazzano et al., 2023; Wen et al., 2024) where participants may be unwilling to share personal experiences in group settings and in general critical care COS development (Connolly et al., 2024).

In contrast, focus groups can generate diverse perspectives from multiple viewpoints simultaneously, potentially revealing both consensus and contestation within the group of outcomes of importance (Holloway & Galvin, 2024). Outcomes, therefore, emerge from the group dynamics, rather than individual contributions, which are co-constructed through dialogue, debate, and collective reflection. Such methods allow researchers to gain insights into the shared understandings of EoLC outcomes, exploring how individuals navigate collective meaning. Power dynamics must be considered, as dominant voices can eclipse marginalised perspectives, while group norms can suppress dissenting opinions (Holloway & Galvin, 2024; Kitzinger, 1995).

Logistical and ethical factors may influence the data collection methods. Individual interviews are labour-intensive, necessitating multiple separate encounters, while focus groups require concurrent availability of multiple participants. Focus groups can be homogeneous or heterogeneous, ideally comprising of between four to eight participants and lasting one to two hours (Kitzinger, 1995). Homogeneity can facilitate explorations of sensitive topics such as EoLC, while heterogeneity allows stakeholder comparison (Kitzinger, 1995). Irrespective of composition, the presence of multiple participants within a focus group can threaten group confidentiality and privacy, with researchers unable to assure anonymity by other participants beyond the focus group (Briller et al., 2007).

Consequently, individual interviews are predominantly used within EoL research underpinned by the premise that they provide participant confidentiality and privacy, yet within COS methodology, neither method has been found to be inherently superior (Jones et al., 2017). The appropriateness of the data collection method is therefore dependent on the research question, epistemological and ontological standpoints.

2.3.5.1.4 PEACE-COS Stage Two

An exploration of what families of critical care decedents feel are important outcome measures in EoLC was planned through longitudinal telephone or online interviews to develop theoretical constructs of person-centred outcomes in EoLC in critical care. Telephone and online interviews were selected due to COVID-19 restrictions. They negated the requirement for in-person visits, simultaneously enabling participation from a wider geographical area whilst reducing costs and enabling the participant to control their social space and the privacy of the interview (Holt, 2010). Compared to standard interviews, longitudinal in-depth interviews have been found to facilitate a deeper exploration of sensitive phenomena (Murray et al., 2009) and *"nuanced understanding of how phenomena change over time".* (Carduff et al., 2015, p. 1). A qualitative longitudinal design was therefore chosen to capture a detailed contextual understanding of the families' experiences and evolving accounts of EoLC. This approach differs from previous explorations of family experiences of EoLC (Kisorio & Langley, 2016) in that it is iterative, capturing the interplay of time and acknowledging that, through re-telling stories, new perspectives or interpretations by participants may be added.

Previous palliative care and critical care research has demonstrated that family members can struggle to talk about death, especially when its trajectory has been rapidly precipitated through organ failure (Kendall et al., 2015; Pattison et al., 2013). Significant recruitment challenges were encountered, resulting in a pragmatic protocol amendment that reduced the number of interviews to one and expanded the inclusion criteria to include health professionals. Qualitative approaches were subsequently modified to permit health professionals to participate in homogeneous focus groups, leveraging the complementary strengths of both to generate a nuanced understanding of the complexity of outcomes of importance in EoLC.

Stage Two employed a qualitative design utilising principles of grounded theory, acknowledging the context of the research and the position of the researchers within it (Charmaz & Thornberg, 2021).

2.3.5.1.4.1 Grounded theory

Grounded theory is a rigorous, systematic, yet flexible research methodology originally conceived by Glaser and Strauss (1967) but has evolved since its inception into three main approaches: Classic Glaserian grounded theory (CGGT) (Glaser & Strauss, 1967), Straussian grounded theory (SGT) (Strauss & Corbin, 1990), and constructivist grounded theory (CGT) (Charmaz, 2006). Each has distinguishing methodological characteristics associated with a particular philosophy and paradigm, but all share an abductive approach to research, generating theoretical abstractions that are 'grounded' in data on specific phenomena (Rieger, 2019).

2.3.5.1.4.2 Classic Glaserian grounded theory

Glaser and Strauss' (1967) seminal work examined the experiences of terminally ill patients and the reactions of healthcare professionals and family members caring for them. Whilst their original work makes little reference to philosophical assumptions, their research occurred during a post-positivism era and appears to reflect ontological critical realism and objective epistemological postpositivist presuppositions (Levers, 2013; Rieger, 2019; Tie et al., 2019).

A significant challenge with traditional grounded theory is the 'tabula rasa' approach to data collection and analysis, coupled with the notion that the researcher must delay the literature review until data analysis is near completion (Charmaz, 2025; Zaidi, 2022). While this enables researchers to generate theory based on the empirical world and avoid pre-existing concepts that have the potential to distort data, it is problematic for a number of reasons:

a) As an experienced critical care nurse, the researcher has a degree of familiarity with the phenomena to be studied and, as such, brings her own lens of EoLC.
b) Integral to the conduct of health research is the advancement of scientific knowledge, and these advancements simultaneously preserve and protect participants through compliance with appropriate ethical, governance and legal standards (Department of Health, 2017; World Medical Association, 2013a). As part

of the UK's rigorous ethical approval process, researchers are required to submit a summary of existing literature that positions the proposed research within the current context and highlights how the scientific knowledge or understanding of the phenomenon will be advanced (Health Research Authority, 2025a). Thus, for pragmatic and strategic reasons, researchers require an awareness of the literature prior to data collection to comply with formal approval processes.

c) Within COS methodology, both COMET and COS-STAD position the systematic review as a distinct methodological component commenced prior to qualitative approaches (Kirkham et al., 2017; Williamson et al., 2017). Interview or focus group findings are then analysed and integrated with systematic review-derived outcomes to facilitate comprehensive outcome identification in stage three of the study.

2.3.5.1.4.3 Straussian grounded theory

Based on symbolic interactionism and pragmatist foundations, the Straussian grounded theory (SGT) emphasises the symbolic significance that individuals attribute to social interactions (Rieger, 2019; Tie et al., 2019). It explores the subjective interpretations individuals place on objects, behaviours, or EoLC based on their perceived truths (Guetterman et al., 2019). In contrast to CGGT, the researcher is active; their professional and personal experiences shape the lens through which analytical choices are made, exploring relationships within and between data categories to generate theoretical density (Zaidi, 2022). The Straussian approach, however, retains positivist assumptions, potentially leading researchers to preference rigid procedural coding compliance over conceptual innovation (Charmaz, 2025).

2.3.5.1.4.4 Constructivist grounded theory

In contrast to CGGT and SGT, constructivist grounded theory (CGT) aligns with a relativist ontology and posits that researchers do not discover data or theories but co-construct them through their interactions with the phenomena and their participants (Charmaz & Thornberg, 2021; Thornberg, 2012). As such, outcomes of importance to the COS are influenced by both the researcher's and participants' perspectives, privileges, values, circumstances and geographical locations (Charmaz & Thornberg, 2021; Thornberg, 2012). This approach makes CGT most suitable for exploring complex dynamic experiences of EoLC, producing more nuanced context-sensitive theoretical interpretations of outcomes of importance that accurately capture the participants' experiences, opinions

and reasons (Charmaz, 2025). CGT affords the researcher greater data coding and analysis flexibility, allowing elements of the constant comparative technique to be employed (Sebastian, 2019), as presented in **Chapter Four 4.8.1**. Outcomes derived from Stage Two contributed to the long list of outcomes considered in Stage Three (**Chapter Five 5.6**).

2.3.5.1.5 Outcome-related frameworks

A range of conceptual frameworks/models/taxonomies exist to classify outcomes identified for potential inclusion in a COS covering outcome domains, measurement approaches and practical applications. Inconsistency is evident between hierarchical structures and outcome domains, while variations in terminology and application are problematic. The WHO definition of health is normative and value-laden; definitions are vague (Schramme, 2023) impeding operationalisation into measurable outcomes. The Patient-reported Outcomes Measure Information System (National Institutes of Health, 2025a), fails to capture proxy or health care providers' outcomes, outcomes that dominate critical care research and is applicable only to outcome measurement instruments. Similarly, the Nursing Outcome Classification solely addresses outcomes pertinent to nursing (Moorhead et al., 2018), ignoring the multidisciplinary nature of critical care and the central tenets of person-centredness with disease-specific outcome taxonomies, such as National Institutes of Health Toolbox, Neuro-QoL and ASCQ-M (National Institutes of Health, 2025b) lacking the breadth required for critical care patient heterogeneity.

Designed for patient registries, the Outcome Measures Framework (Gliklich et al., 2014) also fails to provide an adequate structure for research outcomes. In contrast Wilson & Cleary, (1995) present a linear taxonomy proposing a dominant causal pathway between clinical outcomes to overall quality of life. Within the critical care context, such linearity is ambiguous and oversimplified. Advanced organ support means non-linear relationships are evident with outcomes such as pain impacting on quality of life without traversing functional status.

The OMERACT Filter 2.0 taxonomy (Beaton et al., 2021) advocates that COS developers consider domains developed by the International Classification of Functioning, Disability and Health (ICF) and Wilson and Cleary, suggesting that some domains are mandatory in

all trials, while others are mandatory in specific circumstances. Core areas are therefore broad, compromising granularity.

The COMET taxonomy (Dodd et al., 2018) overcomes the aforementioned limitations, proposing a conceptual framework specifically for classifying outcome measures in research. Five core areas are presented together with 38 outcome domains, providing granularity without compromising comprehensibility and allowing structural differentiation between outcomes. Furthermore, researchers in specialist areas such as critical care are encouraged to subdivide outcome domains, making it the taxonomy of choice for this COS. In line with COMET recommendations, each verbatim outcome was independently mapped to an outcome domain within the COMET taxonomy by two researchers from multiprofessional backgrounds, with conflicts resolved by a third researcher (Williamson et al., 2017).

2.3.5.1.6 Outcome phrasing and formulation

Deciding whether to retain the full list of potential outcomes identified in the systematic review and qualitative study marks a critical juncture in COS development, yet the COMET handbook (Williamson et al., 2017) provides limited methodological guidance. Using outcome phrasing derived from stakeholder interviews or focus groups, coupled with plain language for medical terms, is considered to reduce language ambiguity (Kirkham et al., 2017; Williamson et al., 2017); however, this fails to address how to avoid imbalances in the granularity of the outcome section and associated descriptions. A systematic review of COS development studies demonstrated the difficulties in defining unique outcomes, suggesting a correlation between the level of extraction granularity, measurement time point and number of outcomes (Young et al., 2019). To reduce the disparity and promote transparency Young et al., (2019) proposed the uniting of spellings, concepts and contexts together with the removal of time points, to form a unique outcome and underpinned the methodologies used throughout this COS development. Additionally, outcomes were piloted prior to the consensus process to enhance understanding and readability. Further details are provided in **Chapter Five 5.7.2**.

2.3.6 COS consensus process

Following the long-list generation (Stages One and Two), a consensus process is required to assess the level of importance of each outcome. Methodologies previously used

included group discussions, Delphi Surveys, and the Nominal Group Technique (NGT), with the central tenet being the inclusion of a diverse range of perspectives (Williamson et al., 2017). The reliability and validity of data generated from group discussions, however, present distinct challenges. Social desirability bias, groupthink, and power dynamics can compromise the extent to which the approach accurately captures participants' actual perspectives (Alexander et al., 2025). The structured face-to-face format of the NGT addresses some of these limitations, as participants are able to form opinions independently prior to social influence, equalising participation, reducing power dynamics and capturing authentic individual perspectives (Ven & Delbecq, 1974). Unlike group discussions, NGT includes synchronous voting/ranking prioritisation phases, allowing participants to discuss results and resolve ambiguities while facilitating a transparent process to converge towards consensus. Recommendations for the optimal size for a NGT meeting vary between 7-10 participants (Ven & Delbecq, 1974). Groups consisting of less than five can threaten the validity of the results, while groups accommodating more than ten can be time-inefficient, subject to participant fatigue and disengagement (Harvey & Holmes, 2012). Accommodating large groups of stakeholders is problematic, necessitating multiple parallel or sequential meetings followed by the aggregation of results (McMillan et al., 2014).

In contrast to the NGT, a Delphi survey can simultaneously accommodate larger numbers of stakeholders and is the most frequently employed prioritisation method in COS development (Gargon et al., 2021). Unlike the aforementioned methods, face-to-face communication is not required, with participation possible by post or online (eDelphi) (Belton et al., 2019). Stakeholders are presented with a list of potential outcomes for inclusion in sequential questionnaires (rounds) with controlled feedback and aggregated group responses (Williamson et al., 2017). The distribution of scores, coupled with anonymised rationales, allows participants to appraise the opinions of other stakeholders prior to re-rating each outcome, modifying their initial score on feedback from preceding rounds to achieve convergence of opinion (Williamson et al., 2017). A number of methodological decisions must, however, be made *a priori* as follows:

Stakeholder panels

The importance of including a diverse range of stakeholders has been previously discussed; however, additional consideration is required on how to effectively combine

different stakeholders within the Delphi survey into panels. Panel composition is critical to the study's validity (Hsu & Sandfords, 2007). COS developers can employ a singular panel of experts from a specific stakeholder group or integrate multiple heterogeneous stakeholder groups into a singular panel (Williamson et al., 2017). Methodological limitations are evident in both approaches. A single homogenous approach produces core outcomes considered important to only one stakeholder group (Williamson et al., 2017), whilst a singular heterogeneous approach can be impacted by an imbalance of stakeholder representation, resulting in biases from the stakeholder group with the majority of participants (Schifano & Niederberger, 2025). Furthermore, compared to homogeneous panels, heterogeneous panels have been demonstrated to reach consensus on fewer items (Fraser et al., 1994).

An alternative approach is multiple homogeneous panels. Separate stakeholder groups are retained, preserving opinion equity irrespective of panel size. Such equity is imperative when differences in opinions are anticipated (Williamson et al., 2017) and is the approach adopted in the Delphi study in this COS development due to the wide variations in EoLC and anticipated varying international opinions. To achieve diversity of expertise, Humphrey-Murto & de Wit, (2019) advocate that at least two or three stakeholder groups are required for studies focusing on patient-relevant outcomes. Three stakeholder groups were included as outlined in **2.3.4**.

Group size

No consensus is evident on the optimal group size to achieve consensus in Delphi studies. Decisions are not grounded in statistical power but pragmatic, dependent on expert availability within the COS scope (Williamson et al., 2017). Gargon et al., (2019) undertook a systematic review on COS, concluding that Delphi panel sizes ranged from 9-678 participants. In contrast, Critical Care COS panel size ranges are comparatively smaller, ranging from 1-185 panellists (**Table 2.4**). Rare conditions or interventions of interest that are not widely used have a relatively small size due to limited patient populations and a small pool of clinical experts with specialist knowledge (Williamson et al., 2017). Furthermore, multilevel linear regression analysis has revealed a significant correlation between panel size and response rate, with larger panels having substantially lower response rates (Gargon et al., 2019). Representation from the three key stakeholder

groups with appropriate experience and expertise is therefore essential. The target panel sample size for this COS was 45 based on 15 participants per stakeholder group.

Table 2.4 Critical care COS Delphi panel sizes

Author	COS	Panel N	Panel stakeholder composition	n (%)
Bachmann et al., (2024)	Gastrointestinal function in adult critically ill patients (COSMOGI)	285	1. Healthcare providers 2. Clinical researchers 3. Patient representatives/caregiver	185 (65) 89 (31) 11 (4)
Blackwood et al., (2019)	Critical Care Ventilation Trials (COVenT)	183	1. Clinicians 2. Researchers 3. ICU survivors/carers 4. Industry	82 (45) 76 (41.5) 15 (8) 10 (5.5)
Connolly et al., (2024)	Physical Rehabilitation Core Outcomes In Critical illness (PRACTICE)	329	1. Clinicians 2. Researchers 3. Patients and caregivers	247 (75) 58 (18) 24 (7)
Davies et al., (2022)	Core outcome measures for clinical effectiveness trials of nutritional and metabolic interventions in critical illness (CONCISE)	213	1. Healthcare professionals 2. Clinical researchers 3. Patients/caregivers	122 (57) 50 (23) 41 (19)
Freeman-Sanderson et al., (2024)	Interventions to Enable Communication in Patients With an Artificial Airway (Comm-COS)	134	1. Clinicians 2. Researchers 3. ICU survivors/family	91 (68) 28 (21) 15 (11)
Hodgson et al., (2021)	Patients on Extracorporeal Membrane Oxygenation	46	1. Clinicians 2. Researchers 3. Funders 4. Consumers 5. Industry	31 (67) 9 (20) 1 (2) 2 (4) 3 (7)
Johnston et al., (2023)	Critically Unwell patientS (COS-ABACUS)	Aim 15-30	1. Users 2. Healthcare professionals 3. Patients	5-10 (aim) 5-10 (aim) 5-10 (aim)
Kjær et al., (2022)	Adult General ICU Patients	Aim 400	1. Clinicians 2. Family members 3. Patients	200 (aim) 100 (aim) 100 (aim)
Rose et al., (2021)	Delirium in Critically Ill Adults (Del-COrS)	179	1. Clinicians 2. Researchers 3. ICU survivors/family	100 (56) 41 (23) 38 (21)

Number of rounds

The number of rounds required to reach consensus in a Delphi study varies according to the study scope, how consensus is operationalised and resource availability (Hsu & Sandfords, 2007). Between two and four rounds have traditionally been employed in COS development (Williamson et al., 2017), allowing sufficient iteration for consensus while minimising participant burden (Niederberger & Renn, 2023). Up to three rounds were planned for the COS. A minimum of two rounds is required to allow panellists to consider their opinions based on one round of controlled feedback; however, the number of rounds is not significantly associated with response rate (Gargon et al., 2019). This suggests that questionnaire design may be more influential.

Questionnaire structure

The questionnaire design, structure, item sequence and complexity can significantly influence cognitive load, response patterns/rates and level of consensus in Delphi studies (Brookes et al., 2018; Niederberger & Renn, 2023). Jargon or complex medical terminology may introduce measurement bias (Belton et al., 2019; Keeney et al., 2010), reducing data validity and leading to an inaccurate rating of outcomes. The consistency effect can occur, whereby panellists provide ratings logically coherent with prior responses instead of authentic opinions (Williamson et al., 2017). Additionally, the context (order) effect can occur if prior questions influence how panellists rate subsequent questions (Brookes et al., 2018). Item sequence is therefore imperative, with empirical research demonstrating a correlation between context and the number of outcomes retained between rounds (Brookes et al., 2018). Although limited methodological guidance exists on the optimal questionnaire structure, including a logical outcome domain order from general to specific, has been demonstrated to enhance panellist engagement and reduce cognitive load (Hasson et al., 2000; Keeney et al., 2001) while randomising the outcome sequence may reduce the context effect (Brookes et al., 2018). Outcomes were therefore randomised within specific domains. Working with public research partners mitigated ambiguity, ensuring that items and their associated descriptions used language reflective of stakeholder experiences (Schifano & Niederberger, 2025). Extensive piloting with representatives of different stakeholders was undertaken in line with recommendations (Khodyakov et al., 2023). Specific details are provided in **Chapter Five 5.7.2.**

Scoring

The choice of scoring system represents a fundamental methodological decision. Core outcome set studies have employed a range of scoring methods, including ranking or rating scales and point allocation. Likert rating scales allow panellists to evaluate each outcome independently and are most frequently employed within COS development due to their ability to reduce cognitive load (Schifano & Niederberger, 2025). In contrast, ranking scales which force discrimination between outcomes become unwieldy and difficult to manage where the number of outcomes exceeds 10-15 (Keeney et al., 2010). Likert rating scales are preferable, as they facilitate statistical analysis of agreement and generate more nuanced outcomes, allowing panellists to assign equal importance to multiple outcomes (Belton et al., 2019). A range of ordinal Likert scales exists, incorporating 3 to 11-point scales; however, reliability and validity vary according to scale. Alwin & Krosnick, (1991) found a 3-point scale had the lowest reliability, with 9-point scales demonstrating superior discriminatory power and reliability. In contrast, 5 and 7-point scales are simpler to comprehend and are more user-friendly (Niederberger & Renn, 2023). Remus et al., (2021) discovered that a 5-point scale led to a twofold increase in outcomes reaching consensus for inclusion in a COS compared with the 9-point scale; yet, Hasson et al., (2000) concluded that scales with seven or more points reduced central tendency bias, providing better variance.

The Grading of Recommendations, Assessment, Development and Evaluations (GRADE) 9-point Likert scale where 1 represents the outcome of least importance and 9 represents the outcome of critical importance (Guyatt et al., 2011) was selected for this COS development based on the need to balance psychometric properties against cognitive load and COMET recommendations (Williamson et al., 2017). The scale demonstrates robust content validity by allowing respondents to convey nuanced distinctions when evaluating outcomes with the three-category interpretive structure (ratings of 1–3 indicating not important, 4–6 important, and 7–9 critical), facilitating meaningful rating aggregation and enhancing interpretability (Khodyakov et al., 2023). Participants were also encouraged to provide explanations or rationales underpinning their scores to enhance the quality and relevance of controlled feedback in subsequent stages.

Controlled feedback

Controlled feedback is a central tenet of the Delphi technique. Between rounds, researchers summarise and present anonymous panellist collective responses, enabling

panellists to reconsider their opinions in the context of collective expert opinion promoting convergence towards consensus (Shang, 2023). Statistical aggregation per outcome, such as measurement of central tendencies with dispersion, percentage, and graphical frequency of distribution, have been employed (Nasa et al., 2021). Conversely, how feedback is presented and the choice of statistical summary can influence subsequent responses and convergence (Shang, 2023). Depending on the panel composition, feedback can be presented as single homogeneous, heterogeneous, or multiple homogeneous panel feedback. Single-panel feedback collates scores for each outcome across all participants, thereby removing disparate opinions between stakeholders (Niederberger & Renn, 2023). A comparable approach is possible with multiple panel feedback, whereby participants receive an overall average across all stakeholder groups (Williamson et al., 2017). Yet, crucial to the Delphi technique is opinion diversity, with the presentation of feedback being the sole mechanism for reconciling divergent opinions (Brookes et al., 2016). Alternative multi-panel approaches include providing feedback exclusively to each stakeholder group (peer only) or separately to all stakeholder groups (multiple) (Williamson et al., 2017). Brookes et al. (2016) compared peer feedback to multiple feedback, demonstrating greater agreement on outcomes retained and a relatively small reduction in variability in round two scores amongst stakeholders receiving multiple feedback. Similarly, MacLennan et al., (2018) conducted a randomised Delphi study providing peer-only, multiple separate or multiple combined feedback with a combination of mean, median or distribution for each outcome as a histogram. Although the study revealed no meaningful differences between the feedback groups, results demonstrated that multiple separate feedback reduced variability, consistent with Brookes et al. (2016). Multiple separate feedback was therefore used in this COS development.

When using Likert scales of ordinal data, mean and standard deviation are not recommended for providing statistical summaries; instead, median and interquartile ranges are advocated (Belton et al., 2019). Although the reporting of central tendencies enables panellists to compare their responses with the collective group response, such measures may conceal the score distribution (Williamson et al., 2017). Empirical evidence suggests that patient participants lack comprehension of the term median, whilst struggling to understand averages (Fish et al., 2020). An alternative is therefore to provide visual percentages of participants' rating each outcome in a histogram (Fish et al., 2020). For this COS development, public research partners advocated for the use of multiple

homogeneous panel feedback with histograms displaying the full distribution of scores with supplementary quotes.

Qualitative analysis is recommended when including open-ended questions or eliciting explanations for responses (Khodyakov et al., 2023), yet limited guidance exists on how to aggregate qualitative feedback in Delphi rounds. Vicarious thinking, whereby an individual considers the opinions of others, has been demonstrated as one of the most common reasons for participants changing scores between rounds in COS development (Fish et al., 2020). However, anonymously providing key arguments, concerns and rationales for divergent opinions is challenging. Representative quotes must balance comprehensiveness and readability whilst preserving minority and nuanced opinions within the aggregation process, illuminating the rationales behind the statistical patterns. Content analysis, thematic analysis, and framework analysis have been previously employed (Khodyakov et al., 2023; McPherson et al., 2018). Content analysis prioritises objectivity and replicability, which may oversimplify complex rationales, losing important EoLC nuances (Krippendorff, 2018). In comparison, thematic analysis can preserve nuances but risks researcher bias (Braun & Clarke, 2006). Framework analysis addresses such concerns, balancing inductive and deductive coding, facilitating systematic cross-panel comparison, and providing a transparent structure (Ritchie & Spencer, 1994). Consequently, it was used in this COS development and is discussed in **Chapter 5 5.10.2**.

Retention or outcome removal

Following the initial Delphi round, each outcome may be retained, revised or removed for subsequent rounds based on *a priori* criteria (Spranger et al., 2022). Retaining all outcomes throughout each round enables panellists to continually reconsider their opinion within the context of the whole COS, but is problematic. If the initial list of outcomes is extensive, considerable burden may be placed on panellists, leading to increased attrition between rounds (Williamson et al., 2017). Both approaches are evident within critical care COS development, with no empirical evidence on the optimal approach. Within this COS, only outcomes not achieving consensus were retained between rounds and criteria were defined *a priori*.

Attrition

The level of attrition (non-response) following the initial Delphi round can vary significantly both between and within studies, influenced by a range of factors such as Delphi timing, duration, prior experience, survey fatigue and level of expertise (Hasson et al., 2000; Williamson et al., 2017). Gargon et al., (2019) explored attrition rates within COS development Delphi studies, finding attrition rates varied between 0 to 55%. Multilevel linear regression demonstrated a significant association between lower response rates and the number of outcomes retained in the second round, establishing that every additional 10 outcomes decreased the response rate by 1.4% (Gargon et al., 2019). Furthermore, a high attrition rate can negatively impact the level of consensus subsequently obtained and the credibility of the outcomes (Belton et al., 2019). Attrition bias may occur if the final panel composition is not representative of the original expert group, compromising validity and generalisability (Niederberger & Spranger, 2020). Those with minority or divergent opinions are more susceptible to dropping out (Humphrey-Murto & de Wit, 2019); therefore, assessing attrition and employing mitigation strategies are imperative.

A combination of descriptive and inferential statistical methods have been employed to assess attrition and potential panel bias in COS development. Whilst there is commonality in including round-specific response rates and retention proportions, inferential approaches comparing baseline characteristics versus dropouts vary. Logistic regression models, t-test or non-parametric equivalents have been applied; however, inferential approaches are controversial, constrained by small expert panels, undermining model reliability and masking meaningful attrition (Keeney et al., 2010). Equally assessing attrition bias across individual outcomes can be compounded by multiple significance testing, resulting in false positive findings (Williamson et al., 2017). Underpinned by methodological pragmatism, descriptive statistics were used to calculate round response rates in this COS development.

Strategies used to maximise recruitment and mitigate attrition predominantly focused on panel engagement (communication), study design (number of rounds, questionnaire structure, feedback) and burden reduction. Explicit communication of study aims, time commitments and the importance of completing all rounds is recommended to manage *a priori* expectations (Belton et al., 2019) with personalised approaches/reminders considered good practice (Barrington et al., 2021; Williamson et al., 2017). Hall et al.,

(2018) demonstrated the benefits of a unique brand identity, study acronym and logo with methodological reviews highlighting the emerging importance of utilising communication models such as dedicated websites, social media and animation (Feeley et al., 2023; Hansen et al., 2024). In conjunction with public research partners, a unique brand identity, acronym, study logo and website were created for this study (Humphreys, 2023c).

Study design has previously been discussed, but the time between study rounds should also be considered. No optimum time between rounds was evident in the literature. Short, predictable gaps are recommended to maintain momentum while allowing sufficient time for reflection on feedback, but may increase participant burden (Belton et al., 2019). In contrast, long gaps risk participants becoming disengaged, weakening panel commitment and increasing attrition (Hall et al., 2018). Differentiation is not provided between long and short gaps, resulting in COS-based Delphi studies that allow several weeks to a few months between rounds (Williamson et al., 2017). Although critical care COS consistently outline the number of rounds, only a limited number of studies have provided explicit timings between rounds and the duration (**Table 2.5**). Delbecq et al. (1975) advised that Delphi panellists should have two weeks to complete each round whilst COMET suggest 2-3 weeks with flexibility to extend the closing date for specific rounds to accommodate participants' schedules and scoping their availability to increase response rates (Williamson et al., 2017). Four weeks were planned per round, and between rounds; however, round one was extended to 10.7 weeks at the stakeholders' requests. To minimise the risk of attrition associated with seasonal absences at Christmas, the time between rounds was subsequently extended to 6.1 weeks.

Table 2.5 Critical care COS Delphi timings

Author	COS	Delphi rounds	Time between rounds	Duration of each round	Overall Delphi duration
Bachmann et al., (2024)	Gastrointestinal function in adult critically ill patients (COSMOGI)	2	3.5 – 5 weeks	5 weeks	Not reported
Blackwood et al., (2019)	Critical Care Ventilation Trials (COVenT)	2	Not reported	Not reported	4 months
Connolly et al., (2024)	Physical Rehabilitation Core Outcomes In Critical illness (PRACTICE)	2	Not reported	Not reported	2.8 months
Davies et al., (2022)	Core outcome measures for clinical effectiveness trials of nutritional and metabolic interventions in critical illness (CONCISE)	2	Not reported	Not reported	Not reported
Freeman-Sanderson et al., (2024)	Interventions to Enable Communication in Patients With an Artificial Airway (Comm-COS)	2	Not reported	8 weeks	Not reported
Hodgson et al., (2021)	Patients on Extracorporeal Membrane Oxygenation	3	Not reported	Not reported	9.8 months
Johnston et al., (2023)	Critically Unwell patientS (COS-ABACUS)	2	4 weeks	2 weeks	2 months
Kjær et al., (2022)	Adult General ICU Patients	2	Not reported	2-3 weeks	Not reported
Rose et al., (2021)	Delirium in Critically Ill Adults (Del-COrS)	2	Not reported	Not reported	Not reported

Defining consensus

Within COS development, consensus represents collective agreement, yet lacks a universal definition, compounding comparability and replicability. Spranger & Niederberger, (2023) undertook a systematic review on how Delphi studies find consensus in health sciences, finding that 30% of Delphi studies defined consensus using statistical measures. Consensus was most frequently defined as percentage agreement; however, the percentage agreement varied according to the scale points used, with cut-off values between 70 and 80% (Schifano & Niederberger, 2025) . Measures of dispersion, such as interquartile ranges or standard deviations, have also been used (Niederberger & Köberich, 2021) but are problematic. A low interquartile range can occur if responses cluster at scale extremes, despite panellists fundamentally disagreeing (Hasson et al.,

2000). Conversely, the aim of Delphi studies within COS development is not to achieve consensus for all outcomes but to determine which outcomes are core (Williamson et al., 2012). As such, not all outcomes may reach consensus (Niederberger & Spranger, 2020), based on the premise that for an outcome to be considered core, a majority threshold is required. Williamson et al., (2012) posits a 70/15% consensus definition whereby *"70% or more of respondents score between 7 to 9 with fewer than 15% scoring it 1 to 3"* (page 4). This definition has been extensively used within all critical care COS listed in **Table 2.5** and was used in this COS development (**Table 2.6**).

Table 2.6 PEACE-COS COS-STAD eDelphi consensus

Standard	Methodology	PEACE-COS Study
8	The initial list of outcomes	A systematic literature review Stakeholder interviews and focus groups
9	A priori scoring process and consensus definition	**Scoring process:** The GRADE 9-point Likert scale where 1 represents the outcome of least importance and 9 represents the outcome of critical importance. **Consensus criteria:** ≥ 70% participants scoring 7 to 9 AND < 15% of participants scoring 1 to 3.
10	A priori criteria for inclusion/exclusion /adding Delphi outcomes	**Inclusion** : ≥ 70% participants scoring 7 to 9 AND < 15% scoring 1 to 3 **Exclusion:** ≤ 50% participants scoring 7 to 9 in each stakeholder group **Additional outcomes:** Unique outcomes suggested by two or more participants
11	Avoid ambiguity of language used in the list of outcomes.	All study material and content will utilise plain English language summaries and/or clinical explanations where necessary, reviewed and pilot-tested with public research partners.

Degree of consensus

Examining the degree of consensus or stability across Delphi rounds facilitates an understanding of whether panellist opinions are converging, diverging or remaining static (Hsu & Sandfords, 2007). Inferential statistics, such as the Chi-squared test or Wilcoxon paired signed-rank t-tests, can be employed to assess whether a relationship exists between variables; however, application and interpretation can be problematic (Shang, 2023). If outcomes are dropped between rounds, stability can not be assessed (Schifano &

Niederberger, 2025). Inferential statistics require stable panel membership, yet this is rarely possible as panellist attrition is common, potentially biasing results when panel composition differs (Hasson et al., 2000; Khodyakov et al., 2023). Changing panel compositions can be accommodated through independent sample tests, but this is not congruent with the Delphi's iterative nature, requiring rounds to be analysed as separate groups as opposed to repeated measures, which surrenders statistical power (Keeney et al., 2010). Based on methodological pragmatism, neither of the aforementioned methods was used within this COS development. Instead, descriptive statistics were employed, acknowledging that it is not possible to ascertain whether changes are statistically significant or attributable to panel composition variability.

2.3.7 PEACE-COS Stage Three

In summary, a three-stage international online (eDelphi) consensus study (Hasson et al., 2000; Hsu & Sandford, 2007) was proposed, from which three homogeneous stakeholder panels (**2.3.4**) would consider a range of outcomes derived from Stages One and Two. Questionnaires and controlled feedback were developed in conjunction with public research partners and piloted with representatives of different stakeholders to mitigate ambiguity and strengthen reliability and validity (Khodyakov et al., 2023; Schifano & Niederberger, 2025). Consensus was defined *a priori* (**Table 2.6**). As Stage Two encountered recruitment challenges, extending beyond its designed timeframe, timeline constraints were imposed on Stage Three, necessitating a post-protocol amendment. The number of rounds were reduced from three to two, while the patient/patient representative proxy stakeholder group was expanded to include patient survivors (**Table 2.7**), acknowledging that survivorship bias and recall bias can occur. This pragmatic decision was unanimously supported by the steering committee, and ethical approval obtained. Further methodology is presented in **Chapter Five, 5.3**.

Table 2.7 PEACE-COS COS-STAD eDelphi stakeholder involvement

Standard	Methodology	PEACE-COS Study
5	Those who will use the COS in research	Researchers and healthcare professionals interested in EoLC in critical care
6	Healthcare professionals with experience of patients with the condition	All experienced healthcare professionals (including all members of the multi-disciplinary team) with at least 1 year postgraduate experience, in the provision of EoLC in critical care.
7	Patients with the condition or their representatives	Family members with direct experience of an adult (>18 years) family member dying in critical care within the last 10 years and have recollection of the EoL process or had a family member receive EoLC in critical care within the last 10 years and have recollection of the EoLC process Patients who within the last 10 years have recovered from critical care but had a limited chance of survival whilst in critical care.

Consensus meeting

Delphi surveys are frequently succeeded by a consensus meeting of key stakeholders to discuss and agree the final COS, conducting further voting as required, with a prior consensus threshold (Keeley et al., 2016). Structured consensus development conferences, card-sorting workshops and elements of the nominal group technique (NGT) may also be employed (Beaton, et al., 2021; Williamson et al., 2017). Although limited empirical evidence exists on the optimal method, COMET recommend the use of the NGT through a face-to-face meeting (Williamson et al., 2017). Classical NGT comprises four distinct elements: (1) silent idea generation, (2) round-robin recording, (3) serial discussion for clarification, and (4) individual voting (Delbecq et al., 1975). Modifications have evolved with ideas generated from systematic reviews or surveys, negating or adapting the use of silent generation (McMillan et al., 2016) and/or meetings convened virtually (Lee et al., 2024). Both the NGT and the modified nominal group technique (mNGT) have been adopted in critical care COS consensus meetings (Freeman-Sanderson et al., 2024; Rose et al., 2021). Advantages enabling real-time clarification of ambiguities, providing a structured platform for nuanced discussion and strengthen stakeholder buy-in to the final

COS; however, neutral facilitation is paramount to mitigate dominance (McMillan et al., 2016).

Similar to Delphi surveys, determining consensus group composition is crucial. Homogeneous versus heterogeneous group composition should be considered (Williamson et al., 2017) with COS developers using both approaches. Depending on composition and COS scope, multiple meetings may be required, necessitating further decisions on how to amalgamate results. Common methods include aggregating individual scores/rankings across all groups, preserving group membership, with final outcome inclusion determined by pooled median scores/ranks (McMillan et al., 2016). Alternatively, consensus may be derived from each group separately, then group-level scores/rankings combined through meta-analytical techniques (McMillan et al., 2016). Following either method, divergent results may still be apparent, necessitating a final heterogeneous group meeting to resolve conflicting priorities (Humphrey-Murto et al., 2017).

Ven & Delbecq (1974) posit that using a single heterogeneous consensus group meeting yields methodological advantages, mitigating the challenges associated with combining results from multiple homogeneous groups, reducing the influence of facilitation styles across groups and eliminating the need for post-group synthesis of discordant scores/rankings. Conversely, scheduling an international online consensus meeting that accommodated time zone disparities across multiple continents and facilitator availability was challenging. Selecting a time that accommodates the majority of participants risks creating inequalities in participation and marginalising those in less-represented time zones. Instead, a time was selected to mitigate the most extreme inconveniences, but required some participants to join outside working hours, affecting attendance and engagement. Cultural differences in working schedules and national holidays led to a date change.

The involvement of EoL patient/patient representative stakeholders in consensus meetings presents several challenges. Psychologically, stakeholders may experience ongoing trauma or emotional distress (Sanderson et al., 2022). Discussing EoL outcomes in person may trigger difficult emotions in survivors concerning their own prognosis and losses in bereaved family members. Power imbalances and intimidation can occur if included in heterogeneous groups with technical jargon and complex statistical concepts, excluding stakeholders from meaningful participation, limiting equitable contribution (Fish et al.,

2020; Williamson et al., 2017). Conversely, Young & Bagley (2016) found no consensus on whether patient/patient representative stakeholders should participate in consensus meetings as a homogeneous group or be part of a heterogeneous group.

A pre-consensus patient/patient representative stakeholder meeting was used to mitigate some of the aforementioned challenges and strengthen the consensus process, promoting participant confidence, psychological safety, substantive engagement and more meaningful participation (Davies et al., 2025). Main convergences and any discordances were captured among the group, with voting used to enhance main consensus meeting discussions. Holding a pre-consensus meeting is particularly advantageous in sensitive topics such as EoLC, allowing researchers to improve outcome framing and comprehensibility, reducing the risk of misinterpretation during the main consensus voting.

Irrespective of group composition and the number of occurrences, careful facilitation, adequate stakeholder training and participation, coupled with access to psychological support, strengthen both heterogeneous and homogeneous groups. Preparatory guidance, familiarisation events, and support for organisational contacts were provided for both facilitators and stakeholders, as detailed in **Chapter Six.**

2.3.8 PEACE-COS Stage Four

An online pre-consensus homogenous patient/patient representative stakeholder meeting preceded by a heterogeneous group stakeholder consensus meeting was conducted using mNGT. Within the main consensus meeting, outcomes were initially discussed in two heterogeneous groups running in parallel to accommodate participant numbers prior to combining for summative discussions and formal voting. Further rounds of discussion and voting occurred as required with the aim of achieving consensus and ratifying the final COS. In line with recommendations, qualitative analysis of meeting transcripts was undertaken to increase comprehensiveness of the rationale and context behind the final COS, enhancing clarity and applicability (Liang et al., 2025). Consensus thresholds were established *a priori*. Specific details pertaining to the modifications to the NGT, voting platform and consensus thresholds are presented in **Chapter Six 6.3**.

2.4 Ethical and regulatory considerations

The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki (World Medical Association, 2013a), the relevant principles of Good

Clinical Practice (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, 2016) and the UK Policy Framework for Health and Social Care Research (Department of Health, 2017). Prior to the enrolment of any participants, ethical approval from the Health Research Authority and Health and Care Research Wales (HCRW) ((23/NE/0057) **Appendix 4**)) and institutional approval from the University of Hertfordshire Health, Science, Engineering and Technology Committee ((HSK/PGR/NHS/02993) **Appendix 5**)) were obtained with participating NHS sites required to confirm capacity and capability.

A clear explanation concerning the study purpose, risks and benefits to the participants and the right to withdraw from the study at any time, as outlined in Stages 2-4 was provided to all participants invited to participate. Prior to participation, informed consent (given voluntarily by a person with capacity, with no undue influence and adequately informed) was gained, and participants were free to withdraw from the study at any point.

2.5 Next chapter

Chapter Two has presented the main methodological considerations associated with developing a COS. Further methodology can be found in each relevant chapter. The following chapter reports Stage One of the PEACE-COS study: outcome identification through a systematic review.

Chapter 3: A systematic review to inform the development of a core outcome set for end-of-life care in critical care

3.1 Abstract

***Background*:** A systematic review was undertaken to determine what person-centred outcomes and measures are reported in studies evaluating end-of-life care (EoLC) in critical care.

Methods: A systematic search of multiple electronic databases including CINAHL, EMBASE, Joanna Briggs Institute, MEDLINE, PsychInfo, PubMED, Scopus, and the Cochrane Library were searched from database inception to 14th May 2022. Original quantitative, qualitative, and mixed-methods studies describing person-centred outcomes in EoLC were included. Risk of bias was assessed using the Cochrane tool for assessing risk of bias in randomised trials (RoB 2 tool) and the Cochrane tool for assessing risk of bias in non-randomised studies (ROBINS-I). Qualitative studies were assessed using the Critical Appraisal Skills Programme (CASP) quality assessment tool. Outcome quality was independently assessed by two reviewers according to the Management of Otitis Media with Effusion in Cleft Palate Scoring System (MOMENT) criteria.

***Results*:** Searches identified 2,536 citations, of which 25 studies and 37 reports (full-text publications and trial registries) were included, and data extraction was conducted. Studies included 2,914 family members of 27,771 patients and 350 clinicians across a range of ICUs in Australia, Canada, China, France, and the United States of America. 261 outcomes and outcome measures were extracted, 114 were unique across 11 outcome domains of the COMET taxonomy (Dodd et al., 2018). The delivery of care domain had the highest number of unique outcomes, with all studies reporting at least one outcome. No one outcome was common across all studies. 57 outcome measurement instruments were used. The frequency of measurement and instrument selection was variable.

Discussion: Substantial heterogeneity and multiplicity of outcome selection and measurement were evident. Outcome reporting was inconsistent. Standardisation of how outcomes are defined, collected, measured and reported for end-of-life care research in critical care is needed.

Other: PROSPERO registration ID CRD42022344709

3.2 Introduction

3.2.1 Rationale

To progress EoLC, it is necessary to understand how outcomes and associated measures are articulated. The previous chapters present how core outcome sets (COS) can address current problems of outcome heterogeneity and outcome reporting bias, thereby increasing the reliability, relevance, and usefulness of study findings and systematic reviews for patients, health professionals, researchers, healthcare commissioners and policy makers (Kirkham et al., 2017). Although critical care COS are becoming more prevalent (Gorst et al., 2025) no core outcome set exists in EoLC in critical care. Undertaking a systematic review is the first step in developing a core outcome set (Williamson et al., 2017) and forms Stage One of the PEACE-COS study.

Previous systematic reviews predominantly focus on hospice or chronic disease settings (Kearns et al., 2017; Mularski et al., 2007) where EoL relates to the last few days or months of a person's life. This may not be representative of critical care populations where approximately 50% of deaths occur in the first hour following the withdrawal of cardiorespiratory support (Brieva et al., 2013) and the probability of death is 99% within 24 hours (Sprung et al., 2013). The systematic reviews that focus on critical care populations investigate only specific elements of EoLC, such as palliative care interventions, family experience when treatment is withdrawn, pain management, communication and family outcomes/satisfaction (Aslakson et al., 2014; Chen et al., 2020; Coventry et al., 2020; Desanto-Madeya & Safizadeh, 2017; Durán-Crane et al., 2019; Oczkowski et al., 2016; Olsson et al., 2021). All capture a range of outcomes and associated measures using a variety of techniques, yet there remains a limited synthesis of person-centred outcome measures collected, of how these transcend an international context, and of how these address the diverse range of patients cared for within critical care.

This chapter transparently presents the methodology employed in the systematic review and a synthesis of the findings to generate an initial list of outcomes for consideration in the COS development. Without a rigorous and systematic approach, the subsequent consensus processes in Stages Three and Four risk being uninformed, incomplete, or biased toward the perspectives of a particular stakeholder group (Williamson et al., 2017).

3.2.2 Objectives

The primary objective of the systematic review was to identify a list of person-centred outcomes and associated outcome measurement instruments (OMIs) reported in studies of EoLC within critical care to inform the development of a core outcome set. It sought to address the following primary question:

What person-centred outcomes and measures are reported in studies evaluating EoLC in adult critical care?

The secondary research questions guiding the review were:

- How are the outcome measures defined in critical care studies at EoL?
- Which outcome measurement instruments are used to measure person-centred outcomes?
- During which time points are the instruments measured?

3.3 Methods

The systematic review was prospectively registered on the International Prospective Register of Systematic Reviews (PROSPERO) (CRD42022344709), and guided by the Core Outcome Set STAndards for Development (COS-STAR) (Kirkham et al., 2017). The Core Outcome Measures in Effectiveness Trials (COMET) database of core outcome sets was also searched, and the review was registered *a priori* as part of the overall study (COMET ID 1970).

3.3.1 Eligibility criteria

The systematic review included all study designs: quantitative, qualitative, and mixed-methods studies describing person-centred outcomes. Systematic reviews of all study types, meta-analyses, randomised and non-randomised controlled trials, trial registrations and published protocols were included. Conference abstracts relevant to eligible studies were only included where the full published data were not available.
Editorials/commentaries, case reports, case series, quality improvement studies and book chapters were excluded. Publications that only contained abstracts and non-systematic reviews were also excluded.

The following PICO definition guided the review:

Participants/Population

Adult patients (≥18 years of age) and their families managed in a critical care environment prior to death, receiving EoLC. A critical care environment was defined inclusively to encompass all types such as burns, cardiac, medical, neurological, surgical, trauma, or mixed. Paediatric, neonatal, and psychiatric Intensive Care populations were excluded.

Interventions/Exposures

Interventions comprised of any individual or multi-disciplinary team intervention initiated in the EoLC period delivered to critically ill patients or their families (or both) within critical care. In line with critical care best practice guides, a family member was defined inclusively as a relative or other friend with whom the patient had a close or intimate relationship (Faculty of Intensive Care Medicine, 2019). Interventions or outcomes focused solely on organ donation, euthanasia or performed outside of critical care were excluded.

Comparator/Control

Where applicable, control groups comprised of patients or their families receiving standard or usual care.

Main outcomes

To be included, studies required a defined outcome relating to EoLC. All outcomes listed and their definitions used as primary, secondary, and composite outcomes were examined. Examples include quality of dying and/or satisfaction; increased identification/adherence to patient wishes; symptom management. Studies pertaining to outcome development or psychometric properties were excluded as their methodological focus differs from outcome studies. Outcome studies focus on measuring the effectiveness, efficacy or impact of interventions (Sholklapper et al., 2024). In contrast, psychometric studies primarily evaluate the quality and characteristics of measurement tools, concentrating on the validity, reliability and responsiveness (Swan et al., 2023).

3.3.2 Information sources

Using a combination of subject headings (MeSH terms), controlled vocabulary, free text (keywords), truncation and appropriate Boolean operators an extensive literature search of

published peer-reviewed journal articles was undertaken by the researcher in 6 electronic bibliographic databases (**Table 3.1**) on 14th May 2022: Cumulative Index to Nursing and Allied Health Literature (CINAHL Plus via EBSCOhost), Excerpta Medical Database (EMBASE via OVID), Medical Literature Analysis and Retrieval System Online (MEDLINE via OVID interface), PsychInfo (via ProQuest interface), PubMED and Scopus.

Table 3.1 Bibliographic database coverage

Database	Coverage
EBSCOhost	
CINAHL Plus	1961 to present
Ovid	
EMBASE	1974 to present
MEDLINE	1946 to present
ProQuest	
PsychInfo	1967 to present
PubMed	1971 to present
Scopus	1788 to present

Monthly alerts were established. Two international registers of systematic reviews were searched - The Joanna Briggs Institute and PROSPERO. A targeted grey literature search of three clinical trial registries – ClinicalTrials.gov, Cochrane Central Register of Controlled Trials (CENTRAL) and World Health Organisation International Clinical Trials Registry Platform (WHO ICTRP) were undertaken to enable cross-referencing and ensuring that no studies were missing. As EoLC transcends international boundaries, regional trial registry searches were considered superfluous. Whilst Google scholar was not used for the primary review searches due to a lack of transparency and reproducibility (Gusenbauer & Haddaway, 2020), it was utilised as a supplementary source for identifying grey literature.

3.3.3 Search strategy

It is increasingly recognised that involving an experienced medical information specialist correlates with higher-quality systematic review search strategies (Batten & Brackett, 2021; Higgins et al., 2022; Rethlefsen et al., 2015). Therefore, under the guidance of an experienced health information specialist and based on the previously outlined PICO acronym, a preliminary line-by-line search strategy was created in one electronic bibliographic database (MEDLINE) (**Appendix 6**). This iterative process allowed the

refinement of both precision (specificity) and sensitivity, creating a preliminary effective and efficient search strategy where the research team were able to review individual lines, concepts and the overall structure, identifying potential errors (Brackett & Batten, 2020).

A plethora of research guidance focuses on the importance of patient and public involvement (PPI) in all research processes and settings (Health Research Authority, 2025b; National Institute for Health and Care Research, 2024). In line with current recommendations, the initial plan was to engage the University of Hertfordshire's Public Involvement Research Group (PIRG) in all aspects of the systematic review (Staniszewska et al., 2017). PhD research, however, falls outside the group's funding remit, and the group felt that they did not have the necessary skills to be involved in a systematic review. There are currently no critical care EoL support groups within the UK. Existing support groups focus on post-critical care recovery, and whilst they are aiming to expand their remit to include bereaved relatives, this aspect is currently under development. Non-critical care organisations specialising in EoLC and bereavement were contacted, but none considered critical care to be within their remit. This necessitated adopting a more proportional and pragmatic approach to facilitate PPI engagement. A member of the public with recent bereavement experience was informally consulted to ascertain if they perceived any keywords were missing from a lay perspective.

To further increase rigour, prior to performing the main search, a second information specialist was consulted to review the search strategy, and the Peer Review for Electronic Search Strategies (PRESS) evidence-based checklist completed (McGowan et al 2016) (**Appendix 7**). This led to additional refinements of search fields, free text word searching (eg premature) and truncation (eg intensive care unit*) to increase consistency, developing a final comprehensive search strategy (**Appendix 8)** which was translated across databases and trial registries. Due to limited translation resources, funding and time constraints, results were limited to English language. No restrictions were placed on publication dates; each database was searched from inception. Vocabulary and syntax were adjusted with search terms *'exploded'* where applicable and database search strings compared to the Polyglot Search Translator (PST). Whilst it is not possible to reduce translation errors entirely when systematic reviews involve searching multiple databases, the PST model has been demonstrated to be a useful adjunct in translating search strings, with 8.6 errors per translation compared to 14.6 errors per manual translation (Clark et al., 2020).

Where disparities arose, results were compared for precision and recall. To ensure term completeness, an information specialist was consulted with Scopus free-text synonyms as no thesaurus was available. Full search strategies for all databases are located in **Appendix 9**.

3.3.4 Selection process

Exported references were imported into EndNote 20 reference management software, amalgamated, and bibliographic duplicates were manually removed by the researcher following the de-duplication methodology of Bramer et al. (2016). Conversely, clinical trial registry references do not contain the bibliographical data fields author, journal, volume or pages advocated by Bramer et al., (2016). Clinical trial registry references were de-duplicated using the study registration number and title (Hunter et al., 2022). Studies with the same title but different registration numbers were not considered duplicates, as each registry can contain different information. In such instances, both references were included but organised as a single study.

In line with current guidance from the Cochrane Rapid Reviews Methods Group, the remaining records were uploaded into Systematic Review Accelerator (SRA) for automated de-duplication (Affengruber et al., 2024; Guimarães et al., 2022), identifying one further duplicate.

Guided by a specifically produced screening software guide and one-to-one training by the researcher, four reviewers (SKH, RG, DH, SMD) independently manually screened a selection of the same subset of 124 citation titles and abstracts against the previously defined eligibility criteria using Rayyan Intelligent Systematic Review software (https://www.rayyan.ai/) (Ouzzani et al., 2016). Automated screening functions were not used as sensitivity values have been demonstrated to be between 1-29% in previous systematic reviews (Valizadeh et al., 2022). Interrater reliability was determined using Conhen's kappa statistic k (Landis & Koch, 1977) (**Table 3.2**)**.** To promote effective and efficient screening, all reviewers were encouraged to ask for clarity and to make recommendations throughout the rigorous pilot refining process. Discrepancies were discussed and analysed, providing valuable learning and understanding of the context and EoLC processes. Where agreement wasn't reached, an independent reviewer was consulted (NP).

Table 3.2 Interpretation of K statistic

K Score	**Interpretation**
<0	Poor
0.00-0.20	Slight
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Substantial
0.81-1.00	Near Perfect

Source: (Landis & Koch, 1977, p. 165)

Using transparent reproducible methods and a structured process, the remaining title and abstracts were screened by three teams of two reviewers, blinded to each other's decisions, categorising each study as a) included b) excluded or c) maybe. Interrater reliability was moderate (**Table 3.3**). Disagreements were raised with the wider review team and, where possible, resolved through consensus. Where consensus could not be reached, an independent reviewer was consulted (NP).

Table 3.3 Title and abstract screening agreement and interrater reliability

	Team 1	Team 2	Team 3
Both reviewers agree to include	46	7	8
Both reviewers agree to exclude	2,188	218	359
Only reviewer 1 wants to include	44	15	15
Only reviewer 2 wants to include	17	3	5
% of agreement	97.34%	92.59%	94.83%
Cohen's K	0.59	0.40	0.42

Full-text publications of all potentially relevant references (references categorised as included or maybe) were retrieved and examined for eligibility, or if eligibility could not be determined based on the title and abstract. Following a pre-defined agreed process, diligent attempts were made to contact the authors of conference abstracts, clinical trial registries and theses without a corresponding full-text publication (**Figure 3.1**). Several logistical challenges were, however, encountered; many abstracts failed to provide corresponding author details, while other authors were no longer employed by the host institution, or others had changed their names. Discordant information was evident between abstracts and full-text publication relating to authorship, sample size and results, with inconsistent use of CONSORT reporting guidelines for abstracts (Hopewell et al., 2008). Where a full text was available, the original reference was excluded. Where no full-text was available, and the authors could not be contacted, the citation was excluded if outcome measures were not reported or the citation contained inadequate information to appraise the design.

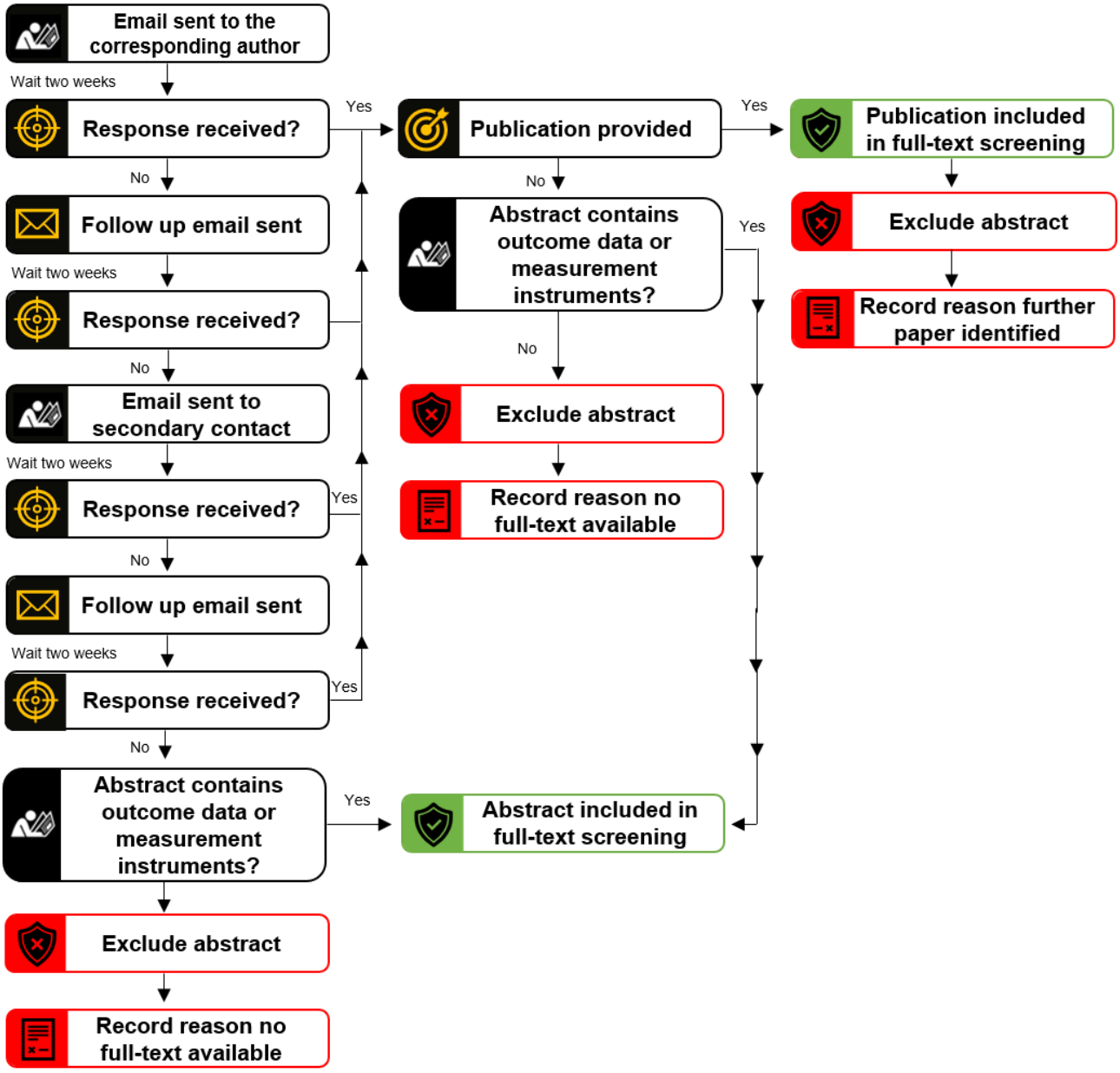


Figure 3.1 Author contact process

Using the same structured process used in the title and abstract screening, each full text reference was screened by three teams comprising two reviewers blinded to each other's decisions, categorising each study as a) included, b) excluded or c) maybe. Within Ryyann, records were maintained detailing all potentially relevant studies with reasons for inclusion or exclusion. One member of the review team (DH) decided not to participate in the full-text screening; consequently, the independent arbitrator (NP) from the title and abstract screening became part of the screening team, with another team member assuming the independent role (NL).

Progress was discussed monthly, where potential problems were addressed in an attempt to preclude coder drift and maintain reliability. A screening checklist, together with coding instructions and trial registry guidance were developed. No substantive alterations were made to the screening process. Conversely, interrater reliability significantly decreased compared to title and abstract screening, with individual variability evident within and among screeners (**Table 3.4**). This can be attributed to a number of factors. Research experience, prior knowledge, discipline and academic backgrounds varied within the team. Screening occurred over an extended period, with less experienced members altering their decisions at multiple time points per study and decisions subject to fatigue effects. Where study methodology were ambiguous, a more lenient, inclusive approach was adopted by some screeners, prioritising sensitivity over precision or specificity while others rigorously adhered to the inclusion and exclusion criteria. To mitigate this, individuals received additional training throughout the process, and regular percentages of the total abstracts screened were shared with the study team to encourage engagement. Despite implementing the aforementioned strategies, a degree of subjectivity remains with screeners making decisions based on subjective criteria that are not explicitly stated (Belur et al., 2021).

Table 3.4 Full text screening agreement and interrater reliability

	Team 1	Team 2	Team 3
Both reviewers agree to include	16	7	13
Both reviewers agree to exclude	43	39	45
Only reviewer 1 wants to include	2	15	4
Only reviewer 2 wants to include	16	12	22
% of agreement	76.62%	63.01%	69.05%
Cohen's K	0.49	0.09	0.31

3.4 Data Extraction

To ensure reliability and reduce the possibility of selection bias, independent dual data extraction was undertaken on all studies by four reviewers (AS, RG, SKH, SMD) using a specifically designed pre-piloted standardised Microsoft data extraction form (**Appendix 10**) underpinned by Cochrane methodology (Higgins et al., 2022). Reviewers were not blinded to study citations. Data were extracted verbatim, including the page number, table, or figure, to maintain transparency and traceability, in line with COMET recommendations (Williamson et al., 2012, 2017), and analysed using Microsoft Excel. Discrepancies were

resolved by discussions between the reviewers. Where consensus was not reached, discrepancies were resolved by an independent arbiter (NL). Where multiple publications were evident in relation to a specific study, data were extracted separately from each report and then combined, treating the publications overall as a singular study (e.g. trial registry and corresponding study publications). Corresponding authors were contacted if data concerning the primary outcome were unavailable.

The following variables were extracted:

- Study characteristics: title, data collection year, publication year, study type, country, first author, total number of participants, clinical setting
- Primary, secondary and composite outcomes
- EoLC intervention, comparator
- Outcome definition
- Outcome measurement instrument (OMI), and time point.

3.4.1 Methodological quality

MOMENT assessment

Outcome quality was independently assessed by five reviewers (AB, NP, AS, SKH, SMD) in duplicate and reported according to the established 6-point Management of Otitis Media with Effusion in Cleft Palate Scoring System (MOMENT) (Harman et al., 2013). Whilst the MOMENT scoring criteria is not validated (Leow et al., 2021) it has previously been used in critical care systematic reviews (Connolly et al., 2018; Rose et al., 2021). Although evaluating the quality of outcomes was not the primary objective of the systematic review, it is imperative for the subsequent stages of the COS development to evaluate if the studies included reported clearly defined outcomes. High-quality outcome reporting was defined as a score of $\geq$4 where one point is awarded to each of the 6 questions outlined in **Figure 3.2.** Discrepancies were resolved through discussion or by an independent arbiter if a consensus was not reached. Composite outcomes were not scored as primary outcomes as they have been demonstrated to be unreasonably combined, inconsistently defined, and inadequately reported (Cordoba et al., 2010; Heneghan et al., 2017).

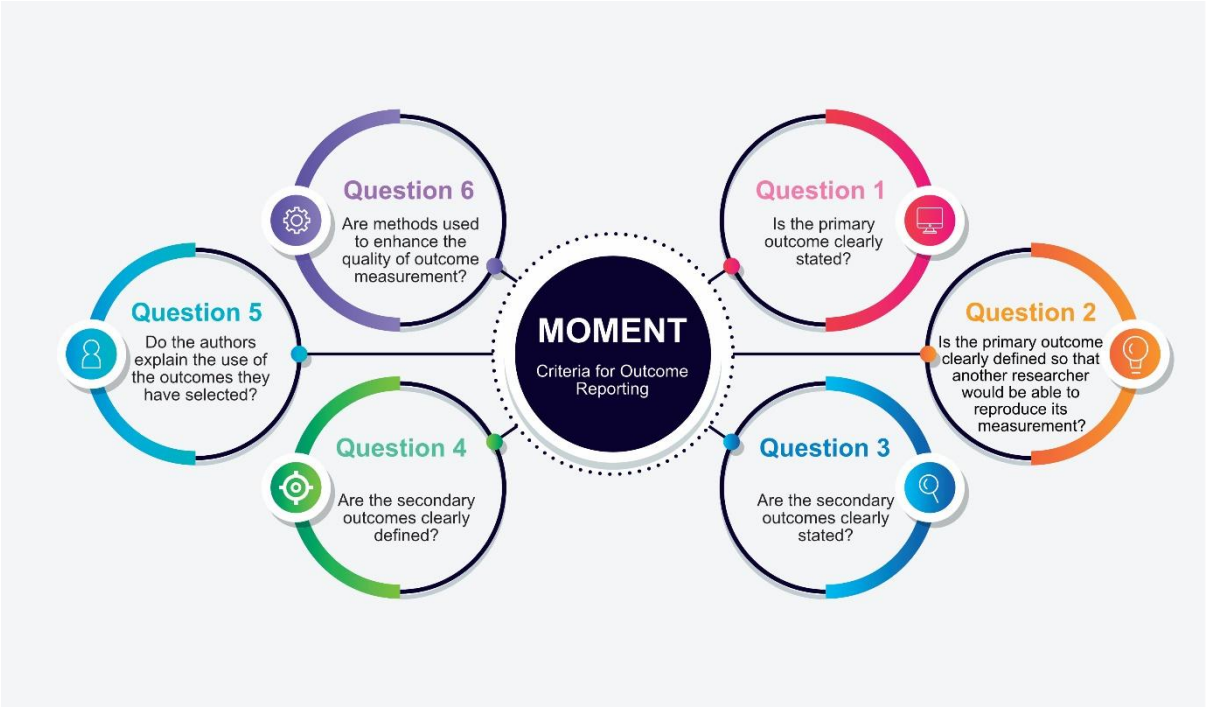


Figure 3.2 MOMENT criteria

Risk of bias assessment

The Cochrane Collaboration tools (Higgins et al., 2022) were used to assess the risk of bias. Five domains were assessed in randomised trials using the RoB 2 tool with the following three categories: low risk of bias, some concerns, or high risk of bias (Sterne et al., 2019). Seven domains were assessed in non-randomised studies using the ROBINS-I tool based on five categories: low risk of bias, moderate risk of bias, serious risk of bias, critical risk of bias or no information (Sterne et al., 2016). No automated tools were used.

Since the systematic review aimed to generate a list of all published outcomes, no studies were excluded based on quality or risk of bias. The quality assessments enabled commentary on the quality of evidence specific to EoL in critical care and were primarily included in the systematic review as deemed a mandatory component of a PhD study by the supervisory team.

Two reviewers (SKH, AS) independently appraised qualitative studies according to the Critical Skills Appraisal Programme (CASP, 2018). In contrast to the ROB 2 and ROBINS-I tools, CASP comprises ten questions, assessed as yes, no, or unclear. In line with Cochrane recommendations, scores to domains were not applied (Noyes et al., 2023).

3.4.2 Data synthesis

The primary aim of the data synthesis was to collate identified outcomes, their descriptions, and measures to inform the development of a core outcome set. Within the context of this systematic review, an outcome was defined as *'one that has original meaning and context'* (Young et al., 2019, p. 15). It was anticipated that outcomes would be reported using a diversity of terminology; therefore, spelling variations addressing the same concept and context were unified, duplicate outcomes were removed, and a unique list of outcomes was generated in line with the methodology developed by Young et al.(2019). Any outcomes considered irrelevant to the study purpose and research questions were removed (with reasons documented). The unified descriptions of outcomes synthesised will be further refined during subsequent stages of COS development.

Four reviewers (AS, RG, SKH, SMD) working in duplicate, independently classified outcomes according to the core areas and domains of the COMET taxonomy (Dodd et al., 2018). To ensure transparency and clarity, composite outcomes were disaggregated, with each individual outcome component classified separately to the relevant domain (The Comet Initiative, 2022). Subdomains were added to facilitate organisation. Discrepancies were resolved through discussion or by two independent arbiters (NL, NP) where consensus was not reached. The COMET team were also consulted to ensure that the classification system was applied consistently and rigorously in line with other systematic reviews. Where opinions differed between the COMET team and the systematic review team, outcomes were allocated according to COMET recommendations. Disparities frequently arose as the COMET taxonomy is primarily developed for patient-reported outcomes rather than surrogate or observer outcomes.

3.5 Results

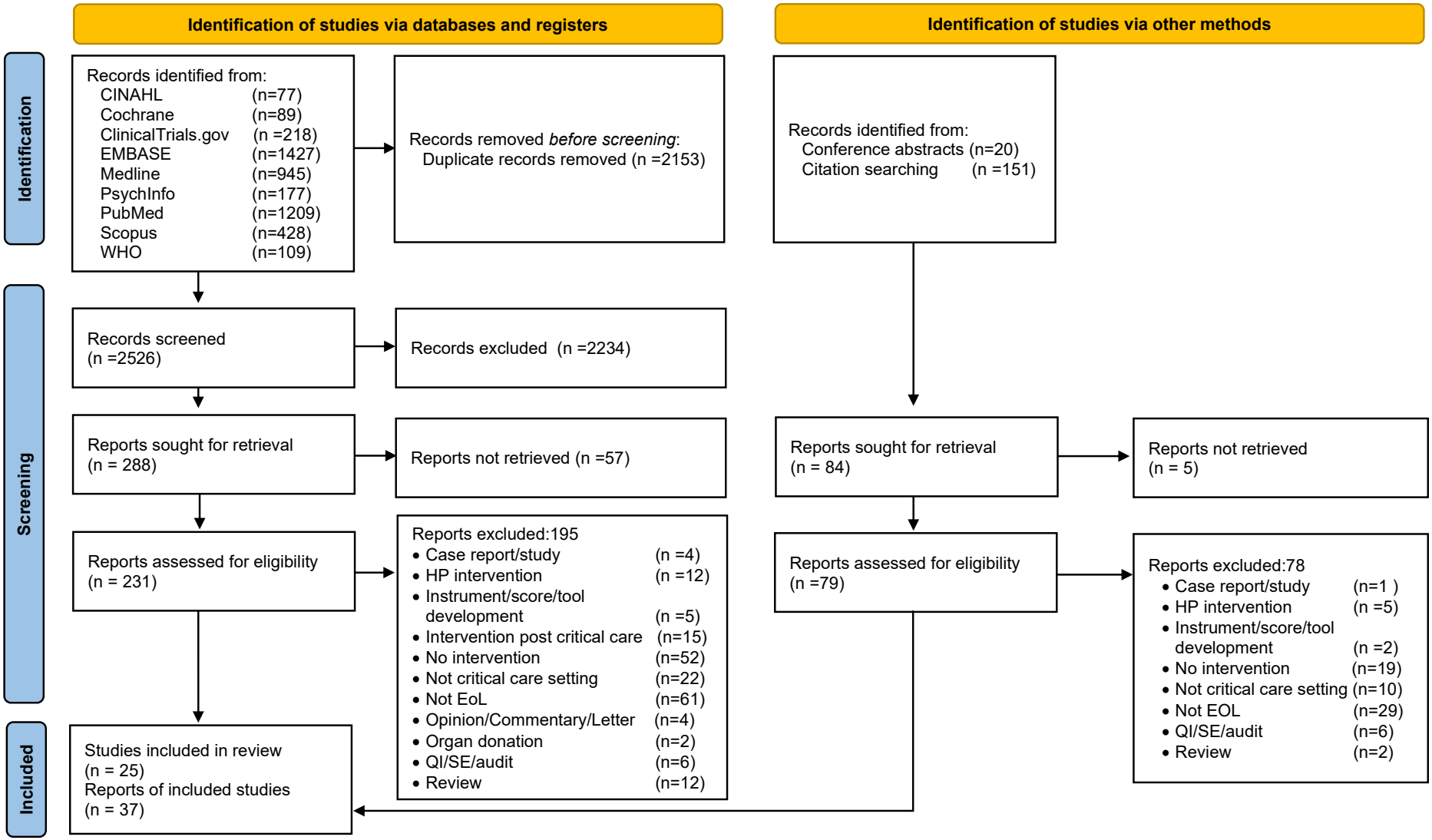
3.5.1 Study selection

The initial search strategy identified 4,679 citations. Manual deduplication identified 2,152 duplicates (Bramer et al., 2016), with the Systematic Review Accelerator identifying one additional duplicate. Title and abstract screening was undertaken on 2,526 citations, resulting in the exclusion of 2,234 citations. 288 citations were sought for retrieval with 232 reports obtained. 25 studies met the inclusion criteria (**Appendix 11**), comprising 25 full-text publications and 12 trial registries (**Appendix 12**), generating 37 reports for data extraction. The study selection process is documented using the PRISMA flow diagram illustrated in **Figure 3.3** (Page et al 2021).

3.5.2 Study characteristics

Study characteristics are outlined in **Table 3.5**. Twelve (48%) studies were randomised controlled trials (RCTs), of which three were cluster RCTs, two were feasibility RCTs, and one was a pilot RCT. Six (24%) were cohort studies, with four (16%) non-randomised pre-/post-studies of an intervention. With the exception of one study, all completed studies were conducted prior to the COVID-19 pandemic. Three study protocols were included, but results were not available during the data extraction period. 16 (64%) studies were quantitative, eight (32%) were mixed methods, and one (4%) was qualitative. All studies were limited to adult participants.

Studies predominantly recruited in America (14 (56%) North America and 5 (20%) South America) with 4 (16%) in Europe. The remaining studies recruited in China (1 (4%)) and Oceania (1 (4%)). Five of the seven continents were represented. Thirteen (52%) studies were single-centre studies, with 12 (48%) multi-centre studies. There was variation in the critical care speciality, with seven (28%) studies not reporting the type. Collectively, 2,914 family members of 27,771 patients were enrolled with 350 clinicians from 158 ICUs in 140 hospitals using both closed and open staffing models. Clinicians comprised of physicians (fellows or residents), nurses, ICU assistants, chaplains and allied health professionals.



EoL= End-of-Life HP= Health professional QI = Quality Improvement SE = Service Evaluation

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

Figure 3.3 Prisma flow diagram

Table 3.5 Study characteristics

Study characteristics	Studies n	(%)
Study design		
Case-control	1	(4)
Cohort	6	(24)
Cross-sectional	1	(4)
Non-randomised, before and after intervention (pre/post)	4	(16)
Randomised controlled trial	12	(48)
Qualitative interview	1	(4)
Study Region		
China	1	(4)
Europe	4	(16)
Oceania	1	(4)
North America	14	(56)
South America	5	(20)
Publication Range		
2004-2006	2	(8)
2007-2009	3	(12)
2010-2013	3	(12)
2014-2016	3	(12)
2017-2019	6	(24)
2020-2022	8	(32)
Site Type		
Single centre	13	(52)
Multi-centre	12	(48)
Multi-centre range	2-43	
Study registered on public research database/register		
ACTRN	1	(4)
ClinicalTrials.gov	12	(48)
Not Reported	12	(48)
Critical Care Speciality*		
Cardiac	6	(12)
General	1	(2)
Medical	15	(30)
Mixed (Medical and surgical)	4	(8)
Neurological	5	(10)
Surgical	9	(18)
Trauma	2	(4)
Not reported	8	(16)

*Multiple specialities available

3.5.3 Intervention type

Interventions were classified according to four areas of the Metaxa et al., (2021) taxonomy (**Table 3.6**) to accurately and reproducibly capture intervention granularity, facilitating a cohesive and comparable approach to evaluate EoLC interventions. Seven (28%) studies involved multifaceted interventions, cross-cutting across multiple domains. Communication

interventions were the most frequent intervention implemented in 14 (56%) studies and used a range of media - verbal, written and mobile apps or online platforms to prepare and support family members (**Appendix 11**). Interventions involving the palliative care team were interspersed across the patient's illness trajectory from identifying those with palliative care needs, to providing integrative (participation in ICU ward rounds and family meetings) and consultative care in 9 (36%) studies.

Table 3.6 Study Interventions

Type	**n**	**(%*)**
Advance care planning or goals of care discussions	2	(8)
Communication interventions	14	(56)
Educational interventions	8	(32)
Ethics consultations	0	(0)
Palliative care team involvement	9	(36)

*The percentage total is greater than 100% due to studies including >1 intervention

Educational interventions focused on ventilator withdrawal algorithms (Campbell, 2017; Robert et al., 2017), staff training (Kaufer et al., 2008; Lincoln et al., 2020; O'Mahony et al., 2010) and the provision of intra-ICU family cognitive-behavioural therapy (Lichtenthal et al., 2022; Prigerson et al., 2019). Advance care planning interventions pertained to the elicitation and implementation of wishes from patients, families and clinicians occurring in only two (8%) studies (Cook et al., 2015; Swinton et al., 2017). Overall, interventions were predominantly delivered by the clinical team in five (20%) studies (Chen et al., 2022; Cook et al., 2015; Cox et al., 2018; Kirchhoff et al., 2008; Lichtenthal et al., 2022).

3.5.4 Outcomes

A total of 286 verbatim outcomes were originally extracted (**Appendix 13**); 25 were considered feasibility outcomes and subsequently excluded. Whilst the Medical Research Council guidelines recommend the extraction of feasibility outcomes (Skivington et al., 2021), the extracted outcomes pertained to recruitment rates, adherence, and fidelity. Such outcomes were considered context-specific and could render the COS too broad, thereby simultaneously reducing its utility and uptake. A total of 261 outcomes, therefore, underwent an assimilation process illustrated in **Figure 3.4** and outlined in **Data synthesis**, with an average of 10.44 outcomes per study. 114 outcomes were considered unique (**Appendix 14**).

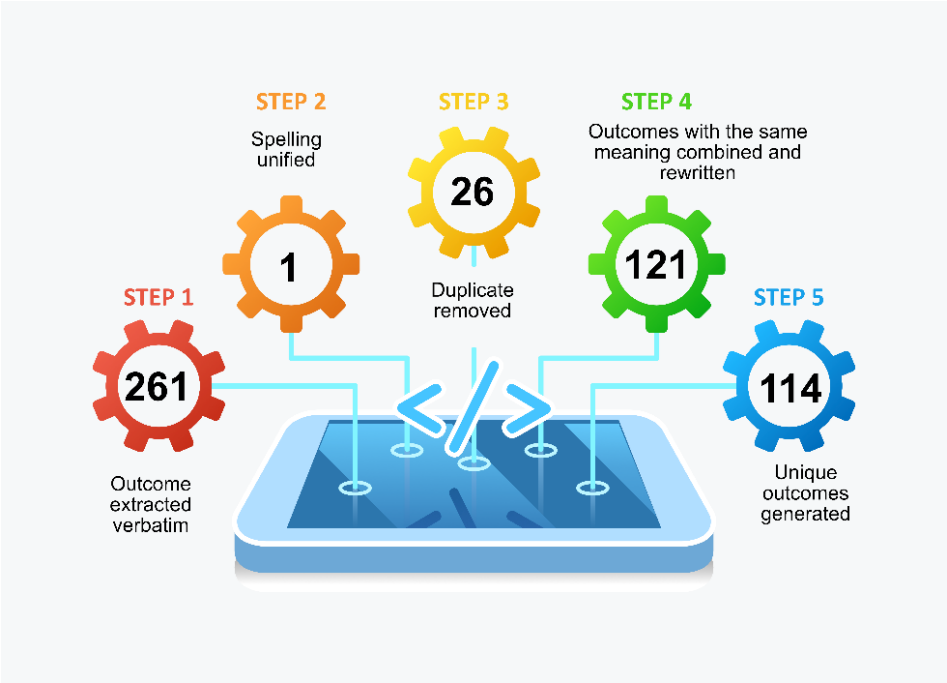


Figure 3.4 Unique outcome generation process

Outcomes were reported in all four core areas of the COMET taxonomy (Dodd et al., 2018) but only 11 outcome domains (**Table 3.7**). Within the core areas, resource use had the highest number of unique outcomes (67, 58.77%). The delivery of care domain had the highest number of unique outcomes (34; 29.82%), with 21 (84%) studies reporting outcomes in this domain. Conversely, no one outcome was common across all studies.

Table 3.7 Outcomes classified according to the COMET taxonomy

Core Area	Outcome Domain	Outcomes		Studies
		Verbatim n (%)	Unique n (%)	25 (100%)
Death	1: Mortality/Survival	13 (14.98)	8 (7.02)	8 (32.00)
Physiological / Clinical	2: Blood and lymphatic system	-	-	-
	3: Cardiac	-	-	-
	4: Congenital, familial and genetic	-	-	-
	5: Endocrine	-	-	-
	6: Ear and labyrinth	-	-	-
	7: Eye	-	-	-
	8: Gastrointestinal	-	-	-
	9: General	1 (0.38)	1 (0.88)	1 (4.00)
	10: Hepatobiliary	-	-	-
	11: Immune system	-	-	-
	12: Infection and infestation	-	-	-
	13: Injury and poisoning	-	-	-
	14: Metabolism and nutrition	-	-	-
	15: Musculoskeletal and connective tissue	-	-	-
	16: Outcomes relating to neoplasms: benign, malignant and unspecified	-	-	-
	17: Nervous system	-	-	-
	18: Pregnancy, puerperium, and perinatal	-	-	-
	19: Renal and urinary	-	-	-
	20: Reproductive system and breast	-	-	-
	21: Psychiatrics	-	-	-
	22: Respiratory, thoracic and mediastinal	2 (0.77)	1 (0.88)	2 (8.00)
	23: Skin and subcutaneous tissue	-	-	-
	24: Vascular outcome	-	-	-
Functioning	25: Physical functioning	1 (0.38)	1 (0.88)	1 (4.00)
	26: Social functioning	-	-	-
	27: Role functioning	-	-	-
	28: Emotional functioning/well-being	-	-	-
	29: Cognitive functioning	3 (1.15)	1 (0.88)	1 (4.00)
	30: Global quality of life	2 (0.77)	1 (0.88)	2 (8.00)
	31: Perceived health status			
	32: Delivery of care	69 (26.44)	34 (29.82)	21 (84.00)
	33: Personal circumstances	-	-	-
Resource Use	34: Economic	13 (4.98)	3 (2.69)	5 (20.00)
	35: Hospital	38 (14.56)	11 (9.65)	12 (48.00)
	36: Need for further intervention	40 (15.33)	21 (18.42)	9 (36.00)
	37: Societal/carer burden	79 (30.27)	32 (28.07)	14 (56.00)
	38: Adverse events/effect	-	-	-

- = 0

Studies using qualitative analysis identified four main themes with eleven subthemes (**Figure 3.5**). Themes were extracted verbatim to preserve theoretical coherence across studies and mapped to two core areas of the COMET taxonomy (life impact and resource use) and three outcome domains (delivery of care, cognitive function and need for further interventions). Six subthemes reflected conceptual definitions of delivery of care outcomes. For example, *"Being on the breathing machine despite stated wishes of the patient to the contrary"* was congruent with the outcome of non-concordant care (Robley & Denton, 2006). Construct similarity was evident with two themes (personalising dying and spirituality); yet, both lacked conceptual alignment with any other outcome and were considered unique.

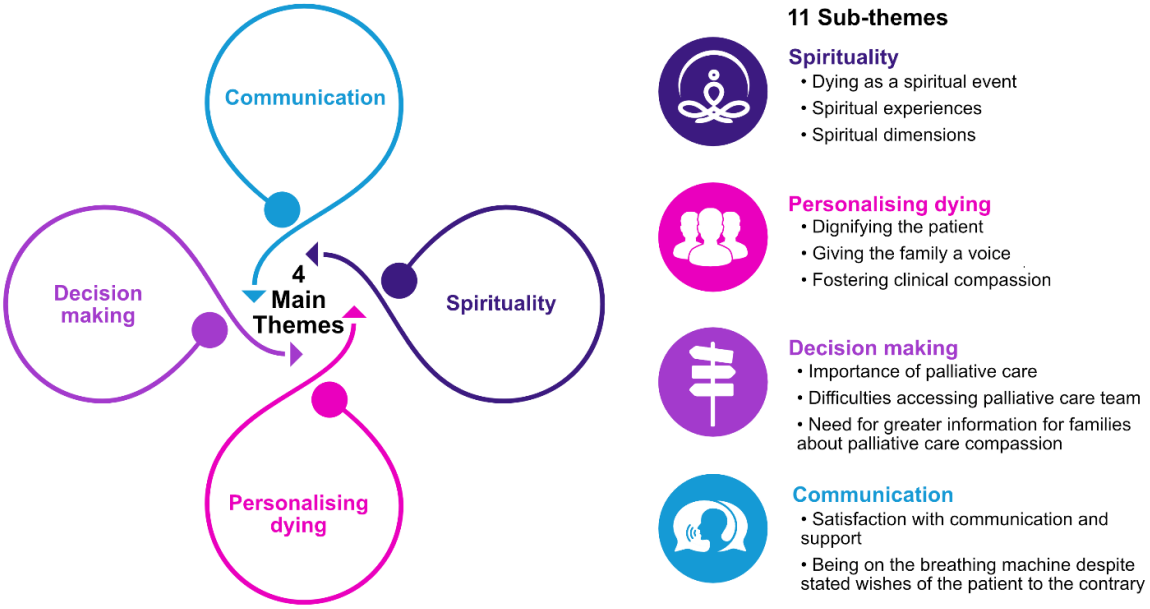


Figure 3.5 Themes

3.5.5 Outcome data source

Outcomes were captured from a range of sources, categorised into eight distinct categories: patient, family, clinical team, health information systems, government databases, insurance systems, obituary searches, and not reported (**Table 3.8**). The family category encompassed outcomes reported by family members, friends, surrogates or proxies, while the clinical team included outcomes reported by nurses and Intensivists. Health information systems comprised outcomes extracted from medical records, hospital databases and administrative databases, with Government databases pertaining to the National Death Index and Social Security Death Master File. Up to three sources were used per outcome, with 257 (98.45%) outcomes captured from one source in 23 (92.0%)

studies. Family members were the most common outcome source used in 128 (45.23%) outcomes, followed by health information systems (104 (36.76%). Patients only contributed directly to two (0.71%) unique outcomes (palliative care needs and patient-centredness of care). Nine outcomes failed to report the source.

Table 3.8 Outcome source

COMET Outcome Domain	Outcome source†								Total N (%)
	Patient n (%)	Family n (%)	Clinical team n (%)	Health information systems n (%)	Government databases n (%)	Insurance system n (%)	Obituary searches n (%)	Not reported n (%)	
01: Mortality/survival	-	3 (1.1)	-	13 (4.6)	3 (1.1)	-	1 (0.4)	-	20 (7.1)
09: General outcomes	-	-	-	1 (0.4)	-	-	-	-	1 (0.4)
22: Respiratory, thoracic and mediastinal	-	-	2 (0.7)	-	-	-	-	-	2 (0.7)
25: Physical functioning	-	1 (0.4)		-	-	-	-	-	1 (0.4)
29: Cognitive functioning	-	3 (1.1)	3 (1.1)	-	-	-	-	-	6 (2.1)
30: Global quality of life	-	2 (0.7)		-	-	-	-	-	2 (0.7)
32: Delivery of care	2 (0.7)	54 (19.1)	11 (3.9)	10 (3.5)	1 (0.4)	-	-	1 (0.4)	79 (28.0)
34: Economic	-	-	-	12 (4.3)	-	1 (0.4)	-	1 (0.4)	14 (5.0)
35: Hospital	-	1 (0.4)	-	30 (10.6)	-	-	-	7 (2.5)	38 (13.5)
36: Further investigation	-	3 (1.1)	-	38 (13.5)	-	-	-	-	41 (14.5)
37: Social burden	-	61 (21.6)	18 (6.4)	-	-	-	-	-	79 (28.0)
Total	2 (0.7)	128 (45.4)	34 (12.0)	104 (36.7)	4 (1.4)	1 (0.4)	1 (0.4)	9 (3.2)	283 (100)

† = Multiple options are possible per outcome - = 0

3.5.6 Outcome frequency

The most frequently reported outcome was family member symptoms of post-traumatic stress disorder (PTSD) (n=14, 5.36%), reported in 11 (44%) studies, followed by ICU length of stay (n=13, 4.98%) in 10 (40%) studies. Forty-eight outcomes were reported more than once, with the top 20 most frequently reported outcomes illustrated in **Table 3.10**. Sixty-seven (25.67%) outcomes were reported on only one occasion.

Outcomes were considered defined and reproducible if they met the following criteria: an explicit or operational definition, or a measurement instrument was provided, the timeframe and context were specified. Where outcomes were provided without explanations, the outcome was not considered defined. Overall, 162 (62.07%) of outcomes were considered defined (**Table 3.9**).

Table 3.9 Outcomes defined

	Outcome	
	Verbatim	**Defined**
COMET Outcome Domain	n (%)	n (%)
01: Mortality/survival	13 (14.98)	13 (100)
09: General outcomes	1 (0.38)	1 (100)
22: Respiratory, thoracic and mediastinal	2 (0.77)	2 (100)
25: Physical functioning	1 (0.38)	0 (0)
29: Cognitive functioning	3 (1.15)	3 (100)
30: Global quality of life	2 (0.77)	2 (100)
32: Delivery of care	69 (26.44)	38 (55.07)
34: Economic	13 (4.98)	9 (69.23)
35: Hospital	38 (14.56)	16 (42.11)
36: Further investigation	40 (15.33)	16 (40.00)
37: Social burden	79 (32.27)	62 (78.48)
Total	**261 (100)**	**162 (62.07)**

Time of outcome assessment was inconsistently reported within studies, with variability both between and within outcomes evident (**Appendix 15)**.

Table 3.10 Top twenty outcomes per outcome

Outcome domain	Outcome		
	Unique outcome	Reporting frequency n (%)	Outcome defined n (%)
37 Societal Carer Burden	Family member symptoms of post-traumatic stress disorder (PTSD)	14 (5.36)	12 (85.71)
35 Hospital	ICU length of stay	13 (4.98)	5 (38.46)
35 Hospital	Hospital length of stay	12 (4.60)	3 (25.00)
36 Further Investigation	Use of nonbeneficial interventions	10 (3.83)	2 (20.00)
37 Societal Carer Burden	Family members' symptoms of anxiety and depression	8 (3.07)	8 (100)
32 Delivery of care	Family satisfaction with end-of-life care	7 (2.68)	3 (42.86)
34 Economic	ICU costs	7 (2.68)	4 (57.14)
32 Delivery of care	Quality of death and dying	6 (2.30)	3 (50.00)
37 Societal Carer Burden	Family members’ symptoms of depression	6 (2.30)	5 (83.33)
32 Delivery of care	Quality of communication	6 (2.30)	3 (50.00)
32 Delivery of care	Family satisfaction with decision-making	5 (1.92)	3 (60.00)
37 Societal Carer Burden	Family members’ symptoms of anxiety	5 (1.92)	4 (80.00)
36 Further Investigation	Mechanical ventilation duration	5 (1.92)	4 (80.00)
34 Economic	Hospital costs	5 (1.92)	4 (80.00)
01 Mortality	Hospital mortality	4 (1.53)	4 (100)
32 Delivery of care	Concordant care	4 (1.53)	3 (75.00)
35 Hospital	Hospital discharge disposition	4 (1.53)	4 (100)
32 Delivery of care	Satisfaction with end-of-life communication	4 (1.53)	2 (50.00)
37 Societal Carer Burden	Prolonged grief	4 (1.53)	4 (100)
36 Further Investigation	Anticipatory medication prescribed	4 (1.53)	4 (100)

3.5.7 Outcome Measurement Instruments (OMIs)

Overall, 57 outcome instruments were used, with up to six OMIs used to assess the same outcome construct. Wide variation was evident, while the frequency of measurement was highly variable (**Appendix 15**). Fifty-six OMIs had either undergone psychometric or sensitivity/specificity evaluation or had been used in similar study populations or EoLC settings (**Table 3.11**) capturing 108 (41.38%) outcomes of which 58 (50.88%) outcomes were unique. The highest number of outcomes was measured using the Hospital Anxiety and Depression Scale (HADS), used in eight (32%) studies; however, variations in threshold sensitivity were evident. An anxiety or depression subscore greater than eight indicated clinically meaningful symptoms in four studies (Lautrette et al., 2007; Lincoln et al., 2020; Robert et al., 2017; Robin et al., 2021), while one study used subscores greater than seven (Kentish-Barnes et al., 2022) and another used a score above 11 (Chen et al., 2022).

Fourteen studies (56%) reported study-specific OMIs where no available or validated OMI existed, capturing 73 (27.97%) outcomes. **Table 3.12** illustrates all outcome**s**. Within the novel OMIs, questionnaires were the most frequently used, providing ordinal data that capture nuanced variations in attitudes or perceptions in 34 (13.03%) outcomes. Terminology, however, varied within the study-specific OMIs; for example, one study reported using an analogue scale, yet described a discrete, ordinal scale measuring satisfaction (1 = very dissatisfied to 9 = very satisfied) (Cheung et al., 2010). Likert scales were used to measure the degree or intensity of agreement, frequency, or sentiment along a continuum for 11 outcomes (6.83%). The presence or absence of specific outcomes was only reported as a dichotomous binary rating (e.g. yes/no) for only one outcome (concordant care) by one study (Cox et al., 2020), yielding nominal categorical data.

Table 3.11 Outcome Measurement Instrument

	All outcomes according to COMET Taxonomy n (%)								
Outcome Measurement Instrument abbreviation	**1: Mortality /Survival**	**9: General**	**22: Respiratory, thoracic**	**25: Physical functioning**	**30: Global quality of life**	**32: Delivery of care**	**37: Societal /carer burden**	**Number of unique outcomes N (%)**	**Number of studies N (%)**
AOS	-	-	1 (0.38)	-	-	-	-	1 (0.88)	1 (4)
APACHE II	-	1 (0.38)	-	-	-	-	-	1 (0.88)	1 (4)
APACHE III	1 (0.38)	-	-	-	-	-	-	1 (0.88)	1 (4)
BEAQ	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
BPS	-	-	1 (0.38)	-	-	-	-	1 (0.88)	1 (4)
CAESAR	-	-	-	-	-	1 (0.38)	-	1 (0.88)	1 (4)
CCFSS	-	-	-	-	-	1 (0.38)	-	1 (0.88)	1 (4)
CEQUEL	-	-	-	-	-	1 (0.38)	-	1 (0.88)	1 (4)
CEQUEL-Revised	-	-	-	-	1 (0.38)	-	-	1 (0.88)	1 (4)
COSMIC	-	-	-	-	-	1 (0.38)	-	1 (0.88)	1 (4)
CSACD	-	-	-	-	-	1 (0.38)	-	1 (0.88)	1 (4)
DASS	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
DCS	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
DRS	-	-	-	-	-	-	1 (0.77)	1 (0.88)	2 (8)
DTS	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
DTS-Revised	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
EEW	-	-	-	-	-	1 (0.38)	-	1 (0.88)	1 (4)
FDMSS	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
FMWBQ	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
FOLLOS	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
FS-ICU-24	-	-	-	-	-	5 (1.92)	-	1 (0.88)	2 (8)
FS-ICU-35	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
GAD-7	-	-	-	-	-	-	4 (1.53)	1 (0.88)	3 (12)
HADS	-	-	-	-	-	-	8 (3.06)	1 (0.88)	8 (32)
ICG	-	-	-	-	-	-	1 (0.62	1 (0.88)	1 (4)

ICUQODD	-	-	-	-	-	1 (0.38)	-	1 (0.88)	1 (4)
IES	-	-	-				4 (1.53)	1 (0.88)	3 (12)
IES-R	-	-	-	-	-	-	6 (2.30)	1 (0.88)	3 (12)
JSS	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
KADL	-	-	-	1 (0.38)	-	-	-	1 (0.88)	1 (4)
MBI	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
MISS-21	-	-	-	-	-	1 (0.38)	-	1 (0.88)	1 (4)
NEST	-	-	-	-	-	1 (0.38)	-	1 (0.88)	1 (4)
NEST - Adapted	-	-	-	-	-	1 (0.38)	-	1 (0.88)	1 (4)
PCCS	-	-	-	-	-	2 (0.77)	-	1 (0.88)	1 (4)
PDEQ	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
PDI ICU	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
PDI modified	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
PG-12	-	-	-	-	-	-	3 (1.15)	1 (0.88)	2 (8)
PG-12 Carer Version	-	-	-	-	-	-	2 (0.77)	1 (0.88)	1 (4)
PG-13	-	-	-	-	-	-	5 (1.92)	1 (0.88)	3 (12)
PHQ-8	-	-	-	-	-	-	2 (0.77)	1 (0.88)	1 (4)
PHQ-9	-	-	-	-	-	-	5 (1.92)	1 (0.88)	4 (16)
POMS-SF	-	-	-	-	-	1 (0.38)	-	1 (0.88)	1 (4)
PPC modified	-	-	-	-	-	1 (0.38)	-	1 (0.88)	1 (4)
PTSD PCL-C	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
PTSS	-	-	-	-	-		1 (0.38)	1 (0.88)	1 (4)
QEOLC-10	-	-	-	-	-	1 (0.38)	-	1 (0.88)	1 (4)
QOC	-	-	-	-	-	4 (1.53)	-	1 (0.88)	3 (12)
QODD	-	-	-	-	-	2 (0.77)	-	1 (0.88)	1 (4)
QODD-1	-	-	-	-	-	4 (1.53)	-	1 (0.88)	2 (8)
QoL2	-	-		-	1 (0.38)	-	-	1 (0.88)	1 (4)
RDOS	-	-	1 (0.38)	-	-	-	-	1 (0.88)	1 (4)
SF-36	-	-	-	-	-	-	1 (0.38)	1 (0.88)	1 (4)
SSDM	-	-	-	-		1 (0.38)	-	1 (0.88)	1 (4)
STAI-Y Trait	-	-	-	-			1 (0.38)	1 (0.88)	1 (4)

- = 0

Table 3.12 Study-specific OMI

Study-specific Outcome Measurement Instrument	All outcomes according to COMET Taxonomy n (%)					
	1: Mortality /Survival	**29: Cognitive functioning**	**32: Delivery of care**	**35: Hospital**	**36: Further investigation**	**37: Societal /carer burden**
Interview	2 (0.77)	3 (1.15)	11 (4.21)	-	4 (1.53)	2 (0.77)
Questionnaire	-	-	14 (5.36)	4 (1.53)	-	16 (6.13)
Standardised Form	1 (0.38)	-	1 (0.38)	4 (1.53)	11 (4.21)	-
Total	**3 (1.15)**	**3 (1.15)**	**26 (9.96)**	**8 (3.07)**	**15 (5.75)**	**18 (6.90)**

Key - = 0

3.5.8 Database registration

Thirteen studies (52%) were registered on two databases with ClinicalTrials.gov predominantly used. Despite attempts to increase accountability and the transparency of clinical study registration at inception, 12 studies (48%) failed to report if their study was registered on a public-facing research registry, with one study publishing a non-identifiable registry ID (Lichtenthal et al., 2022). This low registration rate could, however, be attributed to the location, time point, terminology used and related legislation. Whilst the overarching ethical requirement for every research study involving human subjects to prospectively publish on a public-facing research registry prior to recruitment of the first participant has been enshrined in the Declaration of Helsinki since 2008 and transcends international boundaries, the term ‘clinical trial’ was redacted in 2013 and replaced with ‘research study’ (World Medical Association, 2008, 2013b). This substantive shift in terminology is not, however, congruent with legislation continuing to pertain to only the registration of medicinal products and devices on trial registries (Clinical Trials Registration and Results Information Submission, 2016; European Parliament and Council of the European Union, 2021).

3.5.9 Study quality

MOMENT criteria and Risk of Bias

Based on the pre-defined MOMENT score of 4 or more, overall, nine studies (45%) were determined to be high quality (**Table 3.13**). Study protocols and trial registrations were not assessed against the MOMENT criteria and risk of bias was not performed. Given the

controversy surrounding the uncertain value of quality assessment in qualitative research (Collier & Mahoney, 1996) mixed methods studies where qualitative methods were dominant, and qualitative studies were not assessed using the MOMENT criteria. Stating, defining and explaining both the primary and secondary outcomes varied significantly between randomised and non-randomised studies. Primary outcomes were clearly stated in seven (78%) of RCTs with nine (100%) explaining the use of the outcomes they had selected and seven (78%) using methods to enhance the quality of outcome measurement. Conversely, only six (55%) of the non-randomised studies clearly stated the primary outcome, with four (36%) explaining the use of the selected outcome and employing methods to enhance the quality of outcome measurement. An individual breakdown of the MOMENT score is provided in **Appendix 16** while the CASP quality assessment is provided in **Appendix 17.**

Table 3.13 Assessment of MOMENT criteria[a]

Question	Criteria *(n=20)*	Yes n (%)	No n (%)	Unclear n (%)
1	Is the primary outcome clearly stated?	13 (65)	7 (35)	- -
2	Is the primary outcome clearly defined so that another researcher would be able to reproduce the measurement?	13 (65)	7 (35)	- -
3	Are the secondary outcomes clearly stated?	9 (45)	11 (45)	- -
4	Are the secondary outcomes clearly defined?	8 (40)	12 (60)	- -
5	Do the authors explain the use of the outcomes they have selected?	13 (65)	7 (35)	- -
6	Are the methods used to enhance the quality of outcome measurement if appropriate?	11 (55)	9 (45)	- -

[a]=Excluding trial registrations - = 0

Significant variation was evident in the methodological quality. Overall, randomised controlled trials were considered to have some concerns or be at high risk bias (**Figure 3.6**, **Appendix 18**) while the majority of non-randomised studies were considered at serious risk of bias **(Figure 3.7**, **Appendix 19**).

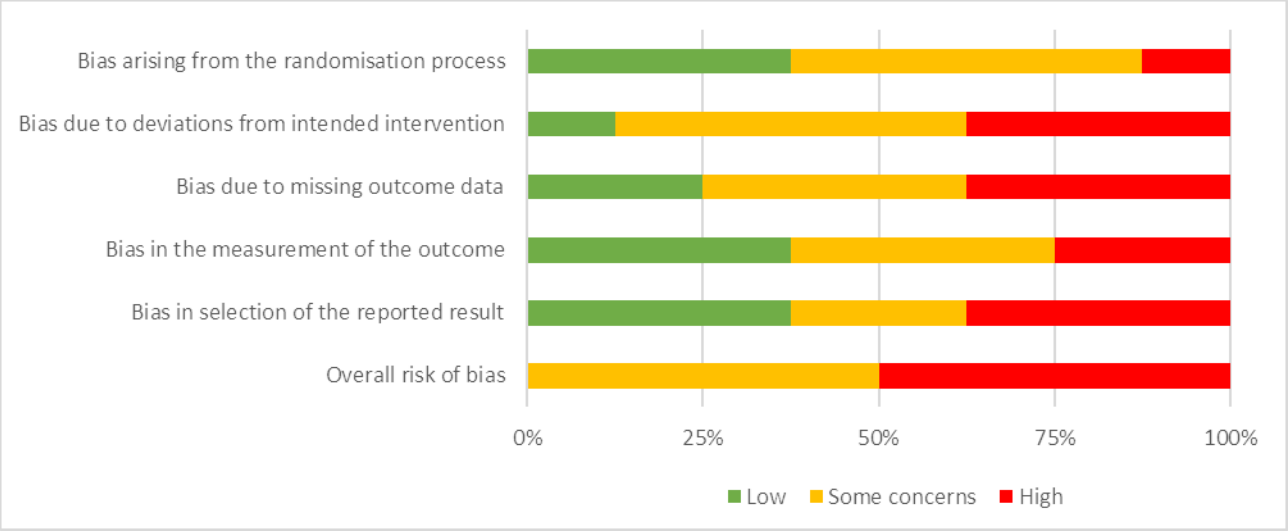


Figure 3.6 Risk of bias assessment for randomised controlled trials

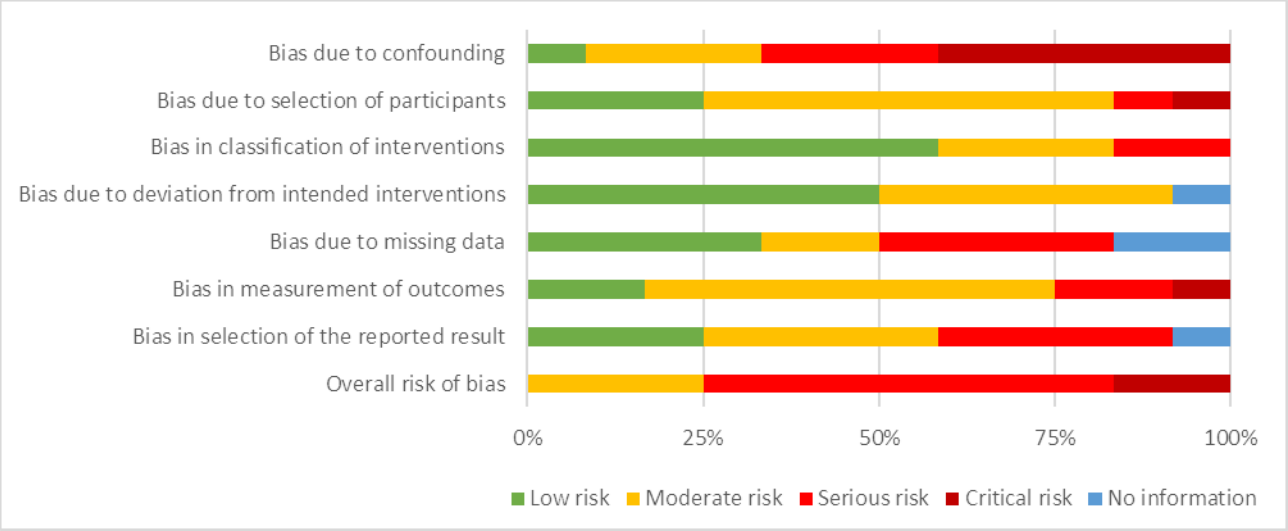


Figure 3.7 Risk of bias assessment for non-randomised studies

3.6 Discussion

To the researcher's knowledge, this is the first systematic review to capture outcomes, OMIs and time points used to evaluate EoLC in critical care. Previous critical care systematic reviews have focused on specific aspects of palliative rather than EoLC, which are important differentials in a patient's illness trajectory where the focus is on a more longitudinal approach. 261 outcomes were identified across 25 studies, of which 114 outcomes were considered unique, with no outcome common across all studies. Although 162 (62.07%) of outcomes were considered defined, definitions were inconsistent, and outcome specificity varied, compounding comparison. Heterogeneity in outcome selection, definition, and reporting was evident, consistent with findings from previous systematic reviews (Aslakson et al., 2014; Metaxa et al., 2021), and continues to preclude quantitative

meta-analysis, highlighting ongoing challenges in EoLC research. Aslakson et al. (2014) identified 46 outcomes, reporting the use of six OMIs, while Metaxa et al. (2021) identified 65 outcomes with ten OMIs. The proliferation of significantly more outcomes and OMIs in this systematic review simultaneously extends the breadth of both outcomes and OMIs, underpinning the need for international consensus on 'what' should be measured and 'how'. Neither of the aforementioned systematic reviews identified outcomes relating to spirituality or provision of spiritual support, continuity of care, or physical functioning, outcomes evident in this systematic review.

González-jaramillo et al., (2024) recently published a systematic review on outcomes of care during the last month of life. Significant population, scope and methodological differences are, however, evident. González-jaramillo et al. (2024) defined the study population as those living with a chronic or progressive disease or condition, resulting in a broader scope that included home, hospital, hospices and other facilities. As such, the majority of outcomes were associated with medical interventions or the utilisation of hospital services. No outcomes were captured in the core death area of the COMET taxonomy with only 5.8% of outcomes allocated to the outcome domain social/care burden. Furthermore, caregivers and patients assessed limited outcomes. Whilst the use of patient-reported outcome measures (PROMS) was only evident in three (12%) studies in this systematic review, 23 (92%) studies relied on proxy respondents from family or clinicians, reflecting the complex methodological challenges in EoLC in critical care, where a significant proportion of patients cannot self-report their experience or perceptions. Eight (32%) studies specifically reported data triangulation assessing an outcome from multiple sources to enhance validity, reduce bias and ensure comprehensive evaluations of interventions.

Classification challenges arose from ambiguous COMET domain definitions (Dodd et al., 2018), particularly in the resource use core area, where distinguishing between patient, proxy, and professional-reported outcomes was problematic. Anxiety, for example, could be classified into either the functioning domain or the resource domain depending on the measurement method categorisation. The inability to adequately capture outcomes that span multiple measurement approaches has the potential to lead to inconsistent application across different contexts and studies, thereby limiting the taxonomy's utility. Although valuable for capturing patient-reported outcomes (PROs), the COMET taxonomy's implicit bias towards PROs inadequately addresses the full spectrum of

outcomes essential for comprehensive EoLC evaluation, where patient, proxy, professional and objective clinical outcomes must be integrated cohesively. Furthermore, the taxonomy requires composite outcomes which span multiple domains to be classified in all relevant domains (The Comet Initiative, 2022). Whilst this ensures granularity and transparency of outcome classification, there is the potential to introduce redundancy and complexity. Nearly all composite outcomes lacked detailed descriptions to accurately categorise them in all domains, while others conceptually overlapped. Clear guidance on prioritising outcomes within composite outcomes is lacking. To mitigate redundancy and complexity, measurement methods (patient, proxy, professional, and objective clinical) were employed to facilitate prioritisation; however, future research is warranted to establish a standardised, comparable process.

This systematic review is comparatively novel to the aforementioned reviews, in that it reports details of OMIs, facilitating comparability across studies, promoting the need for uniformity in outcome reporting and assisting in the first step for selecting standardised instruments and tools for future research. Whilst the purpose was not to evaluate the psychometric properties (eg validity, reliability and responsiveness) of OMIs, capturing OMIs revealed wide variation and a range of outcomes lacked robust or widely accepted OMIs. Quality of death and dying for example was reported in six studies using six different OMIs at four different time points. Such gaps highlight areas for future research to develop new instruments or refine existing OMIs and will be essential for operationalising the outcomes identified in the COS. Regulatory guidelines reinforce the need for outcome measures to be rigorously validated and contextually appropriate, advocating early stakeholder collaboration to ensure outcome measures are meaningful (ICH, 2025). Stages Two, Three, and Four of this study are built on the outcomes identified in the systematic review, ensuring stakeholder collaboration and that the outcomes are relevant to the real world.

3.6.1 Strengths and limitations

A rigorous methodology comprising blinded dual screening, data extraction, and quality assessment/risk of bias was employed throughout the systematic review process, with the study protocol registered *a priori*. Search methods employed an extensive range of terms reflecting the breadth of terminology used to define end-of-life internationally. Studies not reported in English were excluded for pragmatic reasons, potentially leading to the omission of relevant studies.

To try and comprehensively capture all relevant studies, no date limits were imposed; however, the time period over which the review was undertaken was extensive. The abstract screening tool time stamps when screening decisions were made indicated that decisions changed over time. Earlier reconciliation and stop points may have been beneficial as a substantive attenuation in interrater reliability occurred between screen rounds despite the implementation of training, regular discussions and the use of standardised abstraction forms.

The PEACE-COS systematic review included study protocols, ongoing trials and trial registries, examining the totality of research to provide a complete picture of the evolving EoLC landscape beyond the time point of the systematic review. It enabled the identification of additional outcomes across all core areas of the COMET taxonomy not previously identified, as well as confirming existing outcomes. Since completing the review, both Lichtenthal et al., (2024) and Cox et al., (2025) demonstrated consistency between the pre-specified outcomes documented in published protocols, trial registries and the outcomes reported in the final publications, with no evidence of selective outcome reporting or post-hoc outcome introduction.

The geographical concentration of American-based studies is problematic, limiting the generalisability of findings to other healthcare systems. Stage Three of the study aims to mitigate this limitation by adopting an international approach.

3.7 Conclusion

This systematic review presents a comprehensive description of the outcomes, outcome measurement instruments and time points used to evaluated EoLC in critical care. Substantial heterogeneity and multiplicity of outcome selection and measurement were evident in the included studies. Outcome reporting lacked consistency and transparency, highlighting the need to standardise how outcomes are defined, collected, measured and reported for EoLC research in critical care. It has generated a preliminary list of published outcomes and OMIs, a prerequisite for COS development (Kirkham et al., 2016) which will inform a subsequent consensus-building eDelphi study with stakeholders to ensure that the COS developed is underpinned by empirical evidence.

3.8 Next chapter

The next chapter presents additional outcomes identified through qualitative interviews and focus groups.

Chapter 4: What outcomes are important in EoLC research in critical care? A qualitative study of EoLC experience

4.1 Abstract

Background: **Chapter 3:** identified 114 outcomes reported in literature; however, these may not be congruent with the outcomes that family members and healthcare professionals perceive as important in EoLC in critical care. Whilst previous research has focused on eliciting what family members and healthcare professionals perceive as a good death, there is a dearth of research focusing on what outcomes people perceive as important in EoLC in critical care.

Aim: To explore what family members of critical care decedents and healthcare professionals feel are important outcome measures in EoLC in critical care.

Design: Elements of constructivist grounded theory were employed using constant comparative analysis. Interviews were conducted with nine health professionals, and seven health professionals participated in focus groups.

Findings: No family members were recruited due to limited access to appropriate support services and NHS sites. 175 unique outcomes were identified in total, representing eight interlinking themes: care satisfaction, communication, decision-making, impact on family, patient- and family-centred, professional competency, staff burden, and resource use.

Conclusions: Findings provide insights into the diverse range of outcomes healthcare professionals perceive as important in EoLC in critical care.

Public Researcher Partners Contribution: Study design, public-facing study documents, and piloting.

4.2 Introduction

To design and evaluate interventions for critical care patients receiving EoLC, researchers must identify the outcomes most significant to patients, their families, and healthcare professionals. **Chapter 3:** has highlighted the outcomes and measures reported in the previous studies; however, research demonstrates that these may not align with the priorities perceived by family members or healthcare professionals (Sinha et al., 2011). While qualitative studies have previously concentrated on defining what constitutes a good death (Hafifah et al., 2025; Liu & Kondo, 2019), or experiences of treatment withdrawal (Efstathiou et al., 2020; Efstathiou & Walker, 2014) there remains a notable gap in

research regarding the outcomes and measures that family members and healthcare professionals consider important in EoLC within critical care.

Comprised of four stages, the PEACE-COS study aims to develop a core outcome set for EoLC within critical care. Stage One has been presented in **Chapter 3:**. This chapter focuses on Stage Two, an exploration of the outcomes stakeholders consider important, and follows the Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines (Tong et al., 2007). Outcomes identified from both stages will be combined to inform Stage Three, an international eDelphi study. To the researcher's knowledge, no qualitative study has been undertaken to inform a COS for EoLC in critical care.

4.3 Background

Sinha et al., (2011) posits that stakeholder involvement in identifying outcomes through qualitative methodologies is imperative for developing comprehensive and relevant core outcome sets (COS) that reflect what matters most to those affected by healthcare interventions. One suggestion is to use an international open-ended survey to aid the identification of outcomes in COS development (Chevance et al., 2020), yet such methodologies fail to provide the granularity required to comprehend the complexity of stakeholder EoLC experiences or ascertain why certain outcomes are significant. In contrast, COMET recommends the use of interviews or focus groups to elicit outcomes of importance (Williamson et al., 2017) while Keeley et al., (2016) suggests employing such methods to verify the scope of the outcome.

Previous critical care COS demonstrate how qualitative approaches enable participants to articulate outcomes in their own words, identifying nuances and unique outcomes that may not emerge from systematic reviews of prior studies (Freeman-Sanderson et al., 2024; Rose et al., 2021). Furthermore, using participants' wording preserves outcome authenticity, ensuring constructs remain grounded in participants' experiences rather than researcher-imposed interpretations (Charmaz, 2025). Such linguistic framing is fundamental to Stage Three of the PEACE-COS study, strengthening outcome clarity, relevance and acceptability.

4.4 Study design

4.4.1 Aims

Stage Two of the PEACE-COS study aimed to explore what family members of critical care decedents and healthcare professionals consider important in end-of-life care in critical care, what outcomes they feel should be assessed and why to inform the development of a core outcome set.

4.4.2 Theoretical framework

Grounded theory is a systematic qualitative research methodology suitable for exploring specific phenomena where limited prior knowledge exists (Charmaz, 2025). Underpinned by theoretical sampling, it employs an iterative abductive approach; data are collected and continually analysed using constant comparative analysis, generating theoretical concepts grounded in participants' experiences (Rieger, 2019). From a theoretical standpoint, constructivist grounded theory acknowledges the context of the research and the position of the researchers within it (Charmaz & Thornberg, 2021). This stance enables multiple realities of EoLC to be considered, recognising that knowledge is interpretive, constructed with study participants in relation to specific times and situations (Charmaz, 2017). It is therefore an optimal methodology to achieve the study aims, and has previously been used in EoL critical care research (Long-Sutehall et al., 2011; Thornton et al., 2021).

4.5 Participant selection and setting

To capture experiential knowledge of what constitutes important person-centred outcomes, the study population of Stage Two was originally designed to consist only of family members with direct experience of an adult (≥18 years) family member dying in or receiving EoLC in critical care within less than two years and have recollection of the EoLC process.

Potential participants were invited to participate in two interviews approximately three months apart to capture the changing nature of grief (Carduff et al., 2015; Kendall et al., 2015; Pattison et al., 2013). One NHS Trust in England and one healthcare board in Scotland, providing level 3 care (Intensive Care Society, 2021), opened to recruitment; however, no recruitment occurred from either site during the initial five-month recruitment period. Consequently, the Chief Investigator made a pragmatic decision, and an

amendment was implemented, reducing the number of interviews from two to one, and the inclusion criteria widened to include health professionals who had experience of an adult (>18 years) receiving EoLC in critical care within the past two years and had recollection of the EoLC process. All participants were required to participate in either a telephone, online, or face-to-face interview, with a focus group option also available to health professionals. For pragmatic purposes, only UK-based participants proficient in English were recruited. No participant received any payment or other considerations to participate in the study.

4.5.1 Sampling

Consistent with grounded theory, multiple sampling approaches were strategically employed (Charmaz, 2025). The first three participants (one nurse and two doctors) were recruited using purposeful and snowball sampling, before transitioning to theoretical sampling (Coyne, 1997; Tie et al., 2019; Timonen et al., 2018). The initial aim was to recruit the family member/health professional most closely involved in EoLC, whilst theoretical sampling emerged iteratively through the constant comparative technique to explore codes of interest, clarify uncertainties and test interpretations (Tie et al., 2019; Zaidi, 2022). Snowball sampling was also used to recruit participant six (a physiotherapist) to address practical recruitment challenges and ensure access to participants.

In contrast to quantitative methodologies, sample size can not be determined *a priori* and does not aim to be statistically representative (Varpio et al., 2017; Vasileiou et al., 2018). Instead, Charmaz, (2025) posits that sample size should be emergent, guided by the research question, the context, and the analytic process. Direct comparison of sample size across studies is therefore inappropriate, as numerical equivalence eclipses the study scope (Charmaz, 2025). Recruitment continued until theoretical data saturation was achieved i.e. constant comparative analysis did not reveal any new outcomes or provide any additional insight into outcomes of importance in EoLC (Rahimi & Khatoon, 2024; Saunders et al., 2018). Theoretical data saturation was thought to have been reached after coding two focus groups and eight interviews. One additional interview was undertaken, but no new outcomes were identified.

4.5.2 Methods of approach

Family members

Patients who had received EoLC were identified from the critical care clinical information systems and databases at NHS sites by members of the clinical team responsible for their care as outlined in **Appendix 20**. Hospital records were screened to identify the patient's family, i.e. the first and second contacts who had previously consented to be contacted as part of established NHS bereavement follow-up services. Eligible family members were approached in writing or in person by a clinical team member using a personalised letter based on those used in previous research studies. This process has previously been demonstrated to minimise intrusion into participants' lives, protecting their autonomy and allowing as much time as needed to consider participation (Butler et al., 2019). A participant information booklet and consent form, developed in conjunction with public research partners and in line with current expert consensus guidelines (Coleman et al., 2021), were included. The information booklet also directed potential participants to a webpage providing information about the study (Humphreys, 2023a). If interested, potential participants returned an *'opt-in'* card using a pre-paid envelope to the clinical team or could contact the research team direct via email or the study website. Providing a range of options for contacting the research team aligned the process with individual reactions to bereavement (McCallum et al., 2019).

Healthcare professionals

Relevant professional bodies, organisations, and charities were identified using existing critical care contacts, networks, and web-based searches (**Appendix 21**). Within each organisation or NHS site, primary contacts were emailed a plain English recruitment invitation to participate in the study and asked to disseminate it to their members. The invitation included an embedded web link to the participant information booklets on the study website **(Appendix 22**). All those receiving an invitation were encouraged to disseminate details to their own contacts who met the inclusion criteria (snowball sampling) to increase the sample size and reach.

Study website and advertising

Awareness about the study was increased throughout the study by displaying posters in the relevant clinical areas at recruiting sites, through charities, and via a study website

(https://peacecos.com/) (**Appendix 23**). The website provided the same information contained in the participant information booklets. In line with best practice guidelines, social media was also used to advertise the study (**Appendix 24**) and redirect interested potential participants to the study website for further information, where, if interested in participating, they could provide their contact details (Arigo et al., 2018; Darko et al., 2022; Gelinas et al., 2018). Study social media accounts were created as appropriate. The non-NHS recruitment processes are outlined in **Appendix 25.**

4.5.3 Study timelines

Significant time delays were encountered during the sponsorship approval process due to organisational restructuring and a lack of sponsor awareness of the HRA approval process or sponsor responsibilities. Sponsor processes were not aligned with contemporary national HRA or NHS processes; no sites or non-NHS routes were permitted to open to recruitment by the Sponsor until confirmation of capacity and capability was received from all NHS sites. This delayed recruitment opening by 91 days (**Figure 4.1**). Furthermore, substantial delays (165 days) were encountered with one site that failed to accept the HRA Devolved Administrations agreement concerning the legal compliance and governance of the study, duplicating governance assessments and mandating additional standard operating procedures and Caldicott Guardian reviews.

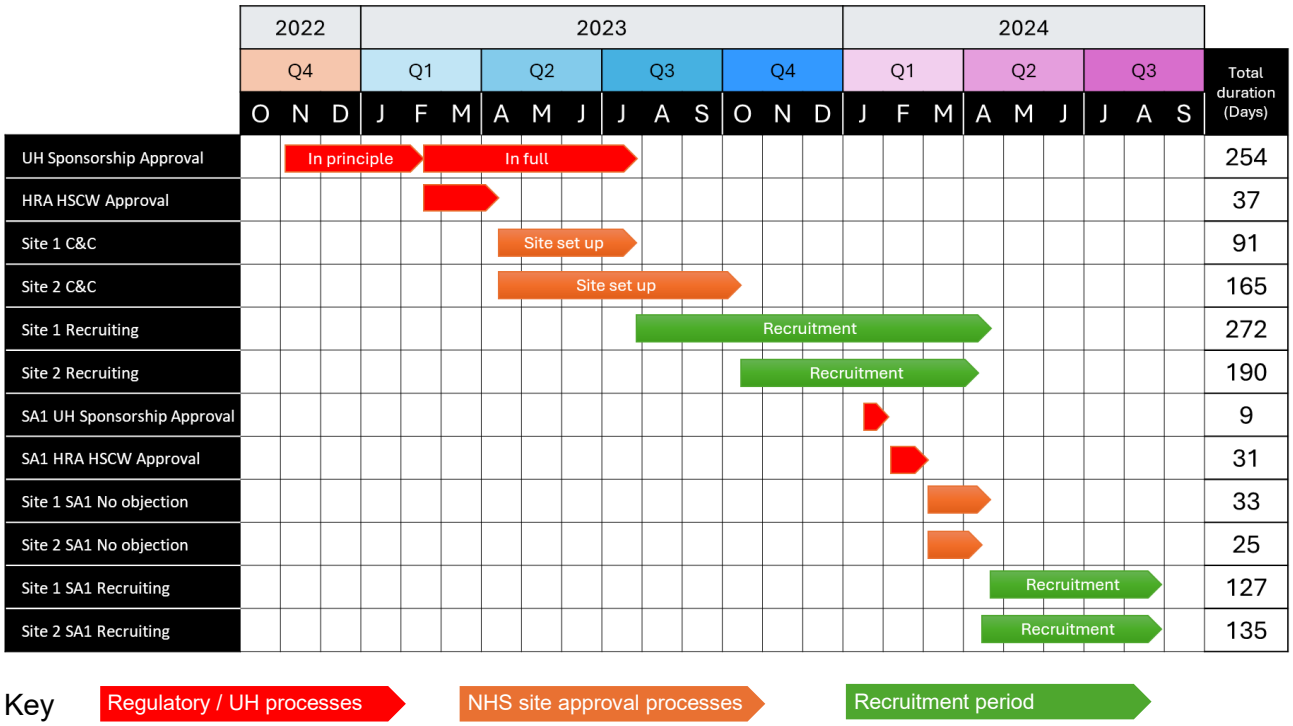


Figure 4.1 Recruitment timelines

Recruitment spanned 13 months, with site 1 open for 399 days and site 2 for 325 days. The study website received 1,448 unique user visits during the recruitment period, from users in 22 countries. 215 people viewed the online family member participant information sheet, and six enquiries were received through the study email account and online enquiry form. Interviews were scheduled with two family members, but neither attended the consent meeting. Local investigators at NHS sites provided no potential family member contacts, and no family members were recruited. No QR scans were performed on NHS sites displaying posters, with 27 QR codes accessed through posters displayed by support and professional organisations.

On the study website, the healthcare professional participant information sheets were viewed by 223 people, of whom 75% (n=167) chose the interview option over the focus group option. The conversion rates from viewing the participant information sheet on the site to viewing the consent forms were similar for both participation routes: 16% (n=26) of those who accessed the interview consent form proceeded to the interview consent form, while 18% (n=10) progressed to the focus group consent form. Conversely, there were marked differences in completion rates for the consent forms. All who accessed the focus group consent form (100%, n=10) completed it, whereas only half of those who accessed the interview consent form (50%, n=13) continued to completion.

Twenty-three healthcare professionals consented to participate, with nine participating in individual interviews and seven health professionals participating in focus groups (**Figure 4.2).** Three people failed to provide details concerning their availability, while four did not attend the pre-arranged interview or focus group, resulting in 16 participants. Interviews were rescheduled up to three times, averaging 52 minutes (range: 38–62 minutes), while focus groups lasted between 54-58 minutes. Characteristic data were self-reported (**Table 4.1**). Participants were under no obligation to participate in the study and were informed that they could withdraw at any time without any implied or explicit disadvantages.

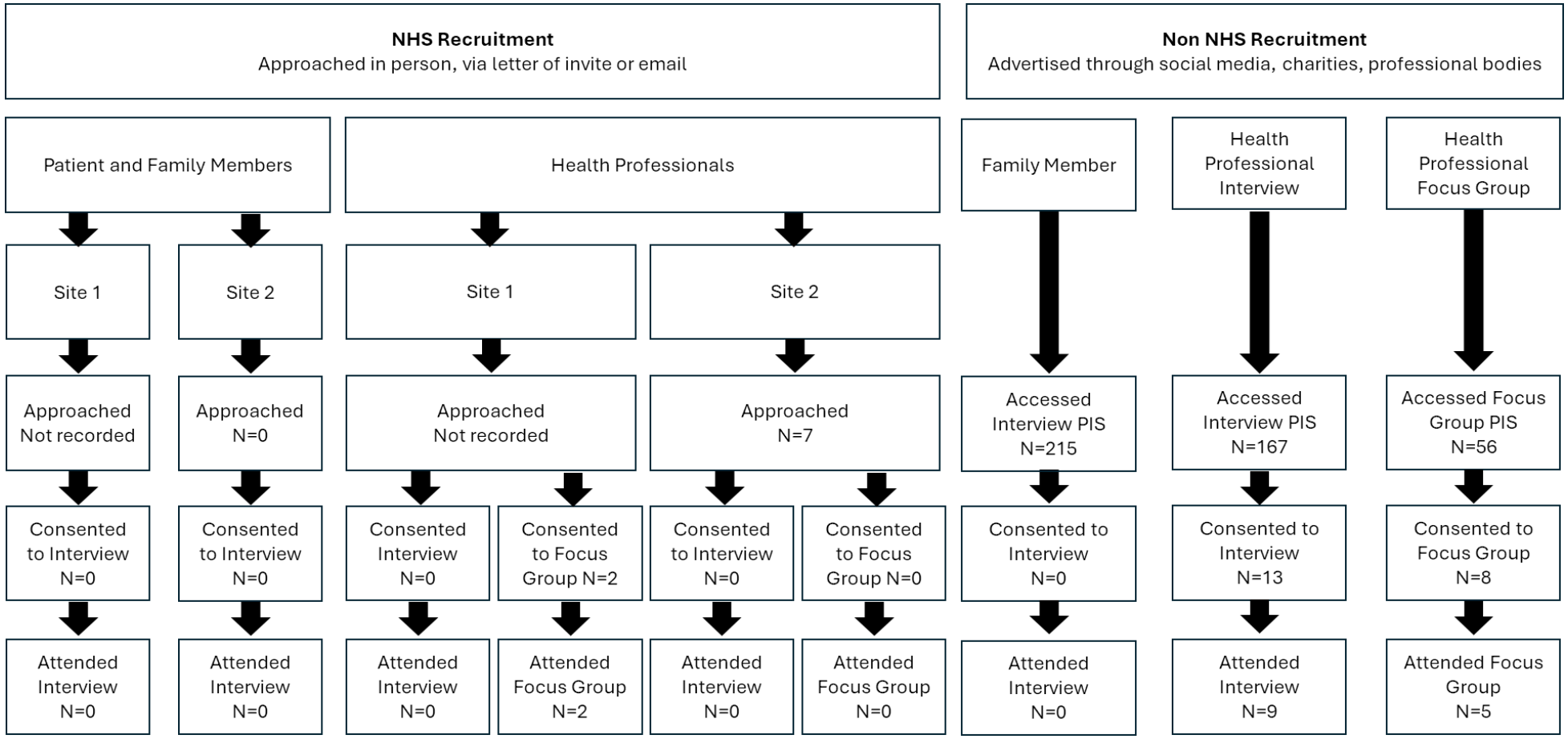


Figure 4.2 Recruitment numbers by method

Table 4.1 Professional characteristics

ID	Focus group or interview	Professional role	Professional experience (Years)	Age in years	Gender	Ethnicity
S2FG01	Focus group	Doctor	2	33	Female	White*
S2FG02	Focus group	Doctor	9	44	Female	White*
S2FG03	Focus group	Doctor	10	37	Male	Chinese
S2FG04	Focus group	Doctor	10	35	Female	White*
S2FG05	Focus group	Doctor	10	51	Male	Ukrainian/Canadian
S2FG07	Focus group	Doctor	10	42	Female	Mixed multiple Latin-American
S2FG08	Focus group	Doctor	20	53	Male	Indian
S2I01	Interview	Nurse	2	41	Male	Indian
S2I03	Interview	Doctor	20	49	Male	White*
S2I04	Interview	Doctor	8	34	Female	White*
S2I05	Interview	Nurse	15	45	Female	White*
S2I06	Interview	Physiotherapist	16	45	Female	White*
S2I07	Interview	Nurse	4	30	Female	White*
S2I08	Interview	Nurse	11	38	Female	White*
S2I09	Interview	Nurse	3	31	Female	White*
S2I13	Interview	Nurse	1	50	Female	African

*= English/Welsh/Scottish/Northern Irish/British

4.6 Ethical considerations

4.6.1 Participant support

Within the context of this research, participants may be considered potentially vulnerable while the topic is considered *'sensitive'*. Participants may be vulnerable to different degrees at different time points during the study, and there was potential to increase a participant's vulnerability when discussing EoLC. Central to conducting research with vulnerable populations is the need to protect participants from psychological harm and undue emotional distress. Whilst it was not feasible to protect a participant entirely from psychological and emotional distress, several measures were implemented to safeguard participant well-being, manage, and mitigate foreseeable risks, with an emphasis placed on risk-benefit analysis for each individual participant. Participant information sheets outlined the benefits and risks of participation, specifically highlighting a range of feelings participants could experience before, during or after the interview, together with the study's purpose, voluntary nature of participation, anonymity, and confidentiality. Participants were given time to cry or express significant emotion. If a participant became distressed, agreement to continue was sought, with participants signposted to appropriate support organisations in line with the study participant distress protocol (**Appendix 26**). Although the recently bereaved may be vulnerable, the stress-helpfulness ratio indicates that participating in research interviews is helpful as opposed to harmful (Emanuel et al., 2004; Williams et al., 2008). A systematic review of the experiences of vulnerable people participating in research on sensitive topics concluded that any distress occurring is short-lived, and excluding participants from research on such a basis denies participants the opportunity to have their voices heard, potentially inhibiting their autonomy (Alexander et al., 2018). By offering participants a range of interview options, they had control over the environment in which they felt safe.

4.6.2 Researcher support

In addition to safeguarding participant well-being, there was also a need to limit the risk of secondary distress to the researcher. Orr et al., (2021) suggest that the characteristics of qualitative research methods, such as intimacy, empathy, rapport and reciprocity, can expose researchers to distress. Whilst Williamson et al., (2020) suggest that the continued engagement with qualitative data required for transcription, coding, analysis and writing can unintentionally amplify secondary distress for researchers. A researcher safety protocol **(Appendix 27**) and a transcriber distress protocol (**Appendix 28**) were available

throughout the study for all researchers/transcribers. The number of interviews/focus groups undertaken in a week was restricted to three to protect the researcher from emotional exhaustion and being overwhelmed by the nature of the topic (Mccosker et al., 2001).

4.6.3 Ethical approval

Prior to commencing the study, ethical and institutional approval were obtained as outlined in **Chapter 2 2.4**. Before consent, participants were given the opportunity to ask questions and to attest that they met the study criteria. All healthcare professionals provided e-consent via the study website and had the opportunity to save a copy of their completed consent form, with verbal consent reaffirmed throughout the interview/focus group process. It was also reiterated that participation was voluntary and that participants could withdraw at any time.

4.7 Data collection methods

Telephone, online interviews and focus groups are a validated method for conducting in-depth interviews in qualitative research (Stuges & Hanrhan, 2004) and have previously been used in a range of bereaved populations (Barlund et al., 2021; Burge et al., 2014; Ewing & Grande, 2013; Hanna et al., 2021; Lewis et al., 2019; Tan & Andriessen, 2021; Turner et al., 2022) and critical care COS development (Connolly et al., 2024). Given the COVID-19 restrictions in place at the time of interviewing, they negated the requirement for in-person visits, simultaneously enabling participation from a wider geographical area, reducing costs and enabling the participant to have control over both the privacy of the call and their social space (Holt, 2010). Whilst it is acknowledged that telephone methods inhibit the observation of nonverbal communication, such as facial expressions and body language, information can be gathered from the participant's emotional cues, such as intonation and tone (Saarijärvi & Bratt, 2021).

All interviews and focus groups were conducted flexibly, tailored to participants' preferences. During the study's development stage, public research partners (PRP) emphasised the importance of participants selecting the platform on which they could participate, advocating that interviews be conducted by phone, online, or face-to-face. This multi-method approach aimed to improve inclusivity and accessibility by supporting diverse preferences. Approval from both the University of Hertfordshire and the Health Research

Authority (HRA) was obtained for all three platforms; however, one NHS health board refused to accept HRA approval, restricting participation to telephone interviews or a specific online platform not accessible to researchers based in England. Except for one participant, all participants chose to participate using Microsoft Teams.

4.7.1 Topic guide

Underpinned by constructivist grounded theory, a broad, open-ended, flexible topic guide was created with PRP and piloted on a member of the public with recent bereavement experience and a critical care health professional (Charmaz, 2025). No changes were made following the pilot. For accessibility reasons, a member of the steering committee (NP or RG) led each focus group, whilst the researcher captured the dynamics and synergy of the group. All interviews were independently undertaken by the researcher. The aim was to gain an in-depth understanding of what participants considered important in EoLC in critical care, what outcomes they feel should be assessed, and why.

After establishing rapport, interviews commenced with an open-ended question designed to elicit participants' stories while creating space for participants to tell their EoLC thoughts and views. The discursive nature allowed participants to tell pertinent points in their own terms, enabling the researcher to discuss emergent outcomes in detail and why they are important (Charmaz, 2025). A combination of silent and echo probing was initially used to build rapport and create space for participants to tell their stories; however, as the interview progressed, directive probes were utilised, culminating in paraphrasing and reflection. This enabled the researcher to seek clarification about key outcomes and the complexity surrounding EoLC critical in the co-construction and quality of data (Charmaz & Thornberg, 2021).

In line with the constant-comparison technique, the topic guide (**Figure 4.3.**) was adapted throughout the study to enable elaboration on emergent outcomes and why they are considered important, seeking confirming and disconfirming perspectives (Charmaz, 2017). As a result, the order and content of the topic guide varied across interviews. The researcher encountered several instances in which participants considered their thoughts and feelings at a more granular level than anticipated. In such situations, prompts were not used to allow the researcher to follow the participant without interruptions or limitations.

Consequently, some outcomes and themes were explored more deeply with some participants than others.

General questions

1. Could you briefly tell me a bit about your critical care end-of-life experience?
2. What are your thoughts about measuring and evaluating end-of-life care?
3. What are the outcome measures you believe should be used in end-of-life care in critical care?
4. Within the literature, a range of different terms are used when referring to end-of-life care in critical care. How do you define end-of-life care?

Theoretical sampling questions

1. What are your thoughts on measuring comfort in end-of-life care?
2. What are your thoughts on measuring symptom management in end-of-life care?
3. What are your thoughts on assessing and evaluating what the family's preferences are in end-of-life care?

Figure 4.3 Sample topic guide

4.7.2 Audio-visual recording

Conducted from a secure location, online interviews/focus groups were undertaken using Microsoft TEAMS provided by the University of Hertfordshire. End-to-end encryption was enabled to safeguard security and confidentiality. Only the interviewer and interviewee had access to the meeting ID and password for a specific session, with participant roles determining control privileges. The interviewee was unable to admit other participants or start a recording in line with online recruitment recommendations (Iflaifel et al., 2024). Video data was recorded and, as such, contained personal data, but this was destroyed, leaving only audio recordings to be transcribed and saved on the University of Hertfordshire's secure OneDrive.

Field notes were taken throughout all focus groups and interviews, and used for triangulation with the interview transcription. Uploaded into NVivo, the notes captured nuances such as significant pauses, sounds, and emotional responses that could be lost in

an audio recording and aid recall during data analysis. One participant became distressed, reflecting on their recent experience of providing EoLC and agreement to continue was sought in accordance with the Management of Distressed Participants During Interview Protocol (**Appendix 26**). Two participants were signposted to appropriate support organisations, as no support mechanisms were provided within their critical care unit.

Due to the sensitivity of EoLC and the constructivist grounded theory approach, interview and focus group transcripts were not returned to participants for comment or correction. Transcripts are not treated as objective representations of participants' experiences, requiring verification, but situated texts co-constructed between researcher and participant (Charmaz, 2025). Transcript review could prompt participants to revise comments, altering the outcomes and meanings co-constructed. Furthermore, such modifications are incongruent with constant comparison analysis, which requires a continuous, iterative cycle of data collection, coding, and analysis where analysis informs ongoing sampling decisions and theoretical saturation (Charmaz, 2025).

4.8 Analysis and finding

4.8.1 Data analysis

Data analysis commenced immediately following the completion of the first interview (**Figure 4.4**), continuing until constant comparative analysis determined when data saturation (Charmaz & Thornberg, 2021) was reached, i.e. no new or divergent EoLC outcomes, concepts or themes were identified. Analysis aims were threefold: i) identification of all outcomes reported by participants, ii) to understand the importance of the identified outcomes and iii) to define outcomes employing participants' terminology for Stage Three of the PEACE-COS study.

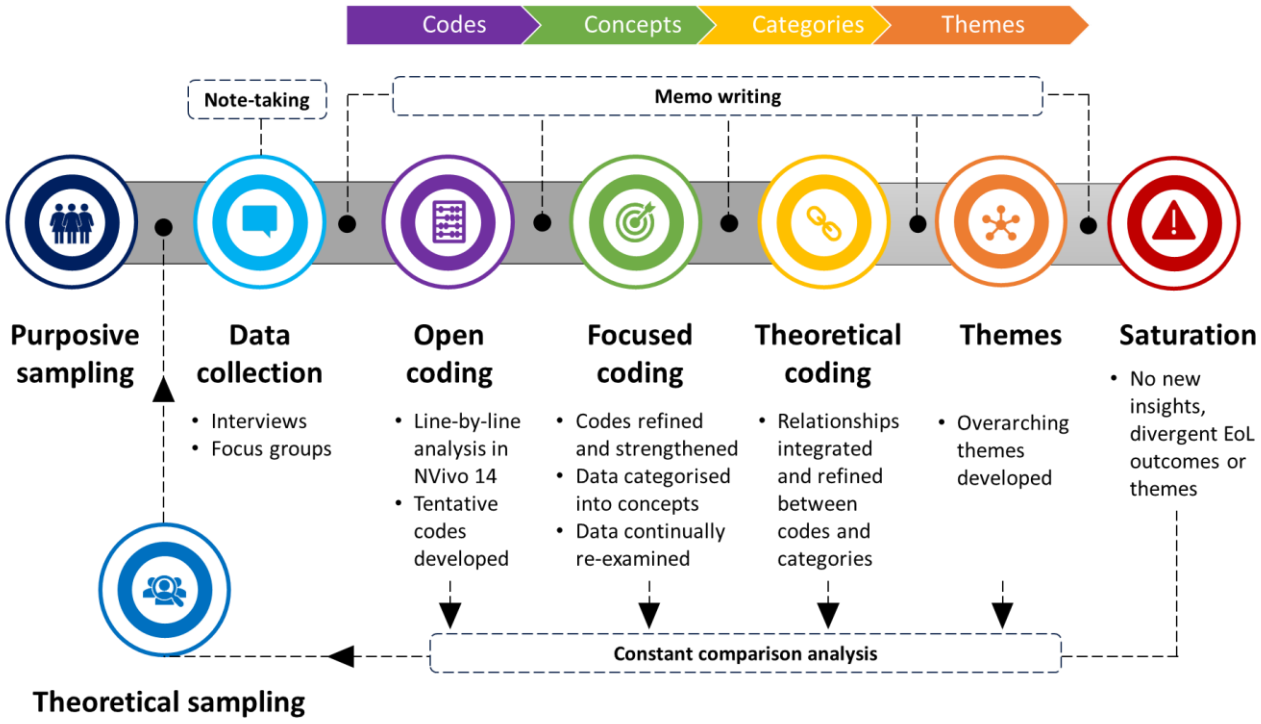


Figure 4.4 Stage Two qualitative data collection, coding and analysis process

Participant interviews and focus groups were transcribed verbatim as outlined in **Appendix 29** with the researcher listening to each audio recording multiple times to check transcript accuracy. Following transcription, a data familiarisation phase was employed, whereby the researcher read and re-read each transcript. Using a systematic inductive technique, each line of the transcript was coded, reflecting participants' exact words, and a codebook was created (**Table 4.2**). As each code emerged, a node was created in NVivo and compared and contrasted to previous codes, allowing the development of a conceptualisation of EoLC outcomes and interconnecting relationships between data. In the case of a focus group agreement, disagreement and challenges were also coded, identifying dominant voices and silences with individual positions extracted (Charmaz, 2025).

Table 4.2 Extract of pain outcomes codebook

Code	Description
Family assessed	How the family can help with pain assessments
Family felt terrible patient was in pain	Impact on the family of the patient being in pain
High blood pressure	Physiological parameters used as indications of pain
Pain scores	Different pain scores used to capture pain
Pain subjectivity	Different pain interpretations
Saying they are in pain	Patient-reported outcome measures
Unable to articulate pain	Patients are unable to verbalise pain due to clinical conditions or treatment
Myriad of analgesia	The extensive range or number of analgesics
Difficulties	Difficulties in treating pain eg pre-existing conditions
Pain is well controlled	Treating the pain so that it is controlled.
Pain medication route	Oral, sublingual, or NG
Preventative analgesia	Analgesia given in anticipation of the patient being in pain
Anticipatory prescribing	Analgesia prescribed in anticipation of pain
Sorting out a syringe driver	Changing the route of analgesia to subcutaneous via a syringe driver

After independently coding the first three interviews, two members of the steering committee (NP and RG) met with the researcher, agreeing consensus on the coding of one transcript passage and the code book. Data was continually analysed into codes, core concepts and emergent themes using iterative comparative analysis in line with broad principles of grounded theory methodology (Tie et al., 2019) and the codebook was updated to develop theoretical constructs of person-centred EoLC in critical care. This continual cyclical process enabled data to be explained by interpretation and conceptualisation, facilitating the development and refinement of key themes or outcomes for exploration in subsequent interviews or focus groups (Charmaz, 2025; Tie et al., 2019). **Figure 4.5** illustrates a snapshot of the pain outcome that emerged during open, focused coding under the theme of care satisfaction outcomes. All coding processes can be found in **Appendix 30 - Appendix 37**.

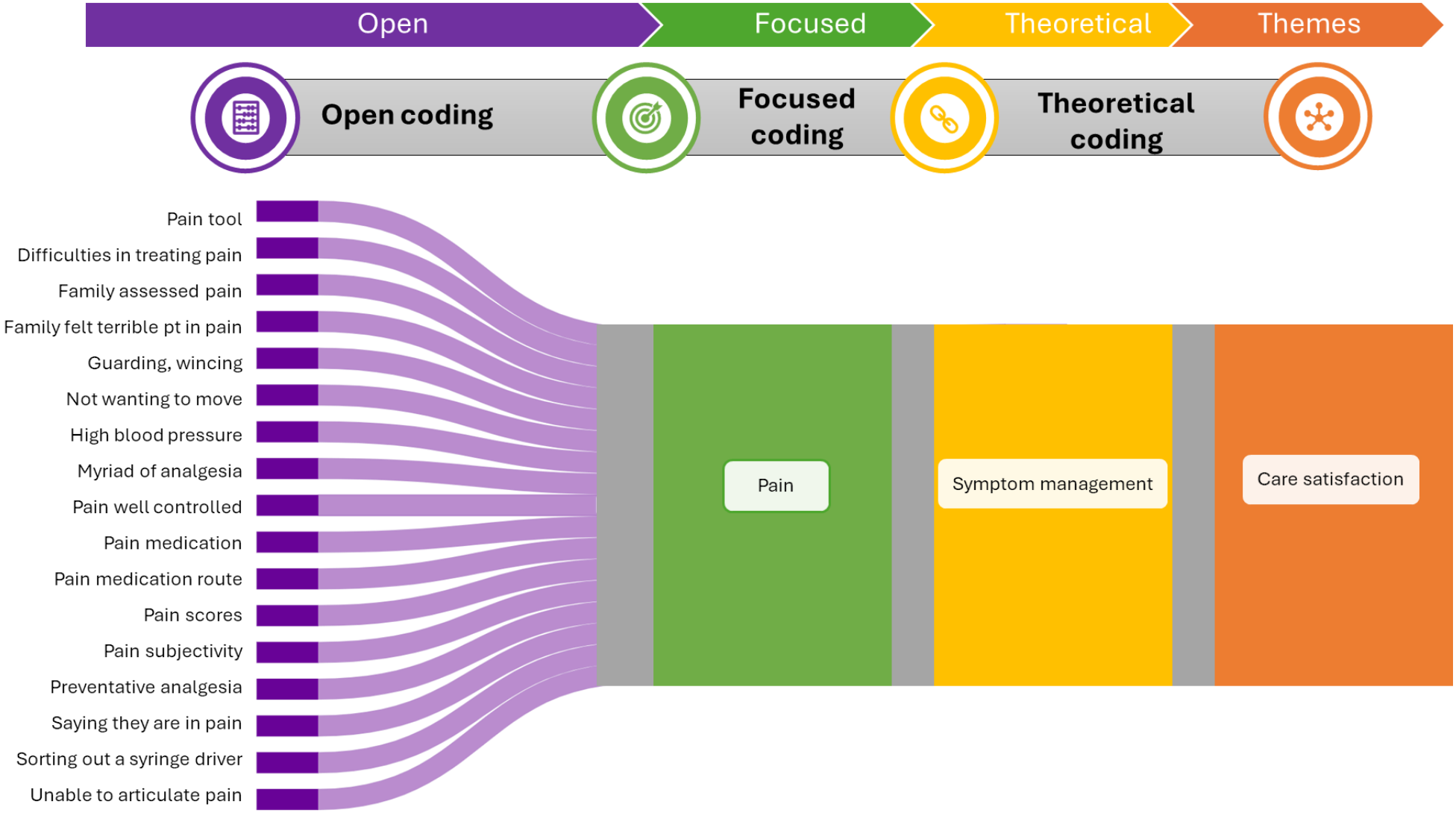


Figure 4.5 Coding example of the outcome pain

A case was created for each participant, capturing descriptive and characteristic information (**Figure 4.6**) to facilitate constant comparative analysis, allowing differentiation between participants based on known characteristics such as professional roles and experience (Charmaz, 2025).

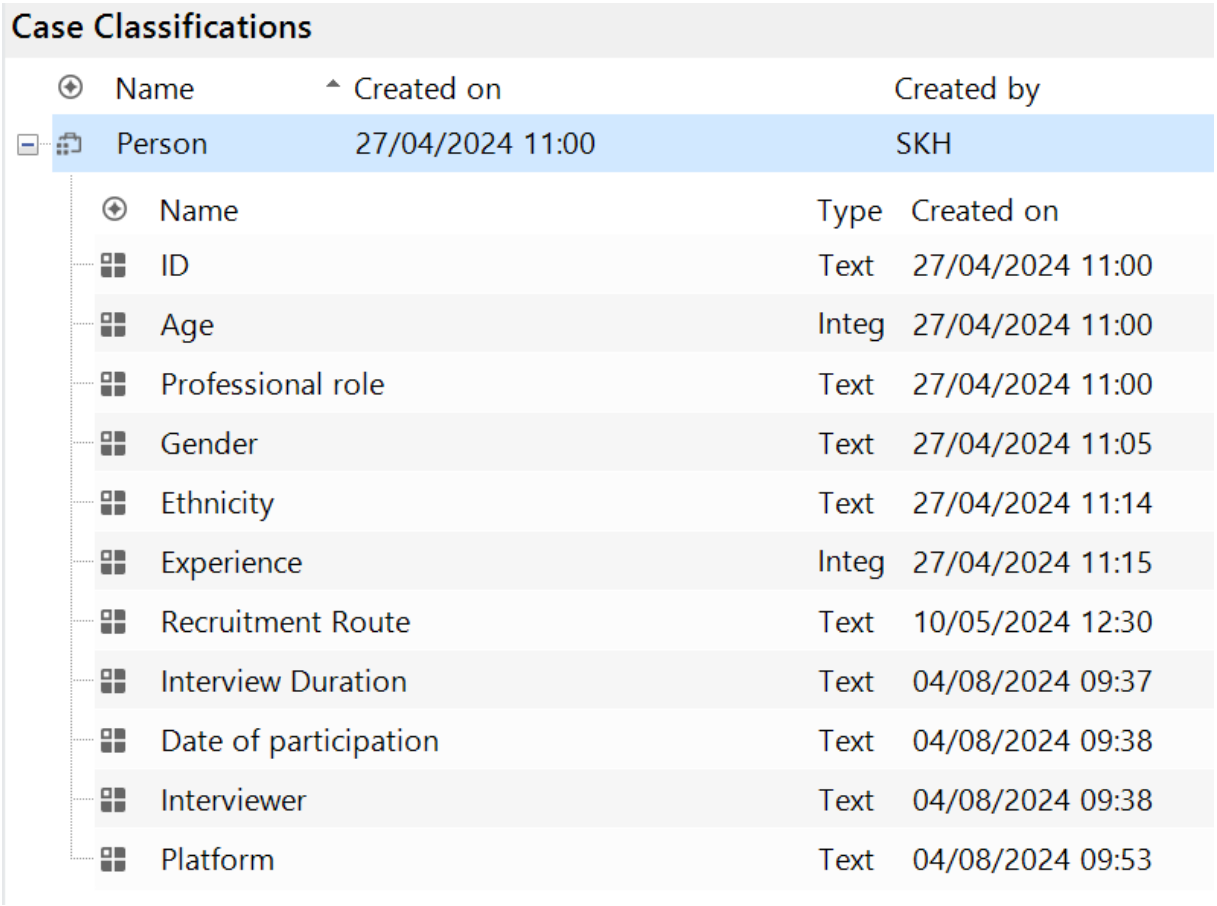


Figure 4.6 Case classifications created in NVivo

In addition to using NVivo, data management and analysis were undertaken using traditional methods (paper, coloured pens, sticky notes, large display boards) to enable engagement with the data on both micro and macro levels. Principles of grounded theory articulated by Charmaz & Thornberg (2021) were used to guide theoretical sampling, interview topic guide and coding. Data was not abstracted into *a priori* theoretical framework during the qualitative study, as this could be perceived to be hypothesis testing. Rather, it was generational to create a long list of outcomes to inform Stage Three of the study.

4.8.2 Research team, rigour and reflexivity

Research team

The research team comprised of three members with differing expertise. At the start of each interview/focus group participants were provided with background information pertaining to the study team members, their role and experience. Interviews were independently conducted by the researcher, an experienced clinical academic (female) nurse working in critical care and researching EoLC who had undertaken qualitative research methods training and an EoL and bereavement care course. Expert qualitative female nurse researchers with critical care and non-critical care backgrounds (NP or RG) led each focus group, allowing an insider-outsider technique (Aburn et al., 2021; McConnell-Henry et al., 2010). The researcher's positionality was provided in **Chapter 2 section 2.1.7** and ***Appendix 1.***

Rigour

Quality in constructivist grounded theory is demonstrated through credibility, originality, resonance, and usefulness (Charmaz, 2025; Charmaz & Thornberg, 2021).

Credibility

Credibility of the data analysis was planned through an inter-coder agreement. Two interview transcripts were sent to members of the steering committee (NP and RG) for independent coding; however, due to competing time constraints, neither was able to fulfil this role during the data analysis period. Instead, RG met with the researcher to discuss iterations to the codebook and transcription coding on four separate occasions, cross-checking for accuracy and dependability. Adherence to the constant comparative analysis and the exploration of developing outcomes with new participants ensured that the findings were conceptually grounded in participants' experiences (Charmaz, 2025). The use of participant quotations in **Findings** demonstrates transparency between the analysis and the narrative, further enhancing credibility.

Originality

Theoretical memoing is integral to the constant comparative technique (Charmaz, 2025) and was continuously employed throughout the data analysis, detailing coding creation,

collapsing, connections and comparisons (**Figure 4.7**). Here, the researcher captured comparative insights into similarities and differences that emerged across and within the data (Timonen et al., 2018). Contradictions and negative cases discovered through constant comparison directed the refinement of outcome constructs to develop a more nuanced understanding of EoLC, providing alternative explanations for familiar experiences and demonstrating originality through fresh analytical insights (Creamer, 2022; Creamer & Tech, 2021).

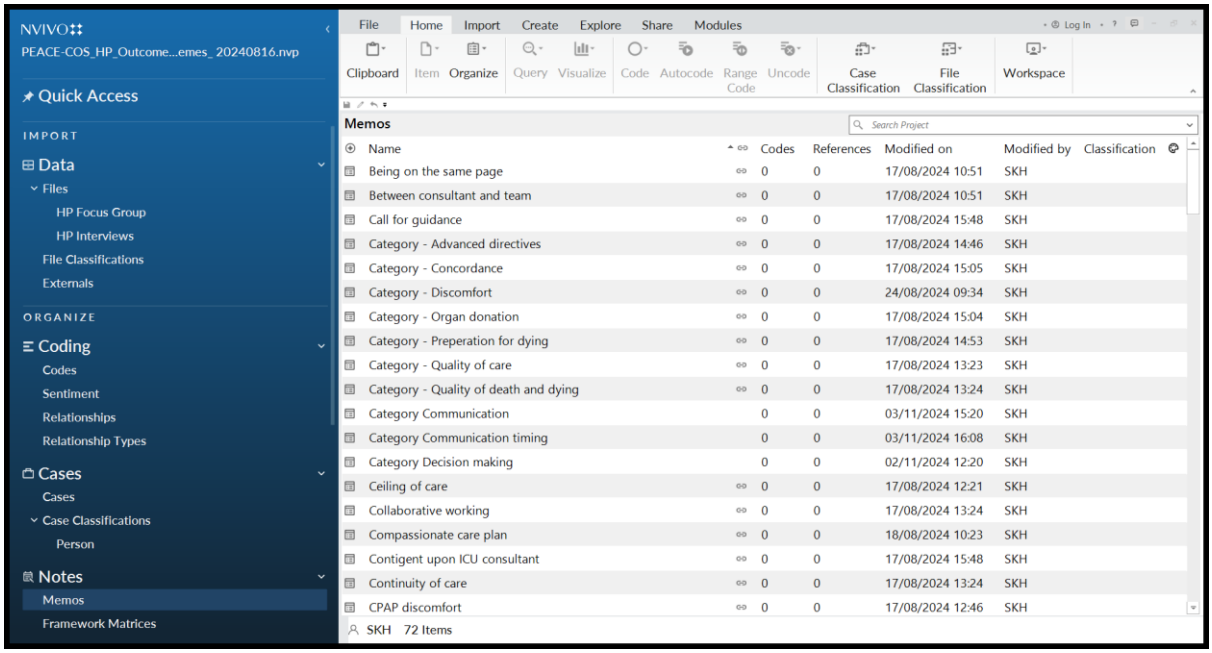


Figure 4.7 Stage Two memos example

Resonance

To ensure resonance, the developing outcomes and themes were continually checked and refined with participants, as constant-comparative analysis techniques enabled the exploration of negative cases identified within the data, enhancing the credibility of data analysis (**Figure 4.4**) (Sebastian, 2019).

Usefulness

The outcomes and themes identified reflect the study's originality and usefulness, not only extending the breadth of outcomes perceived as important to include in a COS, but also providing insights into why these outcomes are important.

Reflexivity

Throughout the study, the researcher engaged in continuous reflexivity, examining how her professional background and assumptions influenced the research process. Data analysis for the systematic review occurred concurrently with the interviews/focus groups, which could have influenced the outcomes identified and the interpretation of the data. Outcomes were not always palpable but implicit, expressed through coping mechanisms, rituals or feelings. Continually returning to the participants' terminology was crucial for developing outcomes that were empirically grounded and conceptually integrated. The iterative nature of theoretical sampling necessitated continual reflection to ensure that sampling decisions were data-driven, rather than driven by the researcher's conceptual preferences. Furthermore, memoing provided a robust audit trail capturing the researcher's thoughts, feelings, and conjectures as the researcher's viewpoint changed throughout the research process, enhancing the study's quality and promoting transparency. A private reflective journal **(Figure 4.8**) captured the researcher's thoughts, emotions experienced, and biases to reduce subjectivity. Three participants encountered difficulties comprehending the term *'outcome'*. Questions were subsequently clarified or rephrased using terminology previously used within their interviews, such as *'effect'* or *'consequence'*, when such instances occurred. Although such challenges have been previously reported in COS development (Alkhaffaf et al., 2020), they have been associated only with patients or family participants and were not encountered during the pilot involving both family members and a health professional.

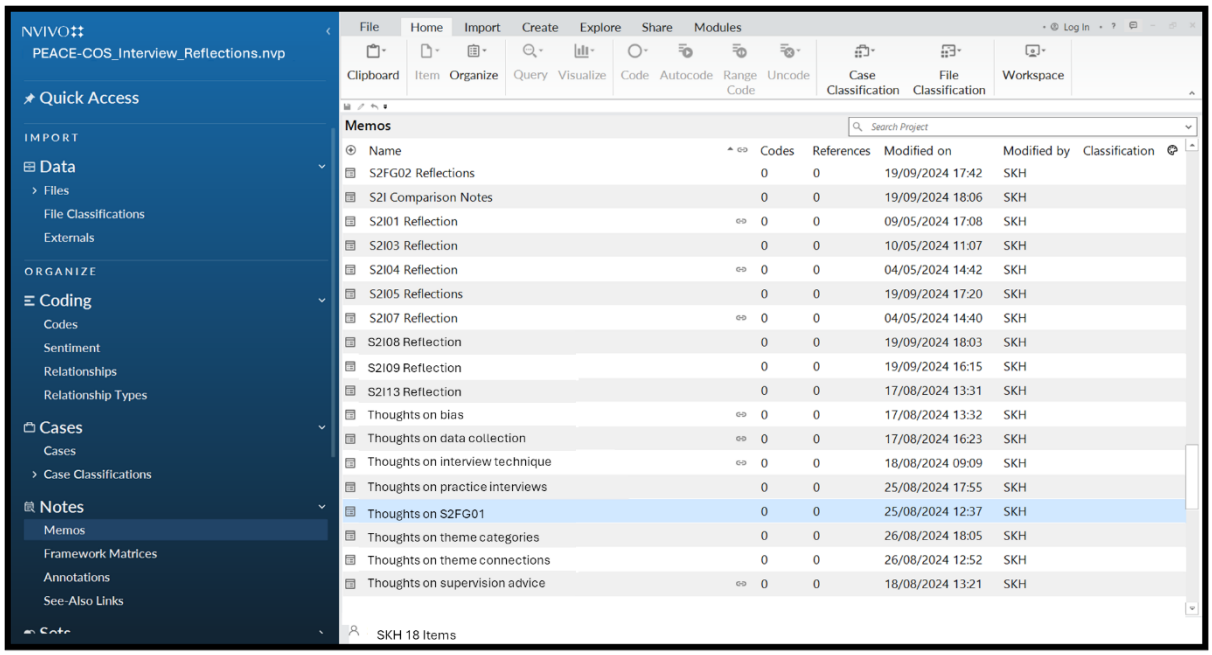


Figure 4.8 Stage Two reflective journal

4.9 Findings

The overarching meta-theme of outcomes reflecting compassionate, person-centred and sustainable quality EoLC emerged from the data. This meta-theme encapsulated eight outcome themes (**Figure 4.9**) encompassing 175 unique outcomes (**Appendix 30 - Appendix 37**). 124 outcomes were not identified in the systematic review. Each theme is presented in conjunction with participant quotations derived from the interview/focus group data. Supplemental quotes are located in **Appendix 38 - Appendix 45.** While the themes are examined independently, all interact and intersect, reflecting the complexity inherent in EoLC.



Figure 4.9 Diagrammatic representation of the eight outcome themes

4.9.1 Care satisfaction

Through constant comparative analysis, care satisfaction emerged as a multifaceted construct, involving objective clinical outcomes and subjective experiential quality. Commonality was evident across all participants and professions that the degree of congruence between anticipated and actual experiences intrinsically shaped care satisfaction. Within this, expectation management was described by one participant as a *'massive'* outcome*,* increasingly influenced by media portrayals, prior experiences, and cultural backgrounds, creating expectations not reflective of EoL complexity. Seven participants deemed it imperative to ascertain the patient and their family's expectations to create a shared understanding of the patient's treatment and possible outcomes. Both doctors and nurses frequently articulated expectation heterogeneity where family members stated *'too much'* or *'too little'* was done for their loved one during EoLC, impacting on both family and health professionals' care satisfaction and how quality of EoLC or death and dying was perceived:

> *"I think it's important in all care without expectation of what they think is going to happen, and what's really going to happen."* [S2I07]

One participant reflected how expectations fluctuated throughout the patient's EoL trajectory, modified by the information communicated and the professionals involved. Care satisfaction in this sense was not static, complicating evaluation outcomes as family members need to integrate multiple encounters with a range of health professionals, each contributing differently to overall care quality. The importance of providing continuity of care during EoL was espoused as invaluable in supporting family members by one participant:

> *"…but it was felt that palliative care would nonetheless still be invaluable with respect to helping provide some continuity of care, some support to his parents who had been through this rollercoaster with him.."* [S2FG05]

Whilst the need to evaluate family satisfaction with care through a patient-reported outcome measure (PROM) was deemed helpful by three participants, trepidations were raised about the practicalities and timing of capturing outcomes by others. Follow-up and bereavement services were suggested as possible mediums through which family

satisfaction could be measured; however, only one participant stated their organisation had any formal bereavement structure or follow-up:

> *"If we had a really great bereavement service that you could meet people and talk through their concerns or talk through what went well and what didn't I think that would be the best way of doing it."* [S2I04]

Two nurses and a physiotherapist espoused the importance of measuring the use of non-beneficial interventions. Invasive lines and monitoring were perceived as no longer needed and uncomfortable for patients, while initiating new treatments was simultaneously perceived as detrimental to both the patient and their family:

> *"I feel like you've taken that time away from that family to do treatments that you know is not going to work."* [S2I07]

Effective symptom management was identified by all participants as fundamentally important in EoLC, directly impacting care satisfaction. However, constant comparative analysis revealed critical and complex challenges in both definition and measurement. One participant stated:

> *"What is the symptom? Is it what you're experiencing or what other people think you're experiencing?"* [S2I06]

This ambiguity of whether a symptom should be a PROM or observer-reported outcome (ObsRO) was evident throughout both interviews and focus groups and across professional roles, indicating the need to use an eclectic range of measures, including PROMs, ObsRO, and physiological or clinical outcome measures, depending on the measured construct (symptom) and the patient's clinical condition:

> *"I think with any symptom control stuff, you just have to ask the patient that's if they're able to communicate.* [S2I06]

> *"I think there is something in looking at, could we use an outcome set that takes into consideration the nurses' and the families' opinions on how symptom managed the patient is?"* [S2FG01]

Whilst there was a commonality in using PROMS and ObsRO measures for symptom constructs, the use of clinical outcome measures was controversial, with opinions divided between participants and within professions. One doctor advocated their use:

> *"We can look at signs of, you know, distress in a patient which could be tachycardia, sweating, difficulty in breathing, so those kinds of things."* [S2FG08]

Whilst another challenged the accuracy and reliability:

> *"You're just looking at essentially external signs of distress, which as we all know, are very unreliable."* [S2I03]

This division was also evident in the instruments used to measure symptomology constructs. Many felt that instruments used in the non-EoLC critical care population, such as visual analogue scales, were unsuitable for EoLC. Without suitable instruments, nurses and a physiotherapist felt reliant on intuition or experience. One nurse highlighted the need to develop specific instruments:

> *"So maybe the creation of a tool that would be more specific towards management of symptoms in ICU towards the end-of-life, which would include maybe physical symptoms, obviously the pain and secretions, agitation, whatever."* [S2I13]

Irrespective of the symptomology construct and outcome measurement instrument utilised, uncontrolled symptoms were perceived as distressing to both patients and their families by all participants, impacting care satisfaction:

> *"There are symptoms which are not well controlled towards the end-of-life. Delirium is perhaps the best example of that, umm and, that's both distressing for the individual, almost certainly, umm but also distressing for families to watch."* [S2I13]

4.9.2 Communication

Deeply embedded in all participant narratives was the importance of communication in EoLC. Differentiating between *'hearing'* and *'listening'* represented a crucial aspect of EoLC communication for family members and the multi-disciplinary team that warranted measuring. Participants conceptualised hearing as a passive process, linked to providing

opportunities for families to express their thoughts, feelings, preferences, and wishes. Listening was related to engaging and understanding the underlying context and emotional state of the patient, their family and staff, requiring an appropriate response to the information communicated. All participants believed that this interactive process was necessary to provide patient-centred care, leading to the outcomes of listening to the family and feeling heard.

> *"The first thing is I always felt is just to listen the families."* [S2I01]

> *"But really what matters, in my mind, is how do patients and families feel that they have been heard and acted on?"* [S2FG01]

The need for outcomes that capture the clarity of communication and the patient's and family's understanding was evident across all professions: doctors, nurses and physiotherapist. All described how the use of simple, clear, transparent, empathetic communication simultaneously facilitated understanding for patients, their families and staff, whilst *'foggy'* and *'technical'* language created anxiety, barriers, frustration and misconceptions for family members. Two participants commented:

> *"They didn't actually say she is actively dying or she's now at a point where we can't do anything for her and we're just keeping well, she said keeping comfortable, but there was no cue of this is the beginning of the end."* [S2I05]

> *"We don't use dying people that's dying. They say, oh, they think they're going to pass soon or, you know, like they are dying. Using words just really simple. They're dying."* [S2I07]

Furthermore, using the terms palliation and end-of-life interchangeably was felt to be problematic, creating *'false'* hope for family members over treatment options and the length of the patient's survival time. Palliative care was seen as a broad overarching term for symptom management, communication and managing complex patients with a life-threatening illness, whilst EoLC was more nuanced, focusing on the *'final hours'* or *'days'* where the pathophysiology cause of dying was not actively treated, and death was imminent. The need for explicit discrimination and distinction between palliative care and EoLC resonated with all participants.

"We're palliating him. He was like, well, what does that mean? Because they can last forever and not last forever, you know, I mean, they can go on for a very long time in a palliative position, but the act of dying and we are at the start of actively dying is something completely separate." [S2I05]

"I think the [core] *outcome sets are probably going to be different for the two of those, and I think it would be helpful to separate those out, not least in aiding the understanding of everybody as to where we stand with the differences between palliative and end-of-life care, because I think, in my experience, that really does feed into the difficulties."* [S2FG01]

One participant suggested:

"Should we have a specific language and words that we use?" [S2I07]

The importance of the timing of EoL conversations was also a recurrent outcome raised by doctors and nurses, viewed as a pivotal role in the patient and their family's ability to absorb and process information. The need to engage in *'early'* EoL conversations was central to allowing patients and their families time to process the severity of the situation, followed by a continual need to '*keep the family up-to-date'*. Views of how *'early'* varied between professions, influenced by the patient's illness trajectory and personal circumstances. One nurse reflected on how a consultant would:

"Say to all families as soon as somebody is admitted and the patient if they are awake you are in a critical care unit there is a chance you may die." [S2I07]

Whilst a doctor highlighted the importance of conversations prior to critical care:

*"…I was taken aback somewhat to find that about 50% of people I went and spoke to about critical care and explained what might happen and how they might be put onto a ventilator, and how that might mean that, you know, they were unconscious for a couple of weeks or something like that. Umm And they might ultimately die said. That sounds completely s***t. No thanks."* [S2I03]

Three narratives illuminated how EoL conversations were frequently compounded by complex family dynamics and the patient's inability to engage in meaningful conversations, yet all participants agreed that, whenever possible, patient and family involvement in communication should be facilitated and measured. Conversely, one participant felt that no adequate alternatives existed when unable to speak to the patient:

> *"I think it's challenging cause a lot of time we get patients and then not in a position to talk to us so they are either intubated on a vent, or confused and not able to have those discussions… There isn't really a great substitute is there for speaking to the patient themselves when you can."* [S2I04]

Patient and family acceptance of approaching EoL was seen as intrinsically linked to the healthcare professional's ability to engage in meaningful conversations by one nurse and a physiotherapist; however, the physiotherapist portrayed acceptance as an individual, complex, dynamic psychological and emotional journey, challenging for all impacted:

> *"We've experienced it quite a lot recently, actually with the case where families are kind of asking for more treatments that aren't perhaps indicated or aren't appropriate and are struggling to come to terms with, with the kind of situation and that's very, very difficult."* [S2I06]

Collaborative multidisciplinary communication was seen as crucial in coordinating comprehensive person-centred EoLC by all professions, yet only one nurse felt collaborative communication could be measured through documentation review:

> *"Just the whole multidisciplinary team. We all need to be like on the same page. And if we have a conversation with family, make sure we document it, and then whoever will be following up so that maybe the next nurse or medical team. If we can kind of all be singing like from the same hymn sheet."* [S2I09]

Technological advances were also considered by two nurses and a doctor to impact EoL communication, with online communication platforms at times replacing traditional face-to-face interaction. The need to measure satisfaction with such communication methods and to integrate and adapt outcome measurement tools is, therefore, essential to capture more nuanced communication outcomes. One participant commented:

> *"And for those of you with* NACEL [The National Audit of Care at the End of Life] *what's even more weird is that to do the quality survey for the bereaved relatives it's a QR* [quick-response] *code; that's the only way that you can access the survey is by means of a QR code, which is already causing digital exclusion and terrible numbers for us here."* [S2FG05]

There was resounding agreement among all participants that satisfaction with communication should be measured and assessed by patients, their families, and the healthcare professionals involved in the EoLC. Understanding all these diverse perspectives was deemed necessary to measure the complexity of person-centred EoLC.

> *"But I think it comes back down to we need to be able to assess our communication and their satisfaction in what we are doing, their understanding and how well do they think that the situation is being managed."* [S2FG01]

Opinions, however, varied on the time point and frequency at which such outcomes should be measured. One nurse suggested distinct time points:

> *"…maybe at the end of your shift you can it could be like a little survey saying like, do you feel like, how do you get the communication was or at the end of the patients life but like when they are put on a end-of-life pathway?"* [S2I09]

Whilst another advocated multiple time points to establish a constant feedback loop:

> *"So I think in those sub-groups of patients it is important that we can have outcome measures or pathway where the feedback between the families is in constant loop."* [S2FG08]

4.9.3 Decision making

Healthcare professionals' decision-making emerged as a complex, multifactorial construct encompassing interlinked outcomes that should be measured and assessed by patients, their families and healthcare professionals. In its broadest terms, it was suggested that overall satisfaction with healthcare professionals' decision-making should be an outcome

captured. However, constant comparison of participant narratives revealed decision satisfaction to be dynamic and recursive, influenced by perceived autonomy, the extent of emotional support provided and individual values and beliefs warranting the need for a number of more nuanced EoLC decision outcomes. One participant commented:

> *"I think it's more of a suite almost or I mean it's a number of measures … There has sometimes been – and again, not to be critical of any colleagues – a lack of decision making, and sometimes patients have languished on the ITU for a large number of weeks."* [S2FG05]

Foremost in decision-making was deciding when in a patient's illness trajectory the patient was at EoL followed by decisions on when or if treatment should be withdrawn or withheld. All these decisions represent profound consequential outcomes fundamentally impacting patient, family and healthcare professionals' experiences, outcomes that all participants felt were important to measure in EoL. One doctor remarked:

> *"And what baffles me, and the most important thing is, about decision making where when the active treatment ends and the decision to start comfort care or palliative care begins."* [S2FG08]

Whilst a physiotherapist focused on the importance of measuring the decision time point:

> *"The point at which a decision is made when treatment should be withdrawn or treatment is changed to conservative measures and how far into the patient's journey that happens. And then having a look at whether the whole MDT felt that could have been recognised earlier."* [S2I06]

Clarity of decision-making was perceived as imperative at this critical juncture by one participant, simultaneously cultivating trust between family members and healthcare professionals whilst reducing potential misinterpretations. Conversely, two nurse narratives revealed how ambiguity and inconsistency in decision-making eroded interprofessional credibility, generating confusion. One nurse recalled:

> *"…I think they are dying he said I think they are dying ring the family. I said OK well so I get them in. We go into this and I'm like, talking to the family, sort of preparing*

them that this is what's coming. They're going to have this conversation about, you know, we're going to withdraw because this is what the consultant told me. And then we walk in to have this discussion in the, in the private family room and he says, so we're going to treat for 24 more hours and we're going to give them some antibiotic and I'm like, you know, like Gobsmack." [S2I07]

Another nurse reflected on the legal complexity surrounding EoLC, advocating for outcomes that capture how decision-making aligns with ethical and legal requirements:

"Where we've got stuck with MDTs or where it's difficult, it's around the ethical decision-making and especially around the withdrawing, withholding treatment, the ethics of it. We've been stuck on that for a very long time, and there are instances where we had to make referrals to the Court of Protection, even to support some of this decision-making." [S2I13]

All participants perceived this existential complexity and inherent uncertainty surrounding EoL decisions to have psychological implications extending beyond clinical decision-making, requiring a nuanced approach balancing compassion and precision.

"The quicker the decision is made in those cases, the better to get our patients comfortable and dignified…I think that's quite an interesting measure to see, because for me, for an end-of-life care situation that the quicker the better really for the patients, for the relatives, for everybody." [S2I06]

Constant comparative analysis revealed how decision conflict was frequently evident amongst and between all healthcare professionals and family members, predominantly arising when making complex, value-laden decisions around EoLC, which were compounded by differing cultural, familial or multidisciplinary expectations:

"I would agree that it is an incredibly important thing to capture. And I think [Name redacted] highlighted there that there can often be a conflict within the ICU team, I think, in terms of the nursing staff and the medical staff, which can be really difficult to navigate." [S2FG01]

Conversely, collaborative and shared decision-making played a significant role in mitigating decision conflict and promoting person-centred care. One nurse suggested:

> *"I appreciate sometimes there's complexity. So, I think that if there was more engagement, more direct engagement with decision-making, I think that you could literally demonstrate in many cases a significant reduction in length of stay."* [S2FG05]

All participants described how family involvement in decision-making provided valuable context about the patient's previously expressed wishes. However, in the absence of an advance directive, two doctors stated that the ultimate decision to withdraw or withhold treatment in EoLC rested with healthcare professionals. While there was an overarching agreement that involvement in decision-making should be an outcome measured across all participants, only one nurse and a physiotherapist felt it essential to delineate decision-making boundaries to reduce emotional burden:

> *"That also then includes the family as well, because these are going to be the lasting memories that are going to be held by the relatives as well. So, therefore, I feel that they need to also be well and truly looked into how they feel about certain decisions that we make and then understanding the decisions*." [S2I05]

> *"I think the whole DNR* [Do Not Resuscitate] *conversation I feel quite strongly about that, that people are asked, well, do what do you think? Do you think we should resuscitate and actually it should be a medical decision then making the family think that they have to make a call on that. It can be it can be a massive burden and they don't understand the implications. They wouldn't, understand and it's happens quite a lot."* [S2I06]

Anticipatory prescribing decisions were thought by all professions to be integral to providing person-centred care, enabling nursing staff to administer pharmaceutical interventions that mitigate potential clinical complications, such as *'death rattle'*, delirium and pain.

> *"So anticipatory prescribing in our ICU, it's done quite well. We use the our own version of the individualised care plan for the dying person, so there is one that we*

use that is specifically designed for ICU and actually that would be a very good measurable outcome." [S2I13]

This strategic approach promoted staff autonomy, collaborative working and patient comfort, avoiding healthcare inefficiencies by streamlining clinical workflows and minimising treatment delays. One doctor said:

"If we've got a patient who's approaching the end-of-life yes, hopefully on ITU you have a doctor somewhere nearby, but that doctor might be intubating someone in resus, in which case we need them there, prescribed, ready to be given." [S2I04]

4.9.4 Impact on family

All healthcare professionals agreed that having a family member in critical care had a profound impact on family members' well-being. This *'emotional roller coaster'* was thought to be influenced by a variety of factors, such as previous exposure to critical care, the patient's length of stay, and preparation for dying, with effects extending far beyond the patient's critical care stay or death. The importance of a range of outcomes that capture family burden emerged as identified by all healthcare professionals.

"I think we should look at the burden that puts on to families. I think families are generally better if and cope with issues better if people come in and die relatively quickly rather than have long periods of uncertainty where they're a bit better today, well, they're a bit worse tomorrow." [S2I03]

The technological complexity of critical care, coupled with communication challenges, generated anxiety and anger amongst some family members, adding a substantial cognitive and emotional burden. Two participants recalled:

"When they didn't tell them that the ventilator wouldn't stop breathing for them. That, situation would be some and these relatives they got really angry. One of them was punching the door, they were screaming, I was like ahh, nobody told them. But we all, we all knew that this, this happened because we've seen it." [S2I07]

"When the person is dying. What that looks like, how we're going to manage it and understanding of the machinery and especially if we have to turn off some of these

monitors. It's doing it with the family members' understanding of why we're doing it. And how the numbers may be more of a source of anxiety for them. Rather than telling the those, you know the nurses or giving the team an information, it's more of the anxiety that brings." [S2I13]

Spending long hours in critical care led to physical exhaustion in some family members, while others neglected their health, leading to a deterioration in their health conditions or new problems. Morbidity outcomes subsequently became evident, as one doctor suggested:

"…but must lead to some morbidity amongst the, the people who are left." [S2I03]

Other families could incur financial burdens from travel, parking, and accommodation expenses. One participant described how assisting with indirect costs could lessen such burdens:

"Private parking is a very expensive family, so staff automatically will provide a car parking system. This is a rate unlimited for the patient's family until whatever days. So it will be supported and that's make family possibly a positive feeling." [S2I01]

Measuring the multifaceted nature of family burden was, however, considered complex, with one participant advocating for a general outcome:

"I'm not quite sure how you'd measure it. I think it would just be a case of, you know, assessing the situation, seeing how the family are, how they are in general." [S2I08]

In contrast, another participant proposed that family needs should be measured first:

"Well, first of all we need to ask patients or families, don't we, what are their needs around palliative and end-of-life care, and I'm not sure we know that yet. But once we had that, I feel like we may be able to measure that better." [S2FG01]

All participants described how family support fluctuated throughout the EoLC journey, depending on the patient's clinical condition, cultural factors, and available resources. Both doctors and nurses identified important gaps in family support, generating outcomes that would be valuable to measure:

> *"So they will look at the money, but the, the psychological side of occasion, their families, they don't measure it."* [S2I01]

Two participants recounted how a psychologist was used in their critical care units pre and post a patient's death to provide psychological family support, aiding patients and their families to navigate the complex emotional journey. Conversely, this was not reflective of most participants' experiences. One participant summarised:

> *"But I suspect there's a huge burden of families who we just don't have anything to offer them support-wise."* [S2I04]

A stark contrast was apparent between the emotional and practical support provided pre and post-death, which in some family members could lead to a profound sense of abandonment:

> *"So here we are having someone dying in ICU, you have one-to-one care, and the nurse is in the room with you, and everything is just focused on you and that patient who's dying. And so when that person has died, how it was described as felt as if, yeah, we finished with you bye bye you can go and that person felt they feel abandoned."* [S2I13]

> *"Certainly we've had feedback from families who slightly felt like they're just sent off into the ether and that's that. Umm and this place has been really important to them while their loved ones died. There's nothing. No follow up. I think that isn't right."* [S2I04]

In the absence of formal follow-up or bereavement support, family members were signposted to charities and their GP, yet it was questionable if any of these were appropriate for critical care bereavement, highlighting the pertinent role of bereavement outcomes. Conveying current practice, one participant revealed:

> *"You can only really send them back to the GP and say that's where the support comes from. But actually again, that's like a tall order for kind of. GP's primary care services, who aren't set up to look after people who've had complex bereavement in critical care."* [S2I04]

With another commenting:

> *"We don't routinely speak to bereaved families."* [S2I03]

Two participants articulated how critical care follow-up could provide opportunities to capture, address and measure the impact of grief; however, one participant firmly disagreed, considering these areas to be outside critical care remit:

> *"I think if they die that's not really ICU's problem in a sense."* [S2FG03]

One doctor specifically spoke about post-intensive care syndrome-family (PICS-F), whilst other participants (doctor, nurse and physiotherapist) described symptoms characteristic of the syndrome, such as anxiety, grief and relative morbidity. Measuring PICS-F and the corresponding constructs was therefore seen as necessary by all professions, yet only one professional indicated the use of patient experience measures (PREMs):

> *"Level of grief is really tricky to manage because it can be so subjective on the individual, the time and how it happened, whether they've had grief somewhere else recently. So it's it's tricky. I don't think you can measure grief. You can only go by what that individual is experiencing at the time."* [S2I05]

> *"So there's a bit of evidence isn't there about post-intensive care syndrome and how that affects family."* [S2I04]

For patients who continued their EoLC trajectory outside critical care, measuring functional ability was deemed beneficial by a doctor and physiotherapist for determining appropriate levels of support, resource allocation, and care planning. Here, the outcomes of importance explicitly focused on the physiological dependency of patients on their families:

"What am I looking at in terms of discharge planning? They're so dependent now. They're so weak. I'm looking at 24 hours in a nursing home." [S2I06]

In contrast, another doctor felt outcomes should focus on the quality of survival and level of disability, incorporating both physical and psychological aspects to capture mental impairment, remarking:

"So most people will tolerate or, or believe they'll be able to tolerate a certain amount of physical disability afterwards, but very afraid of umm, being left with serious mental impairment." [S2I03]

4.9.5 Patient and family centred

The importance of patient and family-centred care in EoL transcended all narratives. Participants conceptualised EoL as a relational experience involving not only the patient but, at times, their entire family and support network. Within this, all participants viewed providing individualised care as a central tenet of both patient- and family-centred care that was important to measure. Conversely, how this was operationalised in practice varied across the hospitals and critical care structures where participants were employed. Reflecting on using individualised care plans, one doctor commented:

"I've experienced now with a couple of large hospitals being a consultant at, my previous hospital did not have a formal individualised care plan for the time as this one does." [S2FG05]

While a nurse commented:

"We use the our own version of the individualised care plan for the dying person, so there is one that we use that is specifically designed for ICU and actually that would be a very good measurable outcome." [S2I13]

Although both doctors and nurses recalled examples of using EoL care plans, all but two recounted how they were *'generic'*, attuned to a chronic, slow death, not reflective of the *'quick'* death trajectory predominantly experienced in critical care. Exploring the use of individual care plans as outcome measures further revealed inconsistencies in when and

how EoL care plans were completed. Many were incomplete due to time constraints or completed in a hurry, making measuring such outcomes challenging:

> *"If these documents were well filled out you can identify what was important individually to that patient before, and then you can, kind of, see if those were addressed in the management of their death, the right family members, music, religious needs, all these sorts of things. But it would all be very individualised in that qualitative way, which makes it a difficult metric to measure."* [S2FG04]

Delivering an individual approach that moved EoLC provision beyond standardised protocols subsequently necessitated more nuanced outcomes that reflect patients and their families as complex individuals. For example, one participant suggested:

> *"So, a measure is, have they assessed holistic needs, so have they looked beyond the kind of, critical care things but have they actually thought about how emotional needs, psychological needs, social needs and all that stuff."* [S2FG02]

Here, a holistic needs assessment emerged as a multidimensional construct integrating the emotional, psychological, and social dimensions of patient and family experience to create a composite outcome. Another participant commented:

> *"100% I think it it's very important because if not, I feel like you're just treating an external disease like a body, whereas it's a lot more personal than that. And I do I think a lot of people don't really see that, they just see a patient in a bed and not the fact that they are humans with emotions and feelings and needs that are outside of what we understand."* [S2I09]

Similarly, doctors, nurses and the physiotherapist described comfort as a pertinent multidimensional outcome applicable to both the patient and their family that could be comprised of PROMs, PREMs, ObsROs, or physiological/clinical outcome measures. Comfort in this context extended beyond physical pain and symptom management to include the preservation of dignity and privacy, attention to spirituality, cultural background and personal preferences. One doctor described personalising the environment as a means to promote comfort:

"Things from home like maybe a blanket or a dressing gown. Like TVs. Just things that can like kind of like reorientate them and like and feel a bit more comfortable and homely." [S2I09]

While another stated:

"They want privacy, they want dignity, they want quiet, they want umm, err, a peaceful environment." [S2I03]

The need to ascertain the patient and family EoL preferences or wishes represented a profound shift from the traditional medical paradigm, fundamentally transforming how participants conceptualised and delivered EoLC. All participant narratives highlighted the importance of non-medical interventions:

"Actually there might be lots of things that are really important to them that don't involve drugs that don't involve umm kind of the machines that we use, but are actually about them as a person and I think that's something that we've not traditionally been very good at in ITU, but is really important and kind of facilitating that and helping staff to facilitate that I think is really important." [S2I04]

Preferred place of death was deemed an important preference by doctors, nurses and the physiotherapist, which should be measured:

"It could be a bit of a crude outcome measure of like; did they die in ITU on the ward or at home because as long as they die in the right place for them at that time. That's the important thing." [S2I04]

Congruence between preferred and actual place of death was, however, also considered to be complex, dependent on hospital resources, transfer capacity, patient stability and family support. One participant stated:

"No one, no one, no one says they want to die in an intensive care bed, that might be the only place available to them that may happen to them, but, but that's not no one's life plan." [S2I03]

Nurses expressed that culture, religion, and spirituality played notable roles for both patients and their families during EoL processes, offering profound psychological and emotional support and mitigating distress by providing meaning and comfort. One nurse recalled:

> *"We have things like, we've had Quran cubes, we've had holy water that we have put on people's lips and bodies as family as directed, and I think obviously that patient's religious are really important to them. But I think a lot of that is family. I think it will. It helps family and I think that's why we do it more than anything else."* [S2I07]

Another nurse reflected on the challenges a lack of awareness of cultural, religious or spiritual beliefs created:

> *"Areas that we both have found quite difficult was quite recently have been patients and their families have religious or cultural beliefs that are; probably we haven't asked them throughout the admission and suddenly becomes a problem when you're trying to withdraw treatment. And they're saying, you know, our religion does not support that, our culture does not support that."* [S2I13]

Ensuring that the patient and their family were prepared for the patient's impending death was perceived by all professions to be a vital component of EoLC. Narratives demonstrated how preparation involved facilitating transparent, honest, meaningful communication to provide a dynamic, ongoing dialogue that could transform a potentially traumatic experience and mitigate long-term psychological trauma:

> *"I think a bit of preparation as well, just sitting down and, saying this is what's going to happen exactly like this and, the ventilator will still breathe for them, umm, but it's not there."* [S2I07]

Nurses, in particular, spoke of the significance mementoes had in preparing families for the patient's death during EoLC, simultaneously providing connection and closure. Knitted hearts and taking *'hair snippets'* provided tactile and emotional anchors, whilst printouts of *'heartbeats'* and creating *'handprints'* bridged the gap between the lived experience,

transforming ephemeral memories into permanent keepsakes, persisting beyond physical separation. One nurse reflected:

> *"We do an angel wing bracelet. So, we'll quite often put a bracelet on a patient and then give out a bracelet to a relative."* [S2I08]

4.9.6 Professional competency

Using protocols, guidelines and EoLC pathways as outcome measures divided opinions between doctors and nurses. Three nurses recalled how, when transitioning from active treatment to EoLC, having a *'streamlined'* pathway was important in facilitating symptom control and psychological support whilst promoting the discontinuing of unnecessary interventions and aiding consistent care. One nurse remarked:

> *"I really encourage people to use it, it does have some symptoms, scoring sheet and umm, of course intensive care patients that generally have the luxury of one-to-one or one-to-two nursing."* [S2I13]

Where participants used such guidelines or pathways, they felt empowered in delivering EoLC, whilst those without felt reliant on experiential knowledge or lost:

> *"I think a lot of us just, just don't have anything to follow. It's just all experience and thoughts."* [S2I07]

> *"Some kind of a pathway would probably help, especially when the workforce is quite junior and inexperienced."* [S2I08]

Conversely, using such pathways as an outcome was considered *'difficult'* by one doctor. Here, adhering to a *'set'* pathway risked prioritising procedural efficiency over the unique emotional and physiological needs of the patient and was not congruent with person-centred care:

> *"It's really difficult in any aspect of palliative care to have a pathway or a set way of doing things because one person can have the exact same pathology as another, but their social circumstances, their symptom set and how they need supporting through that pathology, can be entirely different."* [S2FG01]

Variations in EoLC varied both between participants and within critical care units. Both doctors and nurses recalled how medical decisions based on clinical intuition, personal preferences, and experiences contributed to variations, and that balancing experiential knowledge with empirical evidence was vital to ensure person-centred care. One doctor reflected:

> *"I know some colleagues who would never do a palliative extubation; I know some colleagues who literally switch everything off and pull the tube. So, there's a huge range of practice in critical care. And whether or not there was some way to measure what people actually do, because I don't think we've really captured that anywhere that I could see."* [S2FG04]

One nurse commented on how such variations could place staff in difficult positions, creating uncertainty and professional conflict about appropriate actions and priorities:

> *"One day we might have a decision made so kind of palliate the person and kind of keep them comfortable, you're not treating them anymore. But then maybe the next day a different person would come in and say, let's give them another 24 hours with active treatment and then that kind of as a nurse, it puts you in a position where yeah, kind of torn because you wanna keep the person comfortable and you, you're kind of expecting the worst, but you can't really do that."* [S2I09]

Variations and inconsistencies in care planning and delivery, however, were complex and thought to be attributed to a variety of factors. The physiotherapist summarised:

> *"So is the plan continuously changing? Is it adapting to patient needs, or is it changing because of differing opinions?"* [S2I06]

Navigating such changes posed a professional dilemma, as health professionals were expected to provide consistent, evidence-based EoLC. Consequently, measuring knowledge, skills, and competency in EoL was seen by all participants as valuable and intrinsically linked to a healthcare professional's ability to adapt safely to practice variations and to provide high-quality EoLC. Gaps in understanding and competencies, primarily attributed to differing paradigms, epistemological standpoints and curricula, were identified

by both doctors and nurses, adversely affecting the confidence of healthcare professionals and, at times, contributing to delays in the provision of EoLC:

> *"As nurses, we focus on patients and families and, care and compassion, because that is what we're taught. And doctors taught to focus on treatment and making people better, and you think people don't always get better."* [S2I07]

> *"And we've had various instances where there has been delay in prescription or the nurses not knowing how to institute palliative care"* [S2FG08]

One doctor expressed reservations over measuring EoL knowledge, suggesting an *'overall'* skillset outcome could be a more robust outcome measure. Unlike knowledge outcomes that assess what participants know, skillset outcomes demonstrate an individual's capacity to translate theoretical knowledge into practical competencies and performance capabilities, simultaneously providing evidence of behavioural change, functional ability and intervention efficacy:

> *"It's really difficult because it's just going to be so nuanced depending on the need of the intensive care unit. And if you can somehow capture the skillset overall, maybe that would be more helpful."* [S2FG01]

How EoLC was managed also varied between participants. The majority of participants operated within a consultative model of care. Here, intensivists led and coordinated the patient's care with speciality teams such as palliative care, acting as expert advisors *'invited in'* to provide specialised clinical guidance or recommendations without assuming direct responsibility for the patient's care trajectory. Those working within a consultative model felt it imperative to measure palliative care referrals, availability and involvement:

> *"Sometimes when you call the palliative team on the night midnight patient deteriorates and change the plan you want to call a palliative, palliative team is not available."* [S2I01]

Palliative care involvement was thought to substantially improve the patient, their family and healthcare professionals' EoLC experience, offering expert pain management,

emotional support and coordinating care that transcended the critical care environment. One participant reflected:

> *"They're much better than we are at getting people plugged into Hospice care into available charities, adequate counselling for bereaved relatives, child issues, child bereavement issues, things like that and there is so much more."* [S2I01]

Timely referrals to palliative care teams were described as essential for proactive symptom management by 10 participants, yet measuring referral timelines involved complex, multifactorial considerations. Both doctors and nurses recalled how the patient's illness trajectory, symptom severity, level of knowledge within the critical care team, potential benefits from specialised palliative care involvement and the emotional readiness of family members all impacted the time point at which a patient was referred to palliative care. Nurses, in particular, remarked on a need to move beyond a reactive model to embrace an anticipatory, more patient-centred approach:

> *"Generally it generally takes someone to say, shall we involve the palliative team or when we do get like the booklet out the physical booklet, there's a number on the front page and then that's a good like indicator."* [S2I09]

> *"We might not need them at that particular point, but it's a case of just being ready and being prepared, because there's nothing worse than being out of hours."* [S2I13]

In contrast, one participant described an integrative setup in which palliative care professionals were intrinsically embedded within the core critical care team. Irrespective of the choice of model used, collaborative working was perceived by eight participants as a valuable outcome measure. In contrast to knowledge-based outcomes, which focus on individual understanding, measuring collaborative outcomes was thought to capture both individual contributions and group synergy, facilitating knowledge co-construction and achievement of shared goals. One nurse commented:

> *"Is it an MDT that achieves the ethos from an MDT rather than maybe someone's opinion overriding everything that's being discussed in there."* [S2I13]

Withdrawal or withholding of life-sustaining treatment (LST) was perceived by seven participants as a valuable yet complex professional outcome that reflected a health professional's competence through the integration of clinical judgement, the capacity to balance beneficence and non-maleficence, legal frameworks, and patient values. Variations could indicate potential gaps in training, professional confidence or ambiguous organisational guidelines. Both doctors and nurses considered withdrawal processes and subsequent EoL trajectories to be unique to critical care that directly impacted on patient dignity, family and professional satisfaction. One doctor stated:

> *"In terms of what works for kind of evaluating those rapid withdrawals of treatment where you've got a few hours from the patient being fully actively treated to died is very different from, the ones who are slowly getting more like a ward patient where a lot of those ward-based tools that are more useful."* [S2I04]

Whilst a nurse commented:

> *"It's not the, the patient just dying and like, peacefully or the oxygen points going up. It's we're physically removing breathing tubes and life-supporting medications and filters. And I think that's the big difference to sort of us in other areas is they're not just dying we're taking it away."* [S2I07]

One nurse highlighted the need to focus on outcomes that captured the appropriateness and timing of treatment withdrawals:

> *"…We are quite bad at withdrawing care, where I think other, bigger regions, obviously, would have done it a lot sooner than us."* [S2I08]

4.9.7 Staff burden

Proving EoLC presented profound, multidimensional psychosocial stressors that considerably disrupted healthcare professionals' individual coping mechanisms, which all participants felt necessary to measure. One nurse spoke of using '*gallows humour'* as a method to express and process difficult emotions. Here, it was perceived to provide temporary relief, creating a psychological buffer. Conversely, another participant considered this *'maladaptive'*, which could impair interpersonal relationships and affect professional functioning. Measuring how individuals were coping and the strategies

employed were therefore perceived as important, allowing differentiation between adaptive and maladaptive coping and simultaneously providing insight into an individual's well-being.

Conflict with family members during the dying phase represented a notable stressor for all participants, arising from differing expectations, cultural values and misconstruing medical interventions in EoLC. Nurses expressed how such conflicts led to feelings of professional inadequacy when striving to balance the needs of the patient and their family, impacting their ability to deliver effective EoLC. One nurse commented:

> *"Sometimes it's very difficult when, when the patients wishes are not known and the family member really wants to I guess, override what the what the team are trying to say is in the best interest of that person."* [S2I13]

While another stated:

> *"It could be misconstrued that we've given up on them and we are actively wanting them to die. That's not what that's about."* [S2I05]

Measuring the prevalence and effect of such conflicts was deemed essential to understanding the effects of providing EoLC on healthcare professionals. Conflicts, however, were not limited to family members. All participants recalled feelings of inadequacy or frustration, and at various time points in a patient's EoLC when they felt unable to influence care decisions or advocate for others. Being disempowered was perceived by two doctors and the physiotherapist as having a profound negative impact on self-esteem, leading to diminished confidence and the ability to make EoL decisions. Here, disempowerment could erode professional identity:

> *"The medical part of the palliative care team, feel a bit disempowered dealing with intensive care patients so they kind of shy away a little bit and they need a bit of encouragement to to to come along."* [S2I03]

Doctors, nurses and the physiotherapist all described a complex constellation of emotional responses that arose both during and after providing EoLC. Nurses described persistent feelings of *'worry'* and *'sadness',* recounting symptoms of anxiety and depression

attributed to their close proximity when providing EoLC. One nurse and the physiotherapist recalled the difficulties traversing their personal emotions while providing EoLC. Crying with the family reduced emotional tension, fostering a sense of catharsis that aided both the healthcare professional and the family navigate the complexities of EoLC. One nurse recalled:

> *"These deaths aren't easy because I quite often cry with the family anyway, but that just makes me do the job that I do."* [S2I08]

However, two other participants spoke of how the continuing demands of working long hours meant there was no time to process one patient's death before caring for another, with emotional and psychological support provision varying between professions and between employing organisations. One doctor described how nurses had:

> *"A very different way of coping with the whole situation and had their own well established peer-to-peer network."* [S2I03]

This assertion was validated by four nurses. One spoke of using a private work WhatsApp group to share experiences in real time, creating unity outside work hours that was underpinned by a reciprocal understanding. Another nurse described informal support spontaneously provided by colleagues when required:

> *"If I feel quite burnt out and I've felt anxious about coming back to work, I've gotta chat with the person in charge and they've given me the time to kind of chat to them, and like get advice and things like that."* [S2I09]

Formal support similarly varied between professions and organisations. Both doctors and nurses could access support formally through counselling services, clinical psychologists, welfare officers or hospital chaplains. A stark contrast to the physiotherapist:

> *"I think that would be great. They don't do it, no one's ever asked me, but I think that would be I think that would be helpful actually, yeah."* [S2I06]

Outcomes encapsulating support accessed and psychologist involvement were therefore considered essential for reducing disparities in access, whilst providing empirical evidence of unmet needs for future service provision. One nurse commented:

> *"It is important that we express our feelings so the system knows that what kind of support they can provide or what kind of things they need to be, evolve or whatever generate to support the staff."* [S2I01]

Conversely, the demanding work patterns in critical care were not conducive to accessing support, with appointments not congruent with shift patterns. One nurse reflected how A&E had overcome such operational challenges through an embedded *'debrief'* which enhanced team cohesion and resilience; however, this was not considered a regular occurrence by any other participant.

> *"I used to work in A&E so we'd always have like a debrief at the end of the shift so that could be useful."* [S2I09]

All participants recognised the emotional and psychological sequelae of providing EoLC and the need for outcomes that capture distress, burden, and burnout. Two doctors recalled how high levels of distress impacted colleagues' ability to provide effective care, reducing patient, family and staff satisfaction. Regularly measuring distress would allow the implementation of timely interventions to mitigate compassion fatigue across all staff:

> *"…Post-COVID we've seen so much distress, not only in the nursing staff but all medical staff who are working, all medical and non-medical staff who are working in ICU."* [S2FG08]

Moral injury represented profound psychological distress experienced by doctors, nurses and the physiotherapist emerging when participants witnessed unnecessary suffering or practices that compromised professional integrity or patient dignity during EoLC. Unlike distress, participants conceptualised moral injury as a continuum of more severe consequences involving deeper feelings of *'failure'*, *'guilt',* and overwhelming discomfort. The physiotherapist reflected:

"…You keep going in this horrendous, invasive awful situation and I think it feels like a lot, a lot more of a failure in some cases." [S2I06]

While a nurse stated:

"I think it's horrific. I think it's horrific because it just it feels cruel. Especially when you can see that the patients agitated like you're just keeping them alive." [S2I09]

One doctor felt moral injuries represented hidden burdens which remained unaddressed:

"…So, from time to time, people dying on the intensive care unit cause some degree of moral injury to the staff, which isn't well monitored, recognised or captured." [S2I03]

Here, failure to measure, address or mitigate moral injury was perceived to impact rates of burnout, depression and post-traumatic stress disorder. The doctor specifically reflected how the COVID-19 pandemic had exposed healthcare professionals to moral injury from prolonged periods of providing EoLC with limited interventions and restricted family visiting, resulting in post-traumatic stress:

"…One or two just find that they couldn't cope with the situation and walked out and umm so they, you know, critical care undoubtedly causes some degree of moral injury." [S2I03]

Whilst the COVID-19 pandemic created a unique set of circumstances, outcomes capturing symptoms of post-traumatic stress disorder (PTSD) were considered vital for understanding the long-term psychological and occupational consequences of providing EoLC by five participants. The multifaceted impact of PTSD was considered far-reaching, from emotional exhaustion and impaired interpersonal functioning (compassion-fatigue, burnout) to absenteeism, negatively affecting not only the individual and the organisation as a whole:

"I remember having one that stuck with me for years and years. I remember the day like it was yesterday." [S2I08]

"One or two of them really struggled with um flashbacks and post traumatic stress disorder afterwards and we did our best to get them counselling and and psychological interventions afterwards, which helped…" [S2I03]

4.9.8 Resource use

Including outcomes that encapsulated the financial costs of providing EoLC was controversial. Two participants considered that quantifying the costs enabled the evaluation of organisational effectiveness. In this context, costs were direct, attributable to the provision of physical resources such as equipment, ICU bed use, or transferring patients home to die. Perspectives were shaped by the professional role the participant occupied within the healthcare system. For instance, one nurse commented:

"Management normally look at the financial side other than the other outcomes." [S2I01]

While the physiotherapist surmised:

"I'm more aware of the discharge process and how complex that is and the funding and the forms you have to fill in the arguments you have to have and yeah." [S2I06]

Exclusively focusing on direct tangible costs perplexed one participant, who considered outcomes relating to such costs *'too narrow'* and restrictive. Instead, it was suggested that indirect costs should be measured, such as the economic consequences of absenteeism caused by the emotional and psychological sequelae of providing EoLC:

"Also staff need not working so it cost the money ... they have a traumatising and they need to give an extra day." [S2I01].

The significance of outcomes measuring ICU and hospital length of stay was raised by a small subset of participants. Similar to financial outcomes, opinions were divided. Hospital stay was considered by two doctors to be broad and generic, useful for organisational and financial management. In contrast, one nurse and physiotherapist described how ICU length of stay was more useful on a micro level, facilitating a more nuanced understanding of how demographics, care models and management influenced the patient's ICU length of stay whilst allowing comparisons within and across critical care specialities and regions;

"I've seen this before. When you look at how long people have spent in ITU before they die and the differences between different centres is really interesting." [S2I06]

Location of death was considered a critical component of person-centred care, reflecting an individual's preferences, values and beliefs; yet resource constraints, coupled with a patient's clinical complexity, greatly impacted the patient's location of death, challenging participants' ability to provide person-centred EoLC. One nurse reflected:

"There are some people who just have to die in ITU. And I think sometimes they see that as a failure and that kind of death in a hospital setting maybe isn't the right place to die." [S2I04]

Whilst a doctor stated:

"I'd like to live in a world where we were able to acknowledge dying sooner and move people home for death at home. We have done that once … where we have moved people home, still receiving critical care interventions and then remove those interventions at home with them dying shortly afterwards." [S2I03]

Physical resource limitations, such as inadequate side rooms, hospice beds, and the distance to hospice facilities, not only constrained the choice of location of death but also affected the quality of care and care satisfaction. Critical care bed shortages could result in rushed transitions at crucial time points, undermining person-centred care and creating family distress:

"If somebody is put on end-of-life care, we don't try to move them from critical care to the wards in the middle of the dying process unless there's an absolute need of a bed." [S2FG08]

"So, you know, quite often there is a push for beds, and if you've got a patient that's in A&E that needs an ICU bed, then it's automatically a swap. As in, right, this patient can go to the ward. Quite often, there is a push for bed." [S2I08]

Deaths accompanied by aggressive medical interventions and being surrounded by advanced life-support equipment were perceived by all participants to contribute to the

medicalisation of death, depersonalising the dying process and undermining person-centred care:

> *"We've made dying into a medical problem, and I don't think necessarily it should be in all cases."* [S2I05]

> *"Sometimes they'll switch it off to the non monitoring mode, but in a way it's just so technical focused that some relatives have found it quite difficult to to to having these monitors in the room."* [S2I13]

Mortality outcomes were considered relevant by only one participant, facilitating comparative analysis of a specific patient cohort and providing insights into resource use and performance metrics reported by NHS trusts. Challenges with such outcomes were, however, not limited to cofounding variables, such as age, surgical intervention, but also the clinician's ability to accept reality:

> *"And sometimes for example if I have a patient who was operated on a few days ago, like some of the surgeons they don't accept that this patient is end-of-life care because it comes into their 30 day mortality."* [S2FG07]

4.9.9 Outcomes used

Constant comparative analysis revealed that whilst five participants were aware of the National Audit of Care at the End of Life (NACEL), only two were aware of the Intensive Care National Audit & Research Centre Case Mix Programme (ICNARC CMP). NACEL and the ICNARC CMP differ fundamentally in their focus, population, and methodologies. Using case note review and surveys, NACEL evaluates the quality of EoLC care during the final hospital admission, including all patient deaths (National Audit of Care at the End of Life, 2025). In contrast, the ICNARC CMP provides quantitative, risk-adjusted clinical data specifically on ICU admission (ICNARC, 2025). Audit, however, fundamentally measures compliance and adherence rather than outcomes. Only one participant recalled an ICNARC outcome (ICU length of stay) being specifically used in their critical care units, thereby obscuring opportunities to assess the effectiveness, efficiency, or equity of EoLC. One participant stated:

> *"The intensive care unit where I work currently aren't measuring any of this stuff, and in fact, none of the intensive care units I've worked on are measuring any outcomes in relation to patient experience."* [S2FG02]

While another stated:

> *"It's something that we should be doing and we're not right now because of umpteen other competing priorities."* [S2FG05]

This evaluative vacuum could perpetuate variations in practice, widening the gap between actual practice and evidence-based improvements and delaying the translation of research findings into practice. One participant attempted to rationalise why outcomes weren't used:

> *"Maybe it's because it's perceived that the outcome is always going to be they died. It's like yes, they they do die. But could we have? And that's not necessarily what we should be measuring. It's the experience of the process of dying, but could we improve it?* [S2I05]

Structured reviews were used by one participant's organisation, encompassing a systematic note review. Such reviews facilitated the identification of problems in care, determining whether these problems were avoidable, contributing to death, and extracting lessons to improve future care, but did not capture specific outcome measures. Similarly, five participants spoke of complaints-based evaluations, yet complaints reflect dissatisfaction rather than objective outcome measures.

4.10 Discussion

Stage Two identified 175 outcomes for evaluating EoLC in critical care. Eight interconnecting outcome themes emerged, capturing the importance of a holistic approach at EoLC, where communication, decision-making, and professional competency contribute to high-quality patient and family-centred care, while care satisfaction and family impact underscore the need to include outcomes that measure physical, emotional, social, and spiritual constructs. Narratives revealed how EoLC impacts all those involved: patients, family members and professionals.

Communication acts as a foundation, directly impacting patient, family, and healthcare professional satisfaction with care while facilitating understanding and decision-making. The need for healthcare professionals to demonstrate professional competencies extends through interpersonal and clinical skills to influence how families understand and cope with their loved one being at the end-of-life. Resource use and staff burden are intimately connected and linked to unnecessary treatments, which impact family members. Being patient and family-centred should be at the heart of all EoLC, recognising the significance of a holistic needs assessment, individualised care plans and allowing family members to be present and involved at the end of the patient's life.

Fifty-one outcomes correlated with those previously reported in the systematic review; however, a disjuncture between research and health professionals' priorities is evident, as 124 outcomes were not captured in the systematic review. Outcomes identified in the systematic review were dominated by broad, quantifiable measures, whereas the novel outcomes identified here are granular and reflect the complexity of EoLC. The granular decomposition of symptomology was particularly evident in the discrete constructs. For example, Stage One only identified *'respiratory comfort'*, whereas participants spoke of outcomes capturing changes in respiratory rate, dyspnoea, respiratory secretions volume and consistency, together with accessory muscle use. Such granularity was considered meaningful to participants, enabling not only the evaluation of symptom severity but also functional ability. These subtle variations allow a more precise understanding of the construct under evaluation, capturing meaningful changes that broad outcomes might miss.

Similarly, thirst and hunger also represented new outcomes not identified during Stage One. Interventional studies have previously targeted thirst and dry mouth via bedside bundles (oral swabs, sprays, mouthwash, ice-controlled provision of small amounts of water or lip moisturisers) (Hammond et al., 2023). Studies, however, have predominantly included individuals who are not critically ill, whilst those including critical care patients have excluded those receiving EoLC, relying on patients' rating symptom severity using numeric rating scales (Hammond et al., 2023; Puntillo et al., 2014).

Including healthcare professionals in Stage Two of the study provided a different lens than originally planned, reducing precision but broadening the scope of stakeholders included in the qualitative element. Whilst this move reflects the pragmatic realities of conducting

EoLC research in hard-to-reach populations (Stelzer et al., 2020), it enabled novel person-centred outcomes to emerge. Dignity, privacy, and expectation management, for example, were considered important outcomes, yet none were reported in any of the studies included in the systematic review. This could be attributed to construct complexity, subjectivity and/or the absence of validated OMIs in the EoL critical care population. The findings support the need to develop a range of OMIs and a current research gap.

Family outcomes such as psychological well-being, anxiety, depression and grief were captured in the systematic review, but a health professional lens illuminated that these should be measured among health professionals rather than isolated to family members, recognising that supporting all those involved in EoLC enhances EoLC. Furthermore, the McCormack & McCance, (2021) framework conflates staff prerequisites, such as professional competence, with person-centredness (Santana et al., 2018) demonstrating how neglecting professional needs diminishes quality care, rendering professional wellbeing pivotal rather than peripheral to person-centred outcomes.

At this stage of the study, it is not known if this is congruent, distinct or complementary to the perspectives of family members. Whilst the professional lens generated outcomes that were congruent with outcomes found during Stage One, it enabled the identification of a number of novel outcomes.

Analysis of their narratives demonstrates how including experiential knowledge can aid the development of contextually grounded outcomes. While nurses have a pivotal role in providing EoLC (Pattison & Humphreys, 2025) all professions (doctors, nurses and a physiotherapist) spoke of their individual involvement in the emotional and relational dynamics that define person-centredness. This qualitative approach diverges from the quantitative findings in Stage One, exploring more nuanced person-centred outcomes, facilitating a more granular understanding of the context of EoLC and it's significance in the development of a COS.

The outcomes generated throughout Stage Two have important implications for developing the COS. The range of outcomes identified clearly reflects the nuanced nature of EoLC in critical care, suggesting that future EoLC evaluations should include outcomes beyond those identified in Stage One of the study, encompassing experiential, relational, and systematic dimensions of care. This signifies that the COS should capture not only

clinical effectiveness (symptom management) but also patient, family and staff experiences (eg care satisfaction, communication, decision-making) together with family and staff wellbeing outcomes (eg professional competency, staff burden and resource use).

4.11 Strengths

Transparent, robust methodological reporting is evident throughout the study. Methods were established *a priori* and subjected to a robust peer-review process at the UK Critical Care Research Group (UKCCRG). Data triangulation was achieved through the integration of individual interviews and focus groups, with negative cases presented as examples.

Within both focus groups, there was a prior professional acquaintance between two participants and members of the research team. One participant was known to the researcher, while another was known to a focus group lead (NP). To mitigate these challenges and any potential bias, all data were handled in accordance with the study protocol to enhance consistency, whilst findings and reflections were discussed with another member of the study team (RG) to ensure transparency. Although literature predominantly focuses on the risks of participant-researcher relationships (Creamer, 2022; Holloway & Galvin, 2024; Silverman, 2017), being an *'insider researcher'* was advantageous, expediting rapport formation, allowing quicker, deeper exploration of sensitive topics and contextual understanding (Aburn et al., 2021; McConnell-Henry et al., 2010).

4.12 Limitations

Stage Two of the PEACE-COS provided valuable insights into health professionals' perceptions of important outcomes in EoLC in critical care, but several limitations should be considered. Whilst local and national community groups actively engaged in study promotion, there were no support groups specific to critical care bereavement, and all acknowledged they were unable to ascertain their population's exposure to critical care. Automated restrictions implemented by Facebook prevented the creation of a study-specific Facebook page to share study-related content, misclassified discussions in other groups as violating community standards, removed recruitment posts, and reduced study visibility. No NHS site was able to recruit any family members, and interest generated

through social media or charities did not translate to recruitment. Subsequently, the family's voice was not heard at this stage of the study and may not be congruent with the healthcare professional's voice, limiting the external validity and generalisability of the findings. Stage Three incorporates family member and patient survivor perspectives to mitigate this constraint; however, Remus et al., (2021) suggests that if patients are included in the Delphi survey and the consensus meeting, including them in the indication-outcome identification stage is redundant.

Compared to in-person recruitment, online recruitment, such as social media, can be perceived as distant and disengaging, with limited opportunities to maintain or build trusting relationships (Iflaifel et al., 2024). Whilst this is seen as advantageous for those who may have difficulty interacting in public, it could have been a limitation for a subset of family members with complicated grief, where an in-person approach could have provided greater security, interaction and support to the individual (Iflaifel et al., 2024).

The inability to secure NIHR portfolio adoption and the six-month delay in communicating this to the researcher impacted NHS site participation. The NIHR activity-based funding structure meant that the majority of sites approached were unable to provide infrastructure support for non-portfolio research. Of the sites that opened to recruitment, one was reliant on bank staff working sporadically, making it challenging to maintain relationships. Requests for study updates went unanswered, and the site was unable to maintain records of the number of potential participants approached, thereby deviating from the study protocol. Staff changes within the clinical teams also meant that neither of the NHS sites which opened to recruitment were able to sustain their critical care bereavement support services in place at the start of the study, and potential participant contacts were obsolete.

Another limitation was the relative homogeneity of the sample, which was predominantly White (English/Welsh/Scottish/Northern Irish/British) in origin and female. This gender disparity, however, reflects the demographics of the UK nursing and palliative medicine workforces (Association of Palliative Medicine of Great Britain and Ireland, 2019; Royal College of Nursing, 2023). Although participants were geographically dispersed within England, the critical care practices may not be representative of those in other countries,

healthcare systems, and cultures. To mitigate this, Stage Three includes an international sample.

4.13 Conclusion

To the researcher's knowledge, this is the first study to explore what outcomes health professionals consider important to include in a COS on EoLC in critical care. Conducting in-depth interviews allowed the exploration of participants' EoLC lived experience, generating rich qualitative data that captured not only outcomes in contemporary practice but also how providing EoLC feels, what it means to individuals, and how they interpret their experiences in terms of outcomes of importance. Stage Two of the COS development has facilitated an understanding of the complexity and relational dynamics of an extensive range of outcomes and constructs. It contributes to the growing literature on the importance of core outcome sets and the language used to convey these outcomes. The credibility and depth of the data were increased through probing, clarifying, and creating space for participant narratives, enhancing both the validity and the nuance of the outcomes.

4.14 Next chapter

Chapter five outlines how the outcomes identified during Stages One and Two of the study were reviewed and, where relevant, combined to develop a comprehensive outcome list for prioritisation.

Chapter 5: An International eDelphi study

5.1 Abstract

***Objectives*:** To identify and achieve consensus on outcomes considered critical for inclusion in a COS for research evaluating EoLC in critical care, exploring participants' reasons for score selection and changes in subsequent rounds.

Design: A two-round modified e-Delphi study was conducted where panellists rated the importance of outcomes for inclusion on a 9-point Likert scale. Consensus for inclusion was defined *a priori* as an outcomes scoring >70% 'critical' and less than 15% 'not important'. Framework analysis was employed to systematically organise and interpret qualitative comments to identify key themes.

***Participants*:** Eighty-four panel members representing three stakeholder groups: patient/family members, health professionals and researchers located in ten countries within five continents participated.

Setting: International

Results: Participants scored 93 outcomes in Round One and 69 outcomes in Round Two. One new outcome suggested in Round One was included in Round Two. Consensus was achieved on the inclusion of 27 outcomes. Reasons an outcome was considered either critical or not critical for inclusion were attributed to 14 themes. Ten themes and 29 subthemes emerged from the reasons provided for score alterations between rounds, with the most common reasons being *'human consequences'* and *'importance'*.

Conclusion: The outcomes identified will inform the COS, whilst the reasons for score selection and changes in subsequent rounds, enhance the methodological advancement of Delphi research. A consensus meeting is required to refine and ratify the final set of outcomes.

Public Researcher Partners Contribution: Study design, public-facing study documents, participant engagement resources, piloting, analysis and presentation of findings.

5.2 Introduction

Chapters Three and Four outline how, through a systematic review and qualitative study, an extensive list of potentially important and meaningful outcomes were generated to inform the development of a COS for EoLC in critical care. Chapter Five builds on the findings from previous chapters, presenting Stage Three of the COS development, an international eDelphi study.

5.3 Methods

5.3.1 Research question

Which person-centred outcomes do patients, family members, researchers, and healthcare professionals think should be included in a core outcome set for EoLC in critical care?

5.3.2 The modified eDelphi technique

Informed by current recommendations of standards for developing a COS, a two-round modified international electronic Delphi (eDelphi) study was undertaken to reduce the list of unique outcomes and to achieve consensus on the draft outcomes for inclusion in the COS (Kirkham et al., 2017; Williamson et al., 2017).

The modified eDelphi technique is an iterative, multi-stage process whereby a series of structured questionnaires (rounds) are administered to key stakeholders using an electronic online platform (Niederberger & Renn, 2023). In contrast to the Classical Delphi technique, Round One in the modified technique did not exclusively generate outcomes of potential importance through open-ended questions (Niederberger & Renn, 2023). Instead, Round One involved predefined outcomes identified through the systematic review in Stage One and interviews/focus groups in Stage Two. Whilst the inherent four Classical Delphi traits of anonymity, iteration, controlled feedback and statistical group response (Hsu & Sandfords, 2007) remain, this modification reflects fundamental epistemological differences. The Classical Delphi technique seeks exploration and interpretation underpinned by constructivism (Niederberger & Renn, 2023) whereas the modified technique in COS development prioritises standardisation, comparability and utility (Williamson et al., 2017), reflecting a more pragmatic stance that balances stakeholder perspectives (associated with constructivism) with existing empirical knowledge, and statistical analysis of quantitative data (associated with post-positivism). The modified

technique, therefore, provided a transparent and reproducible mechanism for achieving consensus rather than a tool for knowledge discovery. It has been effectively used in previous critical care COS development (Blackwood et al., 2019; Connolly et al., 2024; Freeman-Sanderson et al., 2024) and to achieve consensus on the principles of EoLC in the critically ill (Sprung et al., 2014).

The online nature enabled a larger panel of geographically dispersed stakeholders to participate than would traditionally be feasible in studies using classical postal techniques (Shang, 2023), facilitating the international development of the COS and, consequently, its global relevance. Furthermore, it afforded panellists greater convenience to participate, overcoming time zone disparities and increasing efficiency (Hasson et al., 2025).

5.4 Stakeholder panel

Using a multi-modal strategy (**Figure 5.1)** employing a combination of purposeful and snowball sampling, participants were invited to participate in three stakeholder groups: 1) patients/family members, 2) health professionals and 3) researchers in line with the consensus-based recommendations for COS development (Kirkham et al., 2017; Williamson et al., 2017).

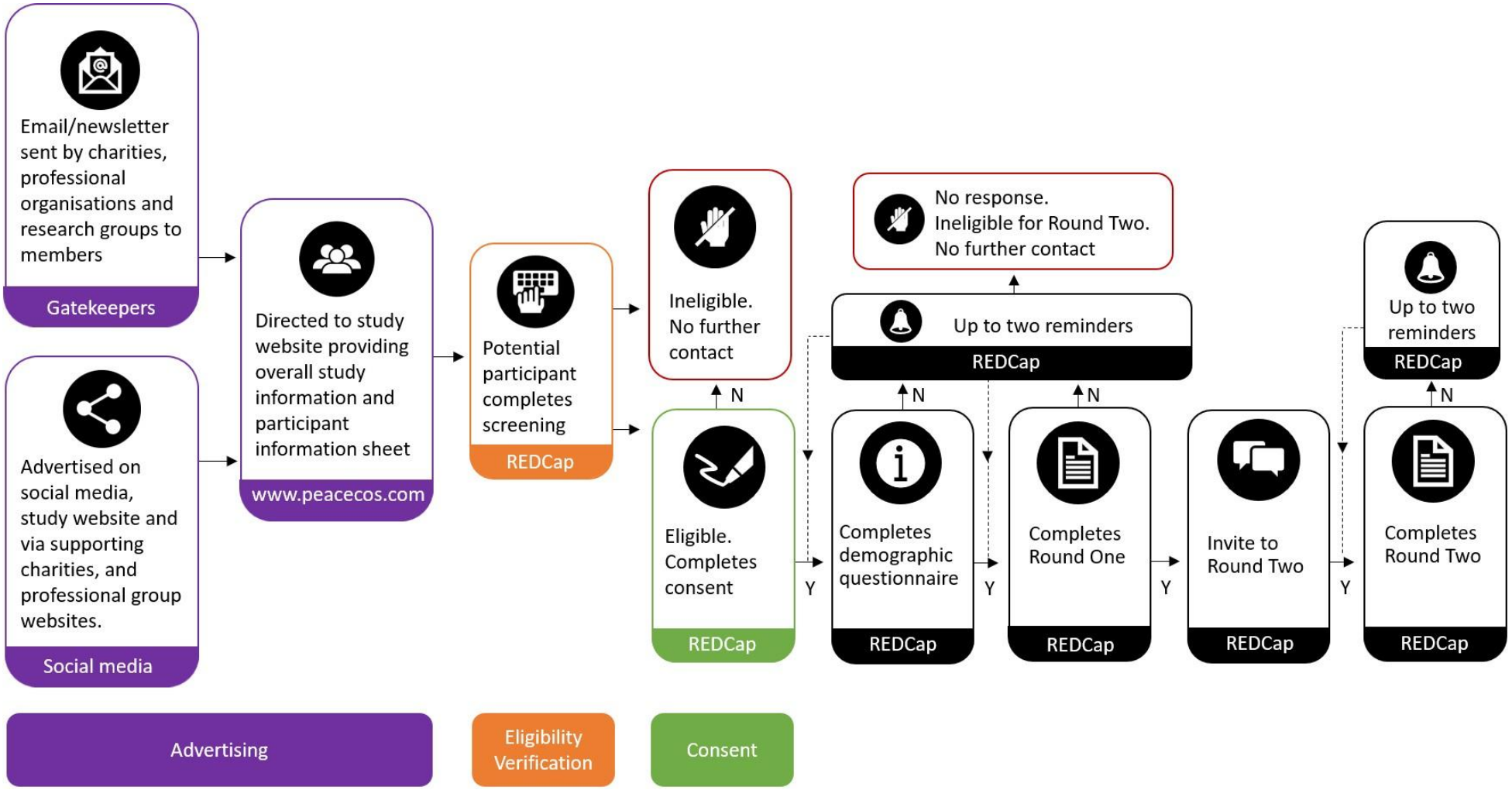


Figure 5.1 Sample identification and recruitment process

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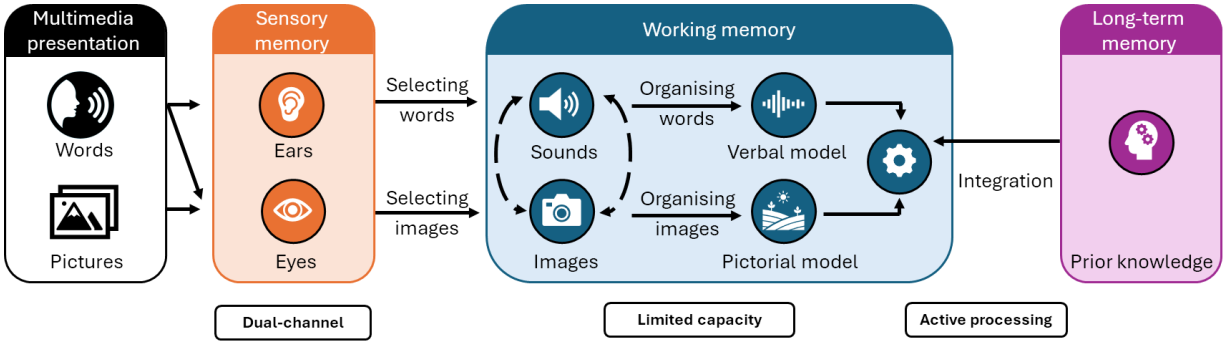
Organisations relevant to each stakeholder group were identified through existing international and national critical care contacts, networks, and web-based searches. Primary contacts within each organisation were emailed a plain English recruitment invitation to disseminate to their members, containing embedded hyperlinks to the participant information sheet on the study website (**Appendix 46**), the recruitment animation, and the questionnaires. Resources developed by the COMET initiative were utilised with participant engagement resources collaboratively developed with public researcher partners and underpinned by the Participant Information Quality Standards (Health Research Authority, 2024).

In recognition that recruitment could be challenging, freely accessible public-facing social media platforms such as Bluesky, X, YouTube, Threads, LinkedIn and Facebook pages were also used to advertise the study (**Appendix 47**). Compared to restricted-access platforms, public-facing social media platforms facilitate rapid dissemination of study information, simultaneously increasing visibility and enabling researchers to reach diverse and often hard-to-reach populations (Darko et al., 2022; Gelinas et al., 2018). Study-specific social media accounts enhanced researcher transparency with separate stakeholder Quick Response (QR) codes permitting granular analysis of recruitment processes. No incentives for study participation were offered.

Emerging literature demonstrates that, in contrast to standard research material (written information and brochures), study-specific animations with voice-over are more effective at explaining research concepts while increasing intention to participate (Morgan et al., 2020; Occa & Morgan, 2019). A systematic review found 73% of studies reported statistically significant improvements in health information recall when using animation videos (Hansen et al., 2024) whilst a meta-analysis demonstrated knowledge acquisition remained consistent across participant demographic variables such as age and sex (Feeley et al., 2023). These findings indicate how animations can provide powerful, engaging and accessible means of promoting research studies across diverse populations.

Dual-Coding Theory (DCT) posits that verbal and visual information is processed differently, while Cognitive Load Theory suggests people possess a finite capacity for information, and Active Learning occurs when pertinent information is processed and

connected to previous learning (Mayer, 2024; Mayer et al., 2001). Underpinned by elements of the DCT, Cognitive Theory of Multimedia Learning (CTML) and Cognitive-Affective Theory of Multimedia Learning (CATML) (**Figure 5.2**) an animation was developed in consultation with public research partners.



Adapted from Mayer et al., 2001, p. 190

Figure 5.2 Cognitive theory of multimedia learning

The animation was pre-tested with a subset of ICU survivors, family members, researchers and health professionals to assess comprehension of the visual metaphors, animation speed, and length. Narration was colloquial to support the personalisation principle (Mayer, 2024). To maximise reach and engagement, multiplatform distribution strategies were employed, encompassing YouTube hosting.

Researchers were recruited through the End-of-Life in Critical Care Network (EPCIN), the Groupe de Recherche Famirea (FAMIREA) and the UK Critical Care Research Group (UKCCRG). Personal invites were also sent to corresponding and senior authors identified in the systematic review during Stage One of the study. Health professionals were recruited from professional organisations and societies relevant to critical care, such as the Intensive Care Society (ICS), the Faculty of Intensive Care Medicine (FICM), the British Association of Critical Care Nurses (BACCN), and the American Association of Critical Care Nurses. Patient survivors/family members were recruited through support groups, and charities such as the Brain Tumour Charity, ICU Steps, and Sepsis Trust UK. All organisations were also invited to display posters directing interested potential participants to the study website for further information (**Appendix 48**).

Inclusion criteria were: adults aged 18 years or older with internet access and an email address who were willing to participate in all rounds of the eDelphi. For pragmatic reasons, all participants required sufficient English-language proficiency (to read and understand the study information and questionnaires). Consistent with established Delphi methodology, an expert was determined based on relevant EoL knowledge or experience as outlined in **Table 5.1**. No specific exclusion criteria beyond those derived from the inclusion criteria were applied. No members of the steering group participated in the actual eDelphi to avoid potential bias.

5.4.1 Group size

Despite the increasing use of eDelphi studies, no standard method for determining the modified sample size is suggested, and the sample size is not determined by statistical power (Nasa et al., 2021; Williamson et al., 2017). Instead, a pragmatic approach was adopted, influenced by the scope of the COS, access to participants and their willingness to participate, together with the resources available for data analysis. The study aimed to recruit 15 participants per stakeholder group based on previous COS studies and guidelines presented in **Chapter Two** (Williamson et al., 2017). No limits were placed on the number of participants who could register to complete the eDelphi, but recruitment closed after Round One was completed.

Table 5.1 Stakeholder inclusion criteria

Group	Stakeholder	Inclusion criteria
1	Researchers	All researchers actively conducting research in critical care or EoL related fields who have published (listed as an author) within the last 5 years.
2	Family*	• Had direct experience of an adult (>18 years) family member die in critical care within the last 10 years and have recollection of the EoL process or had a family member receive EoLC in critical care within the last 10 years and have recollection of the EoLC process. • Not involved in any ongoing complaint or litigation processes.
	Patients	Patients who within the last 10 years have recovered from critical care but had a limited chance of survival whilst in critical care.
3	Healthcare professionals and Spiritual/Religious Leaders	All experienced healthcare professionals (including all members of the multi-disciplinary team) with at least 1 year postgraduate experience of which at least 1 year has been in critical care involved in the provision of EoLC to patients or their families. This includes but is not limited to: ► Clinicians ► Nurses ► Microbiologists ► Advanced Critical Care Practitioners ► Allied Health Professionals ► Radiologists/Radiographers ► Pathologists ► Pharmacists

*Family members are defined inclusively as a relative or other friend with whom the patient had a close or intimate relationship (Faculty of Intensive Care Medicine, 2019)

5.5 Ethical considerations

Prior to commencing the eDelphi ethical approval from the HRA and Health and Care Research Wales (HCRW) (23/NE/0057) and continuation of Sponsorship/ethical approval from the University of Hertfordshire Health, Science, Engineering and Technology Committee (HSK/PGR/NHS/02993, 0890 2025 Apr HSET) was obtained as detailed in **Chapter 2 2.4**.

5.5.1 *Consent*

The opening page of the eDelphi webpage provided a brief overview of the study, highlighting the importance of participants completing all the rounds. Prior to consent, participants were provided with an opportunity to ask questions and attest that they met the study criteria (**Appendix 49**).

Before commencing the first round of the eDelphi, participants were explicitly required to provide informed e-consent via REDCap (**Appendix 50**). It included a consensual agreement to publish anonymised data and non-identifiable data results, to receive copies of study publications and willingness to participate in a consensus meeting. Participants were informed that personal data relating to the study would be kept strictly confidential and not made publicly available. Participants could save a copy of their consent form. For Round Two, completion and submission of the questionnaire was considered implied informed consent. Due to the sensitive nature of EoLC, participants were also directed to appropriate support services.

5.5.2 Study Setting

Online Surveys is a cloud-based web-based GDPR-compliant application designed for academic and public sector research institutions to facilitate longitudinal data (Jisc, 2025). Accessed through a UH subscription, it enables researchers to develop, distribute and analyse questionnaires without requiring advanced technical expertise, making it particularly accessible to novice researchers. Online Surveys was primarily selected for its cost-effectiveness, secure data storage, and configurable anonymisation options; however, a change in the licensing agreement and the availability of versions rendered the application unusable between the study protocol being written and data collection. Alternative online applications, such as DelphiManager, Qualtrics, and SurveyMonkey,

were explored. The cost of purchasing and supporting Qualtrics was prohibitive, DelphiManager was in the process of being withdrawn, and SurveyMonkey did not meet the functionality required for longitudinal research or the University of Hertfordshire's governance requirements. A pragmatic decision and study amendment occurred to undertake all rounds of the eDelphi using Research Electronic Data Capture (REDCap), a secure, regulatory-compliant web application (Harris et al., 2009).

While Online Surveys and REDCap facilitate questionnaire creation and data collection, they differ in technical capabilities and intended uses. REDCap is deployed on the University of Hertfordshire's hardware server, placing greater emphasis on data security and encryption. Designed specifically for longitudinal research, granular control is provided over data access, roles and audit logs, with complex logic, advanced branching, and calculated fields facilitating extensive data validation (Harris et al., 2019). Offering Application Programming Interfaces (API), REDCap enables seamless data transfer and improves operational efficiency. Conversely, such advanced features require greater technical skills and knowledge, with limited training opportunities in the UK. Details of the development and configuration of REDCap are described further on in **section 5.7.**

5.6 Questionnaire development

All outcomes generated from Stage One and Two of the study were extensively examined by the steering committee during regular formulation and review sessions (**Figure 5.3**). Outcomes perceived to conceptually overlap with another outcome were removed or merged, whilst constructs were retained (**Table 5.2**) (Young et al., 2019). Where a range of terms were used for what appeared to be the same outcome, an attempt was made to provide one universal description. Where possible, clinical terms were explained in plain English to aid participants' understanding and reduce ambiguity. In conjunction with public research partners, wording and associated descriptions were reviewed for accuracy and clarity to reduce subjective biases and increase response variance (Markmann et al., 2021) (**Table 5.3**). The final list of outcomes was agreed by the steering committee, and outcomes were mapped to domains of the COMET taxonomy (Dodd et al., 2018). A larger number of both broad and granular outcomes were retained to capture the multidimensional, nuanced nature of EoLC and cover the full breadth of relevant constructs. Whilst Gargon et al., (2019) demonstrated a large number of outcomes in

Round One correlated with decreased response rates. This level of specificity was considered critical given the heterogeneity of critical care patients, diverse disease trajectories and the time-sensitive nature of EoLC.

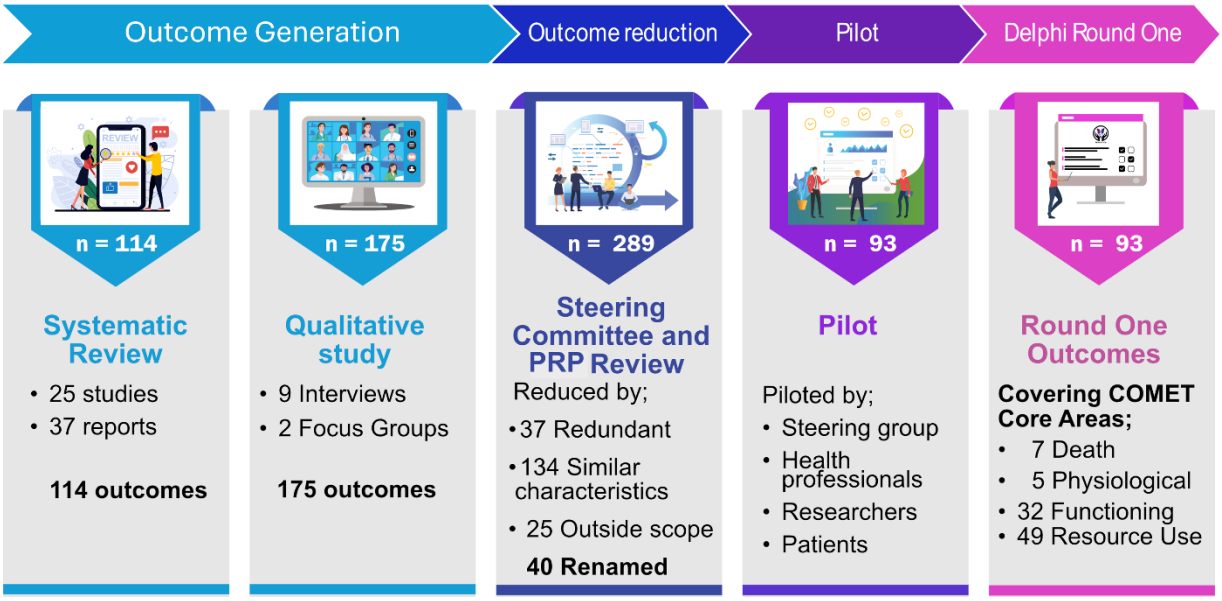


Figure 5.3 Round One outcome generation

Table 5.2 Outcome reduction for Round One

Outcome Domain	Outcomes identified			Outcome reduction				Round 1 N=93 (%)
	SR n=114 (%)	IFG n=175 (%)	Total N=289 (%)	R n=37 (%)	SC n=134 (%)	OoS n=25 (%)	Total N=196 (%)	
Death								
01: Mortality/Survival	8 (7.02)	3 (1.71)	11 (3.81)	3 (8.11)	1 (0.75)	-	4 (2.04)	7 (7.53)
Physiological/Clinical								
03: Cardiac	-	1 (0.57)	1 (0.35)	-	-	1 (4.00)	c	-
09: General	1 (0.88)	4 (2.29)	5 (1.73)	-	1 (0.75)	3 (12.00)	4 (2.04)	1 (1.08)
14: Metabolism and nutrition	-	5 (2.86)	5 (1.73)	-	3 (2.34)	-	3 (1.53)	2 (2.15)
22: Respiratory	1 (0.88)	4 (2.29)	5 (1.73)	-	2 (1.49)	1 (4.00)	3 (1.53)	2 (2.15)
Functioning								
25: Physical functioning	1 (0.88)	1 (0.57)	2 (0.69)	-	1 (0.75)	-	4 (2.04)	1 (1.08)
29: Cognitive functioning	1 (0.88)	12 (6.86)	13 (4.50)	1 (2.70)	9 (6.71)	-	10 (5.10)	3 (3.23)
30: Global quality of life	1 (0.88)	1 (0.57)	2 (0.69)	1 (2.70)	-	-	4 (2.04)	1 (1.08)
32: Delivery of care	34 (29.82)	89 (50.86)	123 (43)	14 (37.84)	75 (55.97)	7 (28.00)	96 (49)	27 (29)
Resource Use								
34: Economic	3 (2.63)	3 (1.71)	6 (2.07)	2 (5.41)	1 (0.75)	1 (4.00)	4 (2.04)	2 (2.15)
35: Hospital	11 (9.65)	3 (1.71)	14 (4.84)	4 (0.811)	1 (0.75)	3 (12.00)	8 (4.08)	6 (6.45)
36: Need for further intervention	21 (18.42)	21 (12.00)	42 (14.53)	7 (18.92)	8 (5.97)	9 (36.00)	24 (12.24)	18 (19.35)
37: Societal/carer burden	32 (28.07)	28 (16.00)	60 (20.76)	5 (13.51)	32 (24)	-	37 (18.88)	23 (24.73)

SR = Systematic Review; IFG = Interviews and Focus Groups; R = Redundant; SC = Similar Characteristics OoS = Out of Scope, - = 0

Table 5.3 Outcomes modified for Round One

Outcome Domain	Outcomes identified		
	Round 1 N=93 (%)	Renamed N=31 (%)	Description updated N=26 (%)
Death			
01: Mortality/Survival	7 (7.53)	-	-
Physiological/Clinical			
09: General	1 (1.08)	-	-
14: Metabolism and nutrition	2 (2.15)	1 (3.23)	1 (3.85)
22: Respiratory	2 (2.15)	-	-
Functioning			
25: Physical functioning	1 (1.08)	1 (3.23)	-
29: Cognitive functioning	3 (3.23)	1 (3.23)	2 (7.69)
30: Global quality of life	1 (1.08)	-	-
32: Delivery of care	27 (29.03)	12 (38.71)	9 (34.62)
Resource Use			
34: Economic	2 (2.15)	-	-
35: Hospital	6 (6.45)	2 (6.45)	2 (7.69)
36: Need for further intervention	18 (19.35)	4 (12.90)	3 (11.54)
37: Societal/carer burden	23 (24.73)	10 (32.26)	9 (34.62)

- = 0

5.7 Data collection methods

All data collection occurred within REDCap through a series of sequential questionnaires. Whilst examples in literature were found of organisations using REDcap for eDelphi studies, this was the first eDelphi study at the University of Hertfordshire to use the application. REDCap uses PHP + JavaScript programming (Harris et al., 2009) of which neither the researcher or steering committee had prior knowledge. Although the REDCap Consortium provides informational videos on the application and functionality, they reflected earlier software versions, were not in an accessible format, and access to the technical community platform is only open to REDCap administrators. The steering committee was therefore expanded to include the University REDCap administrator with the aim of providing additional technical support and expertise. External COS researchers were contacted for advice; however, all had subcontracted the design, development and implementation. Internet searchers and online forums provided initial pathways to gaining

knowledge not readily available; however, navigating and synthesising the fragmented components to enable a coherent understanding of REDCap delayed the implementation of the eDelphi.

5.7.1 Data validation

Within REDCap, validation features were created to ensure accurate, consistent, standardised data entry and collection, enhancing data integrity by reducing missing data or inconsistencies. It was the first study at the University of Hertfordshire to enable the Google reCAPTCHA (Completely Automated Public Turing test to tell Computers and Humans Apart) feature to enhance bot detection using audio CAPTCHA alternatives. Stop logic was used on the screening and consent questionnaires to stop progression if a potential participant indicated they did not meet the required criteria or did not consent to participate (**Figure 5.4**).

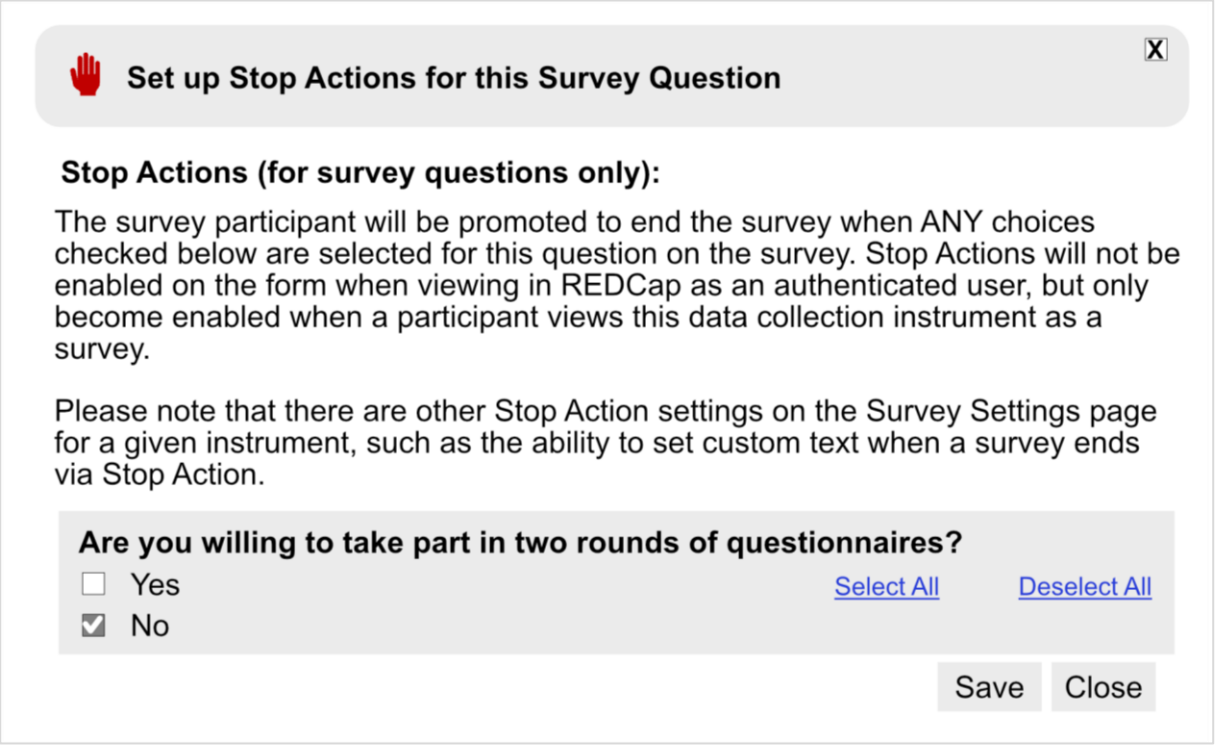


Figure 5.4 Example of stop logic employed

Advanced branching logic was employed using a combination of conditional and Boolean operators, with specific data entry fields only visible when the question was relevant to particular participants. For example, professional role (doctor, nurse, etc.) was irrelevant if the participant was participating in a patient/family member capacity (**Figure 5.5**) and details concerning accessibility needs were concealed unless a participant attested they

had an accessibility requirement. Participants received a personalised email invitation with wording based on data provided in prior questionnaires (piping), where data was incomplete, or to participate in Round Two.

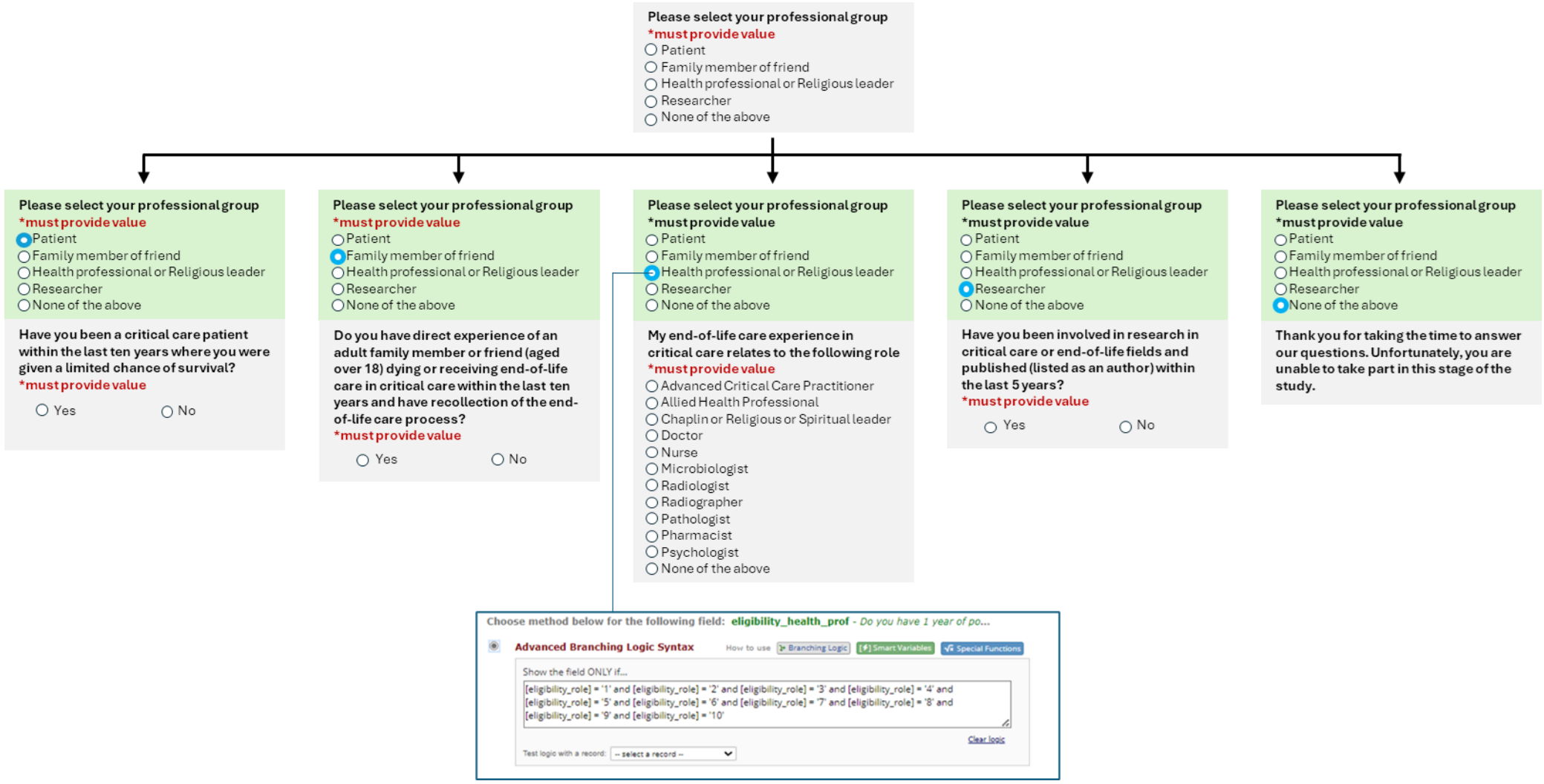


Figure 5.5 Example of how screening questions are presented depending on branching logic related to stakeholder group

5.7.2 Pilot

Prior to recruitment, a pilot was undertaken to assess the usability, face validity and acceptability of the screening, consent, demographics and Round One questionnaires with six people (two representing each stakeholder group) external to the steering committee. There was unanimous agreement that a minimalistic design incorporating descriptive pop-ups triggered by participants hovering over a linked word should be used to convey outcome descriptions and that embedding descriptions either in an additional table or external document looked *'cluttered',* requiring *'more effort'* by participants. Health professionals and researchers perceived the outcomes as self-explanatory, whereas patient/family members found the descriptors useful, facilitating understanding and reducing confusion. As a result, semantics and layouts were altered, with a further pilot undertaken by one member of the steering committee (RG).

5.8 Round One

Following consent and prior to commencing Round One demographic data (participant name, gender, age, country of residence, duration of clinical and/or research experience) and a corresponding email address were requested **(Appendix 51**). This information was used to characterise participants. Demographic data was stored separately with the participant's name and email address required to facilitate personalised communication for incomplete data and invitations to participate in Round Two. REDCap generated a unique study identifier for each participant linked to their survey responses, preserving anonymity. Participants were asked to identify their key stakeholder group (researcher, health professional, patient/family).

At the start of the round, participants were provided with instructions highlighting the overall aim of achieving consensus and how to complete the questionnaires (**Appendix 52**) (Hasson et al., 2000; Sinha et al., 2011). Recruitment was planned for 35 days but extended to 75 (01/10/2024 – 15/12/2024) at the request of external organisations to align with their membership communication timelines.

Participants were presented with a list of 93 outcomes grouped into domains according to the COMET taxonomy. To mitigate primacy and recency biases, outcomes were randomly listed within the specific domains (Hasson et al., 2000; Keeney et al., 2001). Given the sensitive constructs of EoL, randomisation was also imperative to minimise context effects

(Brookes et al., 2018). Outcome descriptions were displayed in descriptive pop-ups visible when participants hovered over the i icon.

5.8.1 Scoring

Using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) 9-point Likert scale where 1 represents the outcome of least importance and 9 represents the outcome of critical importance (Guyatt et al., 2011), participants were asked to rate the importance of each outcome for inclusion in the COS. To facilitate understanding, the GRADE scale was annotated showing that a score of 1 to 3 was interpreted as an outcome having 'limited importance', 4 to 6 as 'important but not critical' and 7 to 9 as 'critical'. A neutral option of 'unable to rate' was available, with participants asked to score a statement as such if they did not perceive themselves to have expertise/experience in that area. In addition to the list of outcomes provided, an optional open free-text response box was available per domain to elicit participant comments on the outcomes (**Figure 5.6**). Participants were encouraged to include any other outcomes or comments that they consider relevant in the free text responses.

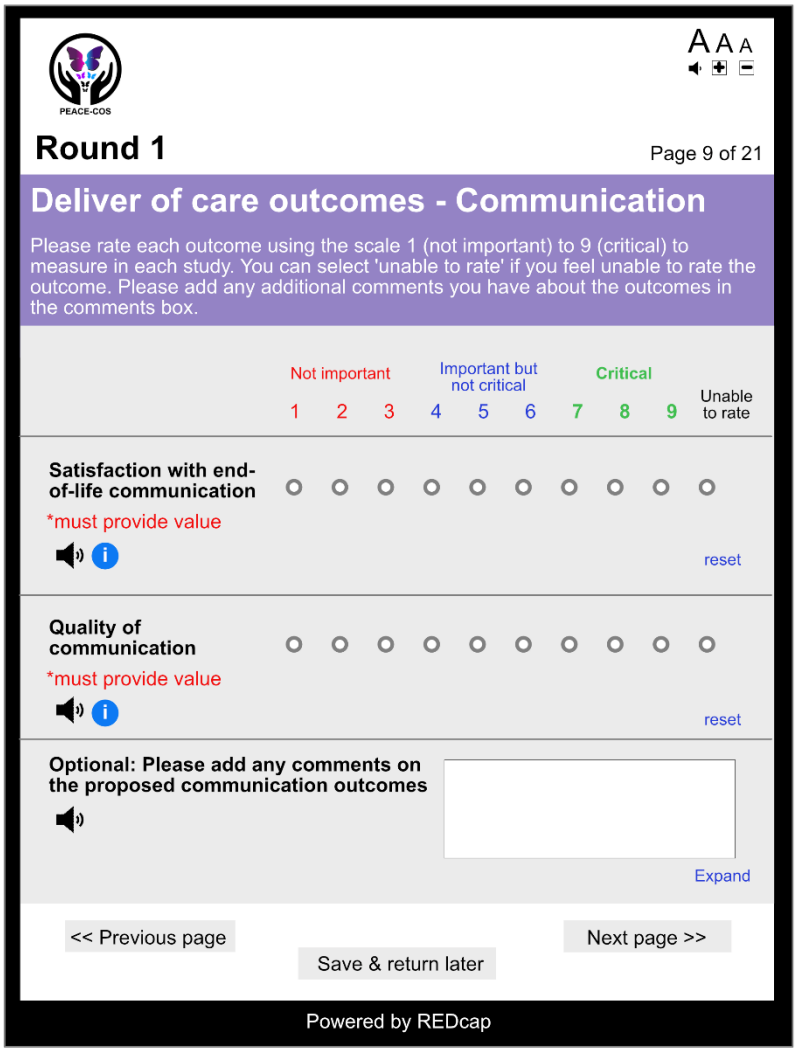


Figure 5.6 Example of Round One free-text box

5.9 Round Two

The primary aim of Round Two was to offer participants the opportunity to reconsider their responses from Round One, where consensus was not achieved, and consider new outcomes identified during Round One. Only outcomes where there was no consensus for inclusion or exclusion were presented to reduce participant burden and attrition and increase efficiency. New outcomes proposed during Round One were only included in Round Two where two or more participants had suggested the outcome. Where outcomes were suggested to be measured at different time points, these were not considered new or unique.

Round Two was open for 37 days (27/01/2025 – 05/03/2025). Participants were presented with the results and analysis of Round One responses with descriptive statistics (medians rounded to the nearest integer) and levels of dispersion (inter-quartile range) in relation to

the outcomes, their response and collective stakeholder opinion. The distribution of ratings stratified by stakeholder group was presented graphically to aid understanding **(Figure 5.7)**. Previous research beyond the scope of COS development has demonstrated that such methodological approaches simultaneously improve inter-participant agreement and response accuracy (Brookes et al., 2016). There is, however, no *'correct'* result in a COS (Williamson et al., 2017), meaning accuracy cannot be assessed and a paucity of evidence on how responses should be presented graphically in COS development.

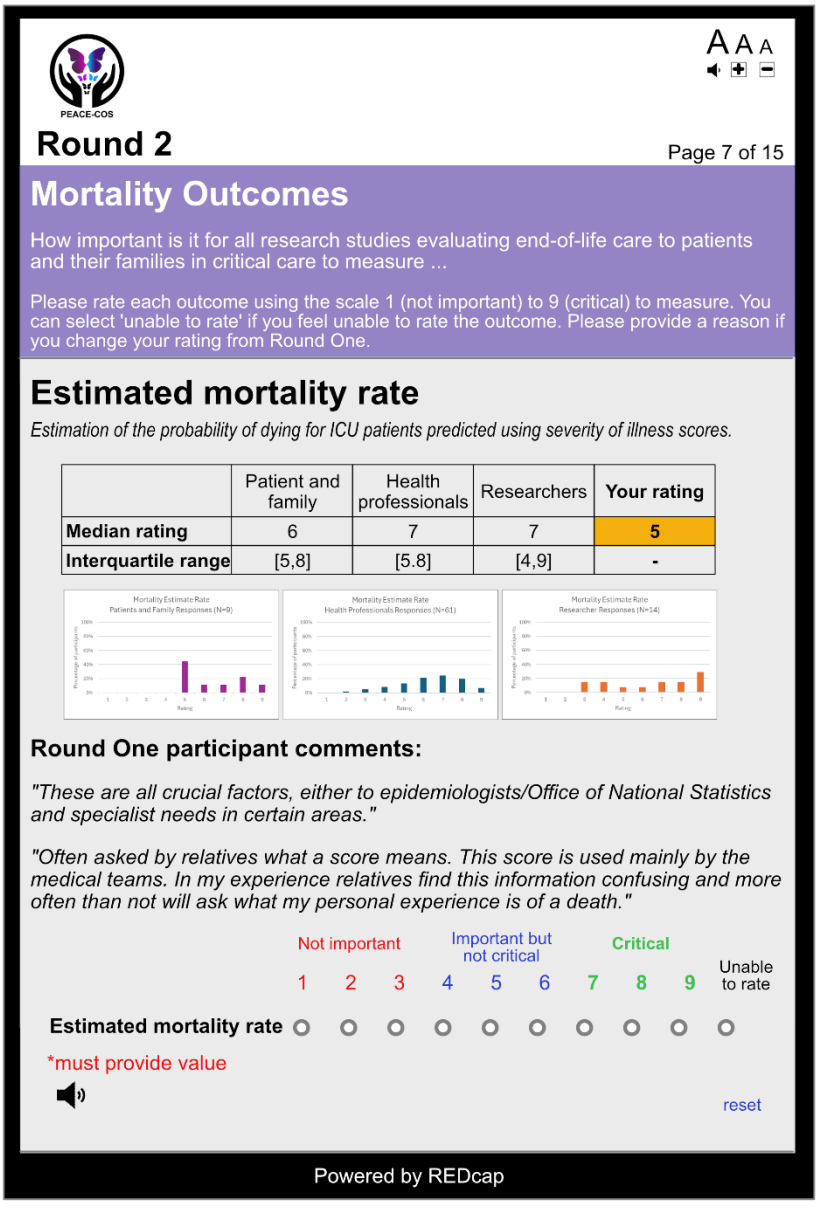


Figure 5.7 Example of Round Two outcome within the Mortality domain

Based on the free-text analysis from Round One, outcomes were revised. Changes to the outcome name were highlighted in red, while changes to the description were highlighted in bold to facilitate differentiation between Round One and Round Two for participants **(Figure 5.8).** Descriptive pop-ups were not used; descriptions were embedded under the outcome. This process provided a validation mechanism for semantic changes. Where relevant, illustrative quotes were provided, outlining stakeholders' opinions on why outcomes should or should not be included. Based on qualitative analysis of the comments in Round One.

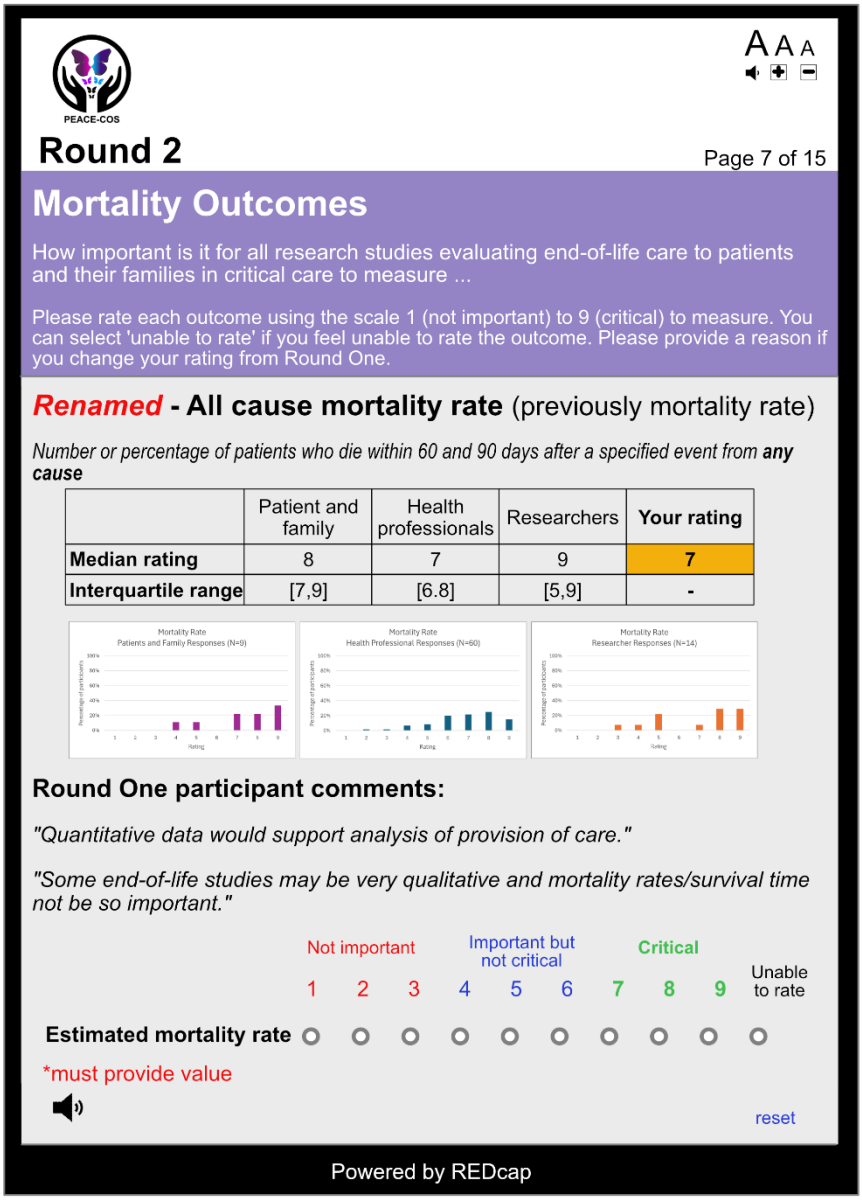


Figure 5.8 Example of changes to Round Two outcome and description

Reflecting on the results presented from Round One, participants were asked to review their responses to previous outcomes where consensus was not achieved, indicating their

priority rating for all presented outcomes via the same GRADE 9-point Likert scale used in Round One. Participants were explicitly asked to comment on reasons for amending scores in Round Two.

5.10 Data analysis

Following the completion of each round, data were downloaded from REDCap and imported into Excel, SPSS and Word. Data were included only in Round One, where participants completed it in its entirety; however, a steering committee decision was made to include all participants in Round Two to ensure that patient/family voices were heard. All data were self-reported and analysed according to the selected stakeholder group (researcher, health professional, patient/family member). At the end of each round, each outcome was either included or excluded according to the prespecified consensus criteria in **Table 5.4**.

Table 5.4 Consensus definition

Consensus Decision	Definition	Scoring
Consensus in	Outcome should be included in the COS	≥ 70% participants scoring 7 to 9 AND < 15% of participants scoring 1 to 3 in each stakeholder group
Consensus out	Outcome should be excluded in the COS	≤ 50% participants scoring 7 to 9 in each stakeholder group
No consensus	Uncertainty about importance of the outcome	Anything else not fitting criteria above for 'consensus in' or 'consensus out'.

5.10.1 Quantitative data analysis

Descriptive statistical analysis was undertaken to describe participant characteristics. In each round, for each outcome, the median score, the number, and the percentage proportion of each stakeholder group were calculated and compared using *a prior* consensus definitions (**Table 5.4**). As data was negatively skewed and not normally distributed, medians were computed to provide a robust measure of central tendency, minimising the impact of skewed values. 'Unable to rate' scores were excluded from median calculations. Further descriptive analysis of the characteristics of stakeholders commenting and not commenting per round was undertaken. Statistical significance was set at 0.05, and the Chi-squared test was applied.

5.10.2 Qualitative data analysis

To facilitate controlled feedback on specific outcomes for participants, free-text data analysis commenced immediately following the completion of Round One and in tandem with Round Two. A modified framework analysis was employed to organise qualitative data into thematic categories, enabling structured comparison of expert opinions and transparent identification of divergence (Ritchie & Spencer, 1994). Historically, framework analysis has comprised of seven stages: transcription; familiarisation; coding; developing a working analytical framework; applying the analytical framework; charting the data into the framework matrix; and interpreting the data (Gale et al., 2013; Ritchie & Spencer, 1994). Participants, however, entered data directly into REDCap, negating the need for transcription (**Figure 5.9**) and a coding framework based on the COMET taxonomy was created.

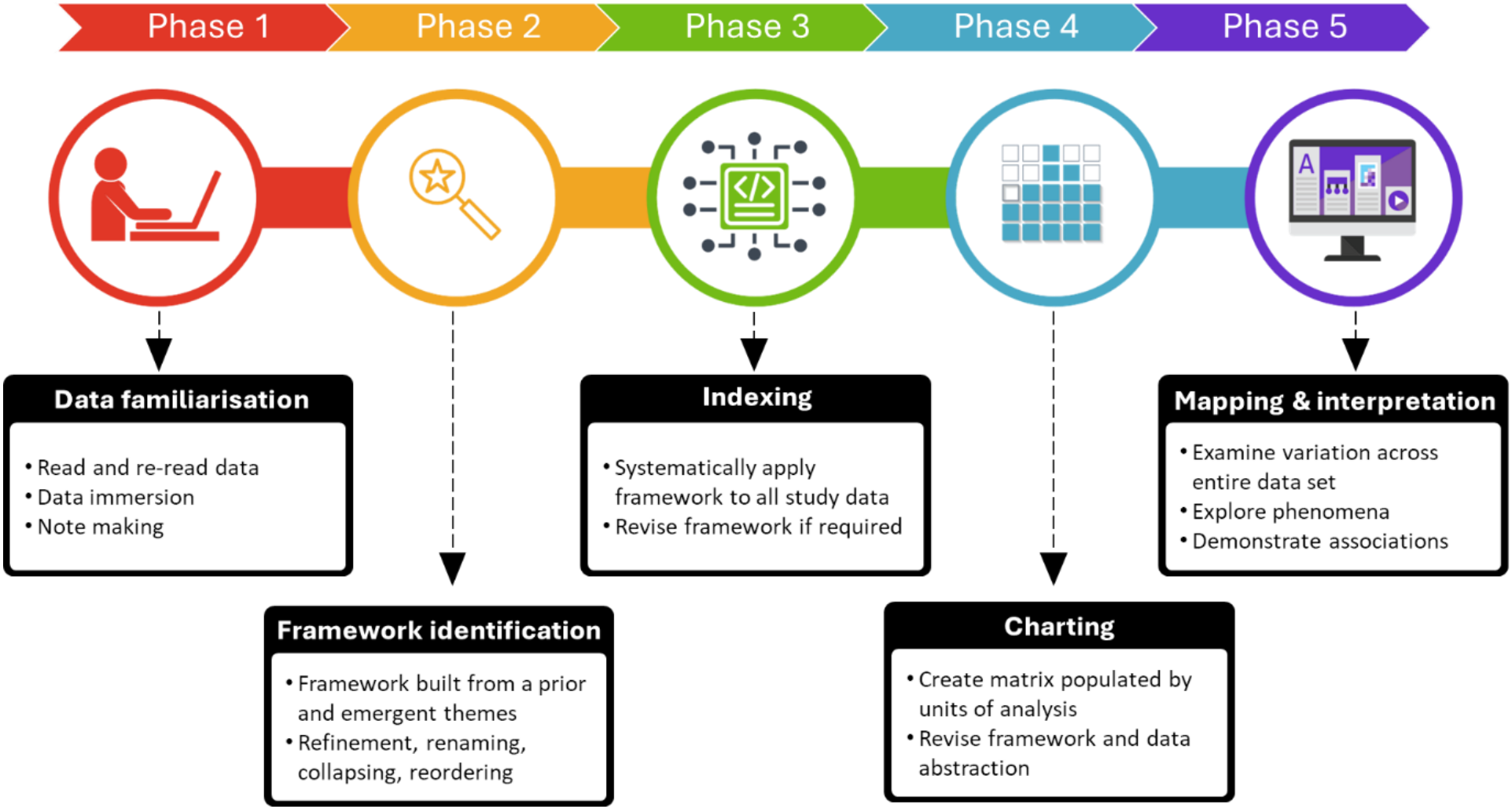
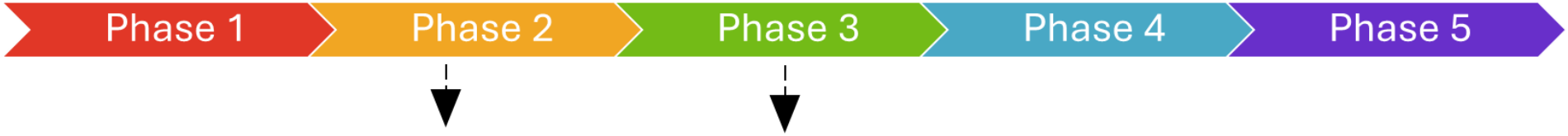


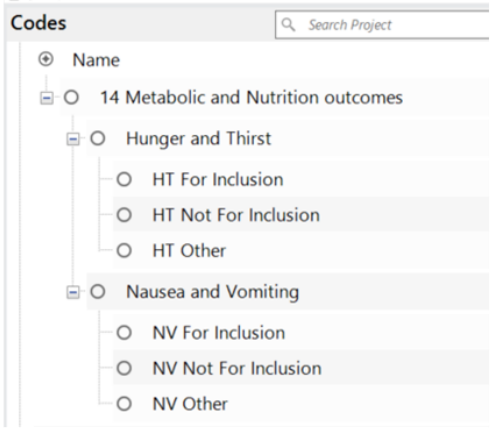
Figure 5.9 Framework analysis process

In contrast to the inductive and iterative approach used in Stage Two, framework analysis permits concepts or themes identified *a priori* to be defined as coding categories at the start, providing an established, transparent, structured, rigorous data analysis and management process (Dixon-Woods, 2011; Goldsmith, 2021; Ward et al., 2013). The interrelated, distinct stages allowed the proposed outcomes to be explicitly and systematically considered by case or theme, whilst maintaining flexibility to detect and characterise additional outcomes or themes that emerge from the data. This pragmatic approach was primarily employed due to the time restrictions between rounds and to facilitate controlled feedback in Round Two.

All free-text participant comments were exported from REDCap into Microsoft Word, deidentified and a document created per participant. Each document was imported into NVivo (version 14), where a case per participant was created, ensuring that all data from each participant who commented was considered. A familiarisation process occurred whereby the researcher systematically read and re-read each case, noting contrasting views and initial thoughts in memos. Data was deductively coded to a coding framework based on the 93 outcomes presented in Round One, organised under the COMET taxonomy core areas (Dodd et al., 2018) and inductively to capture comments pertaining to additional outcomes proposed. The initial coding framework also contained an *'other'* code for data incongruent with critical or not critical for inclusion to ensure no key aspects of data were omitted. The *'other'* code was then refined into statements and descriptions and reviewed by two members of the steering committee (RG and NP). A codebook containing an explanatory description for each code was maintained. The final outcome framework for the 93 outcomes considered in Round One comprised of 372 codes clustered into four categories per outcome. An example of the outcome coding framework development for metabolic and nutritional outcomes is illustrated in **Figure 5.10.**

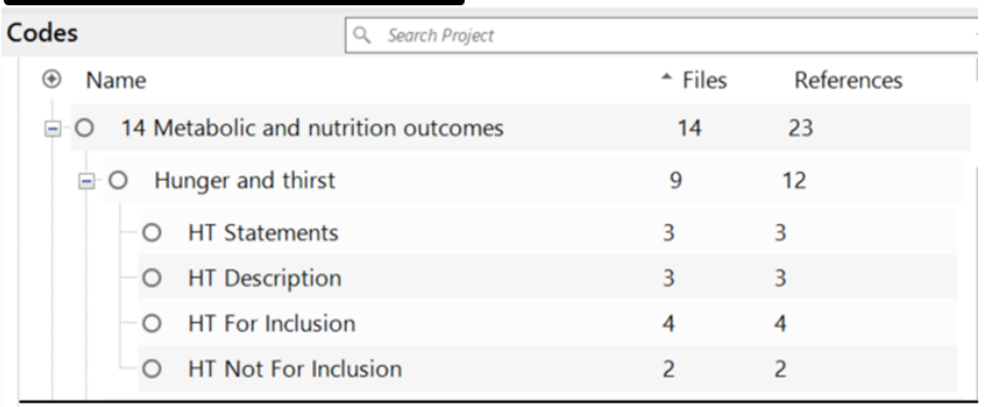


Framework identification



Code	Hunger and thirst descriptions
HT critical for inclusion	Comments supporting including the outcome hunger and thirst as critical in COS
HT Not For Inclusion	Comments not supporting including the outcome hunger and thirst as critical in COS
HT other	Comments on the outcome hunger and thirst that do not cover inclusion or exclusion

Revised framework



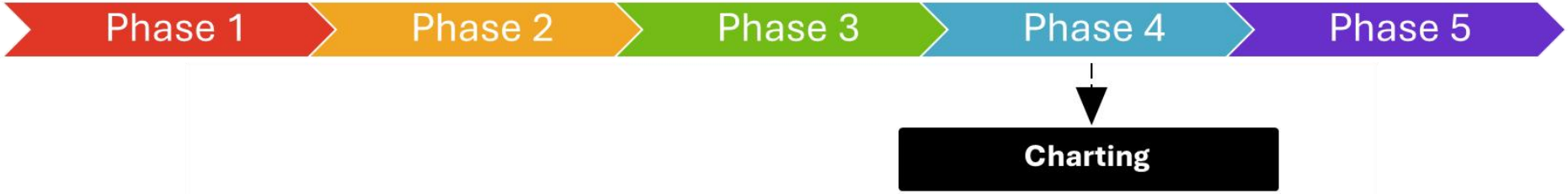
Code	Revised hunger and thirst descriptions
HT statements	Comments that fail to provide adequate justification, clarity, or reasoning to support either the inclusion or exclusion of hunger and thirst in COS
HT description	Comments relating to the description of the hunger and thirst outcome or construct
HT critical for inclusion	Comments supporting including the outcome hunger and thirst as critical in COS
HT not critical for inclusion	Comments not supporting including the outcome hunger and thirst as critical in COS

Figure 5.10 Outcome Framework for Metabolic and Nutrition Outcomes

Following applying the analytical outcome framework to all cases, a charting matrix was created in NVivo and then in Excel, with data abstracted per stakeholder group from NVivo, facilitating data pattern recognition and highlighting deviant cases, empty cells, and contradictory data. **Figure 5.11** provides an illustrative example of one outcome. The outcome charting matrix was used to refine individual outcome descriptions and provide quotes for Round Two of the eDelphi. To mitigate reporting bias, quotes were only presented to participants in Round Two where opposing views could be represented.

Three of matrix themes – outcome description, critical for inclusion and not critical for inclusion were inductively explored to interpret the data in further detail. Codes and themes emerged from the data and were refined during the course of analysis (Klingberg et al., 2024). Similar comments or reasons were grouped together and assigned a code. Here data interpretation extended beyond individual outcomes and cases to explore phenomena and develop themes across all the data. Connections were made across and between cases and stakeholder groups, generating subthemes that explained participants' comments and ratings. The coding frameworks were checked by a member of the steering group committee (RG) and applied to all cases.

Free-text entries from Round Two were independently coded by the researcher following the aforementioned five-stage framework process (**Figure 5.9**). Reasons why the outcome was critical or not critical for inclusion were coded using frameworks developed during Round One, while reasons for score changes followed an inductive-iterative approach (Ritchie & Spencer, 1994). Similar reasons from the first three cases were grouped into an initial coding framework and discussed with a member of the steering group (RG). The researcher then applied the reasons-for-score-change coding framework across all cases, refining and discussing as needed. The final coding framework was independently checked by a steering committee member (RG).



	A	B	C	D
1		**Patients and family**	**Health professionals**	**Researchers**
2	**Statements**	*"Anti nausea medication is usually offered"* [R147]	*"Important to ensure how these are managed appropriately with medications."* [R184]	-
3	**Description**	-	*"How good are the tools available to consistently assess these - very poor I think."* [R109] *"These are important but need a tool relevant to end-of-life"* [R131] *"These are not metabolism and nutrition outcomes."* [R136] *"I think its important to distinguish between outcomes that it is relatively easy to modify eg pain, respiratory distress, nausea and others that are much harder to intervene with eg level of awareness."* [R166]	*"These should have a clear defined measure, but important to assess."* [R130]
4	**Critical for inclusion**	-	*"Nausea and vomiting is often an overlooked symptom that can have significant impact on any outcome and experience."* [R130] *"Nausea and vomiting may be very unrelated to metabolism or nutrition, however, they are all unpleasant symptoms that should be measured."* [R136] *"Proper management of vomiting will reduce on fluid loss and avoids aspiration and promotes comfort."* [R1131]	*"Hunger/thirst/Nausea can be very difficult for family to see and experience and can be seen as pain."* [R1127]
5	**Not critical for inclusion**	-	*"N+V should be assessed however not ALL EOL patients experience these symptoms and asking unnecessarily is not conducive so needs to be holistic."* [R146]	-
6				

N&V Framework 1 | N&V Framework 2 | N&V Outcome Matrix

Figure 5.11 Nausea and vomiting outcome matrix

5.10.3 Reflexivity

Whilst the structural nature of framework analysis facilitated transparency of data analysis, reflexivity was imperative to ensure that the framework was contextually sensitive and grounded in participants' lived experience, enhancing credibility and trustworthiness. A reflective journal was maintained throughout data analysis, and analytic memos were created in NVivo, facilitating the researcher's understanding of the outcomes under consideration. The researchers' hybrid emic-etic positionality is illustrated in **Appendix 1.**

5.10.4 Attrition analysis

To assess attrition, the number of participants completing each questionnaire was recorded and compared to completion throughout Rounds One and Two.

5.11 Results

Forty international organisations were approached to promote the study with 50% providing support through a combination of membership circulation, social media promotion or newsletter inclusion (**Appendix 54**). No response was received from 35% (n=14) organisations, while 15% (n=6) were unable to support due to prohibitive costs, the study team not being members of the organisation or review time constraints. The American Association of Critical Care Nurses was the highest referrer, accounting for 33.06% (n=107) of referrals, followed by Google search engine (21.40% n=70). The recruitment period in Round One was expanded to accommodate organisations' newsletter timelines and review processes. Due to the recruitment method, it was not possible to determine the total number of individual stakeholders approached to participate; therefore, the response rate cannot be calculated.

During Round One, the study website received 880 views, of which 61.59% (n=542) were unique user visits from users in 26 countries. The website was accessed by 62.40% (n=327) of users selecting a link on a referrer site or via a QR code, while 39.67% (n=215) typed the study URL directly into a web browser or selected a link embedded in an email invite.

Of the 304 people who viewed the online participant information sheet, 17.43% (n=53) selected the hyperlink to open the screening questionnaire. Fifty-one QR codes were accessed through email approaches, newsletters and social media posts (**Figure 5.12**). QR codes embedded in email invitations had the highest engagement (54.90% n=28).

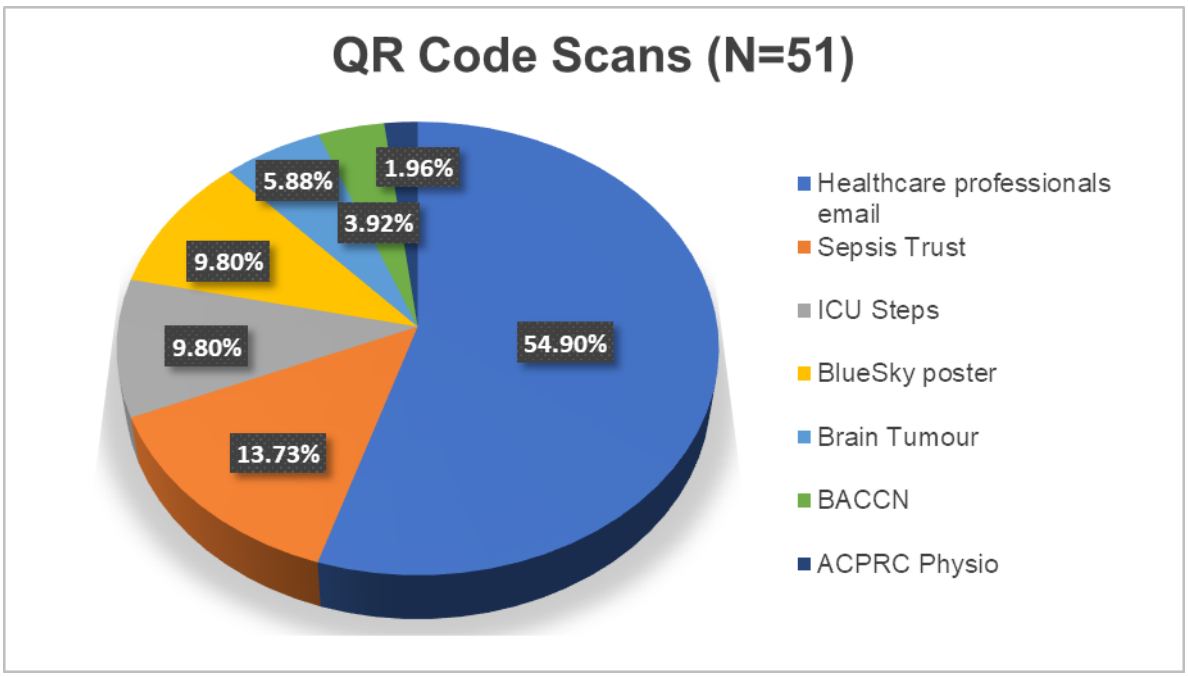


Figure 5.12 Round One QR engagement

During Round One, six email enquiries were received: 83.33% (n=5) met the study criteria and were provided with an email link to access the questionnaires.

Overall, 140 people commenced the screening questionnaire, of which 98.57% (n=138) met the inclusion criteria. In total, 101 consented to participate, with all (100% n=101) completing the demographic questionnaire and 91.09% (n=92) commencing Round One. Round One completion rates and times varied between stakeholder groups, with 83.17% (n=84) of researchers who started round one completing compared to 69.23% (n=9) of patients and family members (**Table 5.5**). Health professionals and researchers took three times longer than patients and families to complete (**Table 5.6).**

Table 5.5 Round One stakeholder progress

Stakeholder	Screening Completed N (%)	Consent completed N (%)	Demographics completed N (%)	Round 1 started N (%)	Round 1 completed N (%)
Patient and family	21 (15.22)	13 (12.87)	13 (12.87)	11 (11.96)	9 (10.71)
Healthcare professional	96 (69.57)	74 (73.27)	74 (73.27)	67 (72.83)	61 (72.62)
Researcher	21 (15.22)	14 (13.86)	14 (13.86)	14 (15.22)	14 (16.67)
Total	**138 (100)**	**101 (100)**	**101 (100)**	**92 (100)**	**84 (100)**
Health professional breakdown					
AHP	2 (2.08)	1 (1.35)	1 (1.35)	1 (1.49)	1 (1.64)
Doctor	47 (48.96)	37 (50.00)	37 (50.00)	34 (50.75)	31 (50.82)
Nurse	46 (47.92)	35 (47.30)	35 (47.30)	31 (46.27)	28 (45.90)
Psychologist	1 (1.04)	1 (1.35)	1 (1.35)	1 (1.49)	1 (1.64)
Total	**96 (100)**	**74 (100)**	**74 (100)**	**67 (100)**	**61 (100)**

AHP = Allied Health Professionals

Table 5.6 Completion times of those who completed Round One

Stakeholder	Range mm:ss	Median mm:ss	IQR mm:ss	Subtotal mm:ss
		Screening		
Overall	00:15 – 07:04	00:46	[00:28, 00:46]	105:21
Patient/family	00:17 - 02:38	00:55	[00:42, 01:27]	10:12
Health professional	00:15 - 07:04	00:38	[00:27, 01:12]	77:04
Researcher	00:23 - 05:50	00:53	[01:25, 00:23]	18:05
		Consent		
Overall	00:52 – 47:23	01:44	[01:18, 01:44]	278:37
Patient/family	00:59 – 03:52	01:56	[01:19, 02:15]	18:58
Health professional	00:52 – 47:23	01:40	[01:16, 02:40]	227:23
Researcher	00:58 – 04:41	01:55	[01:24, 03:15]	32:16
		Demographics		
Overall	00:12 – 30:12	00:30	[00:20. 00:30]	114:18
Patient/family	00:16 – 30:12	00:34	[00:30, 00:38]	34:26
Health professional	00:12 – 13:50	00:28	[00:19, 00:43]	66:13
Researcher	00:15 – 03:57	00:33	[00:25, 01:07]	13:39
		Round One		
Overall	05:11 – 97:27	12:39	[08:47 – 12:39]	1621:36
Patient/family	05:40 – 30:14	15:17	[10:04 – 15:22]	131:55
Health professional	05:11 – 90:26	12:32	[08:31 – 18:53]	1169:45
Researcher	06:28 – 97:27	12:54	[08:45 – 30:46]	319:56

Time is expressed in mm:ss (minutes:seconds), IQR = interquartile range (the difference between the 75th and 25th percentiles)

5.11.1 Participant characteristics

Eighty-four participants completed Round One: male: female ratio = 8:13, age range 22-68 years, (mean 46 years, SD=11.22) with 72.62% (n=61) identifying as health professionals, 16.67% (n=14) identifying as researchers and 10.71% (n=9) identifying as patient or family members. No participant disclosed any accessibility needs. Participants were located in ten countries within five continents (**Figure 5.13**).

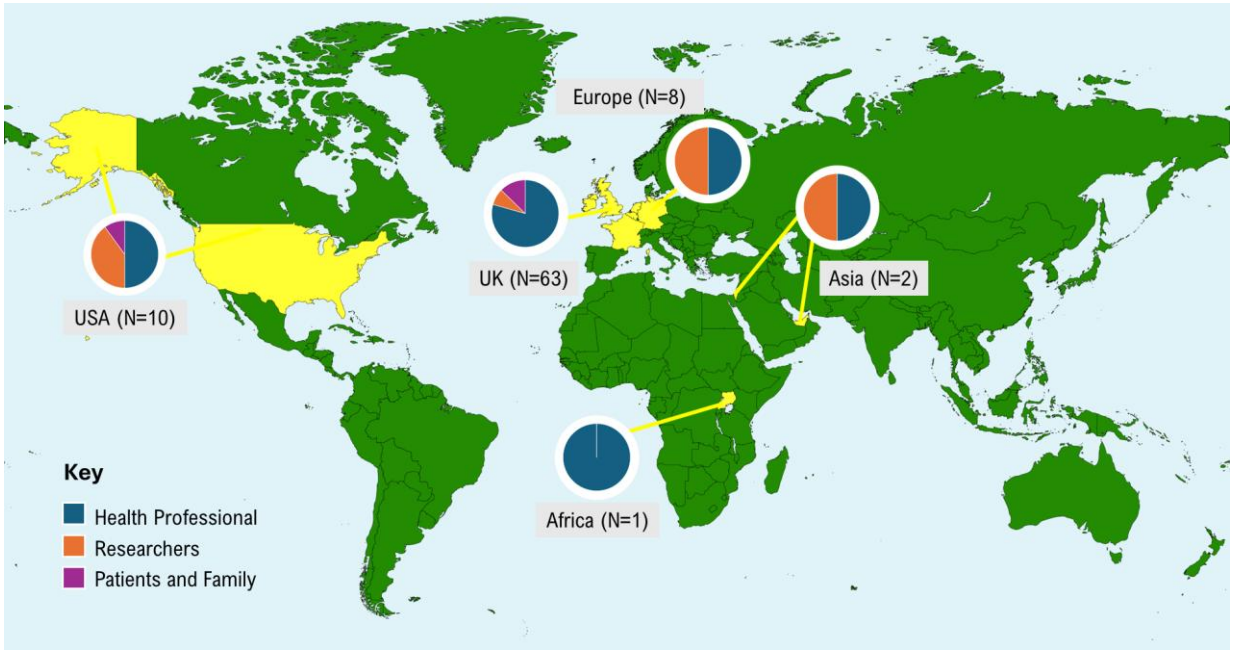


Figure 5.13 Round One participant location by continent

Forty participants provided free-text comments during Round One (comment rate: 47.62%). No statistically significant differences were found between the characteristics of those who did and did not comment (**Table 5.7**). Health professionals had, on average, 17 years of experience in EoLC (SD=10.58, min 2, max 40), while researchers had, on average, 24 years of experience (SD=11.45, min 3, max 44).

Table 5.7 Round One participant characteristics, according to free-text comments

Variable	With free-text comment N=40 (%)	Without free text comment N=44 (%)	p-value
Stakeholder group			
Patient/family	4 (10.00)	5 (11.36)	
Health professional	28 (70.00)	33 (75.00)	
AHP	-	1 (3.03)	
Doctor	17 (60.71)	14 (42.42)	0.772
Nurse	11 (39.29)	17 (51.52)	
Psychologist	- -	1 (3.03)	
Researcher	8 (20.00)	6 (13.64)	
Age in years, mean (standard deviation)	46.1 (10.648)	45.9 (11.964)	0.946
Ethnicity			
African	1 (2.50)	- -	
Arabic	1 (2.50)	- -	
Chinese	- -	1 (2.27)	
Indian	2 (5.00)	2 (4.55)	0.171
Mixed/Multiple - White & Asian	1 (2.50)	- -	
Other	6 (15.00)	3 (6.82)	
Prefer not to answer	- -	4 (9.09)	
White	29 (72.50)	34 (77.27)	
Location			
Belgium	1 (2.50)	-	
France	2 (5.00)	1 (2.27)	
Germany	- -	2 (4.55)	
Ireland	1 (2.50)	- -	
Israel	1 (2.50)	- -	0.301
Netherlands	- -	1 (2.27)	
Uganda	1 (2.50)	- -	
UK	29 (72.50)	33 (75.00)	
United Arab Emirates	2 (5.00)	- -	
USA	3 (7.50)	7 (15.91)	

AHP = Allied Health Professional - =0

5.11.2 Round One

Participants rated 93 outcomes with 17 (18.27%) meeting the *a priori* criteria for consensus in, 15 (16.13%) meeting the criteria for consensus out and 61 (65.59%) reaching no consensus (**Figure 5.14**). **Table 5.8** illustrates the rating per stakeholder group across the domains of the COMET taxonomy (Dodd et al., 2018). Figures within the table are presented to one decimal place to facilitate readability. The 61 outcomes that did not achieve consensus were amended according to stakeholder comments and suggestions (**Appendix 55**).

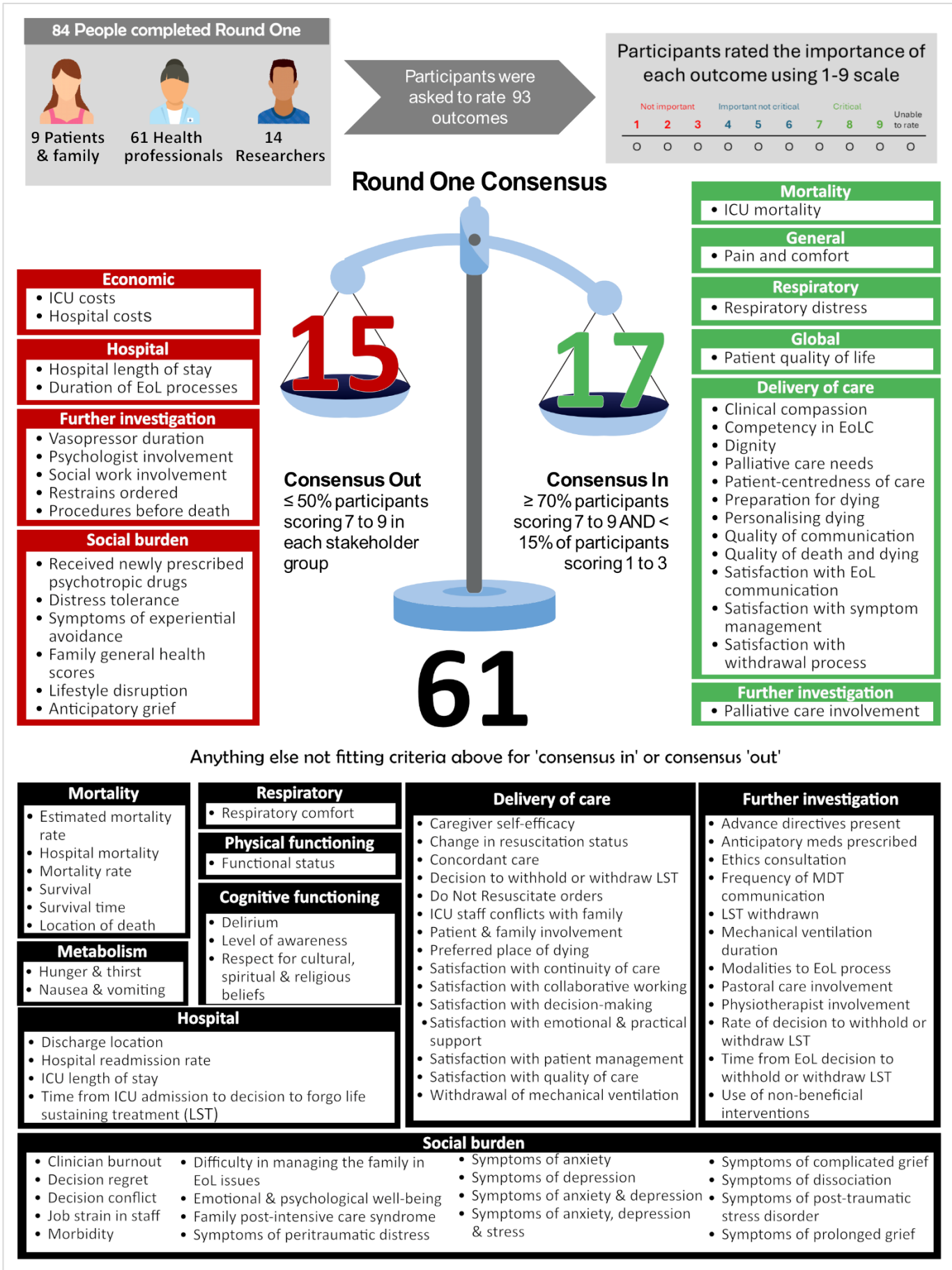


Figure 5.14 Round One consensus infographic

Table 5.8 Round One outcomes per stakeholder group

Outcome	Rating	Patient and Family	Health professional	Researcher	Consensus
		N (%)	N (%)	N (%)	
1: Mortality					
Estimated mortality rate	Not important	- -	4 (6.6)	2 (14.3)	No consensus
	Important	5 (55.6)	26 (42.6)	4 (28.3)	
	Critical	4 (44.4)	31 (50.8)	8 (57.1)	
ICU mortality	Not important	- -	1 (1.6)	1 (7.1)	In
	Important	2 (22.2)	16 (26.2)	3 (21.4)	
	Critical	7 (77.8)	44 (72.1)	10 (71.4)	
Hospital mortality	Not important	- -	3 (5.0)	1 (7.1)	No consensus
	Important	2 (22.2)	22 (36.7)	4 (28.6)	
	Critical	7 (77.8)	35 (58.3)	9 (64.3)	
Mortality rate	Not important	- -	2 (3.3)	1 (7.1)	No consensus
	Important	2 (22.2)	21 (35.0)	4 (28.6)	
	Critical	7 (77.8)	37 (61.7)	9 (64.3)	
Survival	Not important	- -	3 (5.0)	- -	No consensus
	Important	3 (33.3)	13 (21.7)	7 (50.0)	
	Critical	6 (66.7)	44 (73.3)	7 (50.0)	
Survival time	Not important	1 (11.1)	3 (5.1)	1 (7.1)	No consensus
	Important	2 (22.2)	22 (37.3)	6 (42.9)	
	Critical	6 (66.7)	34 (57.6)	7 (50.0)	
Location of death	Not important	1 (11.1)	1 (1.6)	- -	No consensus
	Important	3 (33.3)	20 (32.8)	2 (14.3)	
	Critical	5 (55.6)	40 (65.6)	12 (85.7)	
9: General outcomes					
Pain and comfort	Not important	- -	- -	- -	In
	Important	1 (11.1)	2 (3.3)	1 (7.1)	
	Critical	8 (88.9)	59 (96.7)	13 (92.9)	
14: Metabolism and nutrition					
Hunger and thirst	Not important	1 (11.1)	- -	- -	No consensus
	Important	2 (22.2)	25 (41.0)	5 (38.5)	
	Critical	6 (66.7)	36 (59.0)	8 (61.5)	
Nausea and vomiting	Not important	- -	- -	1 (7.7)	No consensus
	Important	3 (33.3)	12 (20.0)	3 (23.1)	
	Critical	6 (66.7)	48 (80.0)	9 (69.2)	
22: Respiratory					
Patient respiratory comfort	Not important	- -	- -	- -	No consensus
	Important	3 (33.3)	10 (16.4)	4 (28.6)	
	Critical	6 (66.7)	51 (83.6)	10 (71.4)	
Patient respiratory distress	Not important	- -	- -	- -	In
	Important	2 (22.2)	7 (11.5)	3 (21.4)	
	Critical	7 (77.8)	54 (88.5)	11 (78.6)	
25: Physical functioning					

Outcome	Rating	Patient and Family	Health professional	Researcher	Consensus
		N (%)	N (%)	N (%)	
Functional status	Not important	- -	2 (3.4)	3 (23.08)	No consensus
	Important	1 (11.1)	29 (49.1)	6 (46.15)	
	Critical	8 (88.9)	28 (47.5)	4 (30.77)	
29: Cognitive functioning					
Respect for cultural, spiritual and religious beliefs	Not important	2 (22.2)	- -	- -	No consensus
	Important	2 (22.2)	15 (25.0)	5 (35.7)	
	Critical	5 (55.6)	45 (75.0)	9 (64.3)	
Delirium	Not important	- -	- -	2 (14.3)	No consensus
	Important	1 (11.1)	16 (26.2)	5 (35.7)	
	Critical	8 (88.9)	45 (73.8)	7 (50.0)	
Level of awareness	Not important	- -	1 (1.7)	1 (7.1)	No consensus
	Important	3 (33.3)	22 (36.7)	4 (28.6)	
	Critical	6 (66.7)	37 (61.6)	9 (64.3)	
30: Global quality of life					
Patient quality of life	Not important	- -	1 (1.6)	- -	In
	Important	2 (22.2)	11 (18.0)	2 (14.3)	
	Critical	7 (77.8)	49 (80.3)	12 (85.7)	
32: Delivery of care - End-of-life					
Quality of death and dying	Not important	- -	1 (1.7)	- -	In
	Important	1 (11.1)	2 (3.3)	- -	
	Critical	8 (88.9)	57 (95.0)	14 (100)	
Personalising dying	Not important	- -	- -	- -	In
	Important	2 (22.2)	7 (11.7)	2 (14.3)	
	Critical	7 (77.8)	53 (88.3)	12 (85.7)	
Preparation for dying	Not important	- -	- -	- -	In
	Important	1 (11.1)	13 (21.3)	2 (14.3)	
	Critical	8 (88.9)	48 (78.7)	12 (85.7)	
Palliative care needs	Not important	- -	- -	- -	In
	Important	1 (11.1)	6 (9.8)	2 (14.3)	
	Critical	8 (88.9)	55 (90.2)	12 (85.7)	
Dignity	Not important	- -	- -	- -	In
	Important	2 (22.2)	6 (9.8)	1 (7.1)	
	Critical	7 (77.8)	55 (90.2)	13 (92.9)	
Clinical compassion	Not important	- -	- -	- -	In
	Important	2 (22.2)	13 (21.3)	2 (14.3)	
	Critical	7 (77.8)	48 (78.7)	12 (85.7)	
Patient-centredness of care	Not important	- -	- -	- -	In
	Important	1 (11.1)	7 (11.5)	2 (14.3)	
	Critical	8 (88.9)	54 (88.5)	12 (85.7)	
Preferred place of dying	Not important	- -	1 (1.6)	- -	No consensus
	Important	4 (44.4)	17 (27.9)	4 (28.6)	
	Critical	5 (55.6)	43 (70.5)	10 (71.4)	

Outcome	Rating	Patient and Family	Health professional	Researcher	Consensus
		N (%)	N (%)	N (%)	
32: Delivery of care - Communication					
Satisfaction with end-of-life communication	Not important	- -	- -	- -	In
	Important	1 (11.1)	5 (8.3)	2 (14.3)	
	Critical	8 (88.9)	55 (91.7)	12 (85.7)	
Quality of communication	Not important	- -	- -	- -	In
	Important	1 (11.1)	10 (16.7)	2 (14.3)	
	Critical	8 (88.9)	50 (83.3)	12 (85.7)	
32: Delivery of care - Care Satisfaction					
Caregiver Self-Efficacy in the ICU	Not important	- -	2 (3.3)	- -	No consensus
	Important	4 (44.4)	28 (46.7)	8 (57.1)	
	Critical	5 (55.6)	30 (50.0)	6 (42.9)	
Satisfaction with continuity of care	Not important	- -	1 (1.6)	- -	No consensus
	Important	2 (22.2)	27 (44.3)	7 (50.0)	
	Critical	7 (77.8)	33 (54.1)	7 (50.0)	
Satisfaction with quality of care	Not important	- -	- -	- -	No consensus
	Important	1 (11.1)	12 (19.7)	5 (35.7)	
	Critical	8 (88.9)	49 (80.3)	9 (64.3)	
Satisfaction with emotional and practical support	Not important	- -	- -	- -	No consensus
	Important	2 (22.2)	14 (23.0)	6 (42.9)	
	Critical	7 (77.8)	47 (77.0)	8 (57.1)	
Satisfaction with symptom management and comfort care	Not important	- -	- -	- -	In
	Important	1 (11.1)	11 (18.0)	4 (28.6)	
	Critical	8 (88.9)	50 (82.0)	10 (71.4)	
Satisfaction with collaborative working	Not important	- -	1 (1.6)	- -	No consensus
	Important	3 (33.3)	25 (41.0)	9 (64.3)	
	Critical	6 (66.7)	35 (57.4)	5 (35.7)	
Satisfaction with patient management	Not important	- -	1 (1.7)	- -	No consensus
	Important	2 (22.2)	17 (28.3)	8 (57.1)	
	Critical	7 (77.8)	42 (70.0)	6 (42.9)	
Competency in end-of-life care	Not important	- -	1 (1.7)	- -	In
	Important	2 (22.2)	13 (22.0)	1 (7.7)	
	Critical	7 (77.8)	45 (76.3)	12 (92.3)	
32: Delivery of care - Decision making					
Satisfaction with decision-making	Not important	- -	- -	- -	No consensus
	Important	3 (33.3)	17 (28.3)	5 (35.7)	
	Critical	6 (66.7)	43 (71.7)	9 (64.3)	
Patient and family involvement	Not important	- -	2 (3.3)	- -	No consensus
	Important	3 (33.3)	9 (15.0)	3 (23.1)	
	Critical	6 (66.7)	49 (81.7)	10 (76.9)	
Decision to withhold or withdraw life-sustaining therapy	Not important	- -	- -	- -	No consensus
	Important	1 (11.1)	10 (16.7)	4 (30.8)	
	Critical	8 (88.9)	50 (83.3)	9 (69.2)	

Outcome	Rating	Patient and Family	Health professional	Researcher	Consensus
		N (%)	N (%)	N (%)	
Concordant care	Not important	- -	- -	- -	No consensus
	Important	4 (57.1)	16 (27.6)	3 (21.4)	
	Critical	3 (42.9)	42 (72.4)	11 (78.6)	
ICU staff conflicts with family members	Not important	- -	4 (6.9)	1 (7.1)	No consensus
	Important	3 (42.9)	22 (37.9)	7 (50.0)	
	Critical	4 (57.1)	32 (55.2)	6 (42.9)	
Change in resuscitation status	Not important	- -	7 (11.7)	- -	No consensus
	Important	3 (37.5)	19 (31.7)	5 (35.7)	
	Critical	5 (62.5)	34 (56.7)	9 (64.3)	
Do Not Resuscitate (DNR) orders	Not important	- -	3 (5.0)	- -	No consensus
	Important	3 (37.5)	18 (30.0)	4 (28.6)	
	Critical	5 (62.5)	39 (65.0)	10 (71.4)	
Satisfaction with withdrawal processes	Not important	- -	1 (1.7)	- -	In
	Important	2 (22.2)	14 (23.3)	1 (7.7)	
	Critical	7 (77.8)	45 (75.0)	12 (92.3)	
Withdrawal of mechanical ventilation (terminal wean)	Not important	- -	2 (3.3)	- -	No consensus
	Important	2 (22.2)	19 (31.1)	6 (46.2)	
	Critical	7 (77.8)	40 (65.6)	7 (53.8)	
34: Economic					
ICU costs	Not important	- -	10 (16.4)	2 (14.3)	Out
	Important	6 (85.1)	34 (55.7)	8 (57.1)	
	Critical	1 (14.9)	17 (27.9)	4 (28.6)	
Hospital costs	Not important	- -	10 (16.4)	3 (21.4)	Out
	Important	6 (85.1)	33 (54.1)	8 (57.1)	
	Critical	1 (14.9)	18 (29.5)	3 (21.4)	
35: Hospital					
ICU length of stay	Not important	1 (11.1)	7 (11.5)	- -	No consensus
	Important	6 (66.7)	33 (54.1)	6 (42.9)	
	Critical	2 (22.2)	21 (34.4)	8 (57.1)	
Hospital length of stay	Not important	2 (22.2)	6 (9.8)	- -	Out
	Important	5 (55.6)	34 (55.7)	7 (50.0)	
	Critical	2 (22.2)	21 (34.4)	7 (50.0)	
Duration of the end-of-life processes	Not important	- -	4 (6.8)	- -	Out
	Important	5 (55.6)	26 (44.1)	7 (50.0)	
	Critical	4 (44.4)	29 (49.1)	7 (50.0)	
Time from ICU admission to decision to forgo life-sustaining treatments	Not important	1 (11.1)	2 (3.3)	1 (7.1)	No consensus
	Important	5 (55.6)	29 (47.5)	5 (35.7)	
	Critical	3 (33.3)	30 (49.2)	8 (57.1)	
Discharge location	Not important	2 (25.0)	7 (11.5)	1 (7.1)	No consensus
	Important	5 (62.5)	26 (42.6)	4 (28.6)	
	Critical	1 (12.5)	28 (45.9)	9 (64.3)	

Outcome	Rating	Patient and Family	Health professional	Researcher	Consensus
		N (%)	N (%)	N (%)	
Hospital readmission rates	Not important	- -	12 (19.7)	- -	No consensus
	Important	5 (55.6)	26 (42.6)	5 (35.7)	
	Critical	4 (44.4)	23 (37.7)	9 (64.3)	
36: Further investigation - Organ support					
Mechanical ventilation duration	Not important	- -	7 (11.7)	1 (7.1)	No consensus
	Important	3 (37.5)	33 (55.0)	7 (50.0)	
	Critical	5 (62.5)	20 (33.3)	6 (42.9)	
Vasopressor duration	Not important	- -	8 (13.3)	1 (7.1)	Out
	Important	3 (42.9)	34 (56.7)	9 (64.3)	
	Critical	4 (57.1)	18 (30.0)	4 (28.6)	
Use of nonbeneficial interventions	Not important	- -	6 (10.2)	- -	No consensus
	Important	2 (33.3)	19 (32.2)	5 (35.7)	
	Critical	4 (66.7)	34 (57.6)	9 (64.3)	
Life-sustaining treatments withdrawn	Not important	- -	2 (3.3)	- -	No consensus
	Important	2 (25.0)	19 (31.7)	4 (30.8)	
	Critical	6 (75.0)	39 (65.0)	9 (69.2)	
36: Further investigation – MDT					
Ethics consultations	Not important	1 (12.5)	6 (9.8)	1 (7.7)	No consensus
	Important	2 (25.0)	27 (44.3)	4 (30.8)	
	Critical	5 (62.5)	28 (45.9)	8 (61.5)	
Palliative care involvement	Not important	- -	1 (1.6)	- -	In
	Important	2 (22.2)	17 (27.9)	2 (14.3)	
	Critical	7 (77.8)	43 (70.5)	12 (85.7)	
Pastoral care involvement	Not important	- -	- -	- -	No consensus
	Important	6 (66.7)	21 (34.4)	6 (42.9)	
	Critical	3 (33.3)	40 (65.6)	8 (57.1)	
Psychologist involvement	Not important	- -	4 (6.6)	1 (7.1)	Out
	Important	6 (66.7)	28 (45.9)	6 (42.9)	
	Critical	3 (33.3)	29 (47.5)	7 (50.0)	
Social work involvement	Not important	3 (33.3)	8 (13.1)	1 (7.1)	Out
	Important	3 (33.3)	32 (52.5)	7 (50.0)	
	Critical	3 (33.3)	21 (34.4)	6 (42.9)	
Physiotherapist involvement	Not important	- -	5 (8.3)	2 (14.3)	No consensus
	Important	4 (44.4)	32 (53.3)	8 (57.1)	
	Critical	5 (55.6)	23 (38.3)	4 (28.6)	
Frequency of multidisciplinary communication	Not important	- -	2 (3.3)	1 (7.1)	No consensus
	Important	4 (44.4)	19 (31.7)	- -	
	Critical	5 (55.6)	39 (65.0)	13 (92.9)	
36: Further investigation - Prescribing, procedures and processes					
Anticipatory medication prescribed	Not important	- -	- -	- -	No consensus
	Important	3 (42.9)	8 (13.1)	4 (30.8)	
	Critical	4 (57.1)	53 (86.9)	9 (69.2)	

Outcome	Rating	Patient and Family	Health professional	Researcher	Consensus
		N (%)	N (%)	N (%)	
Time to end-of-life decision to withhold and withdraw therapies	Not important	- -	3 (5.0)	1 (7.7)	No consensus
	Important	2 (22.2)	21 (35.0)	3 (23.1)	
	Critical	7 (77.8)	36 (60.0)	9 (69.2)	
Modalities of end-of-life processes	Not important	- -	5 (8.9)	1 (8.3)	No consensus
	Important	2 (25.0)	16 (28.6)	3 (25.0)	
	Critical	6 (75.0)	35 (62.5)	8 (66.7)	
Rate of decision to withhold and withdraw life-sustaining therapies	Not important	- -	5 (8.6)	3 (23.1)	No consensus
	Important	3 (42.9)	23 (39.7)	2 (15.4)	
	Critical	4 (57.1)	30 (51.7)	8 (61.5)	
Advance directives present	Not important	- -	6 (9.8)	1 (7.1)	No consensus
	Important	3 (37.5)	20 (32.8)	5 (35.7)	
	Critical	5 (62.5)	35 (57.4)	8 (57.1)	
Restraints ordered	Not important	- -	8 (14.5)	- -	Out
	Important	4 (66.7)	23 (41.8)	8 (57.1)	
	Critical	2 (33.3)	24 (43.6)	6 (42.9)	
Number of procedures performed before death	Not important	- -	9 (15.5)	1 (7.7)	Out
	Important	5 (55.6)	20 (34.5)	9 (69.2)	
	Critical	4 (44.4)	29 (50.0)	3 (23.1)	
37: Social burden - Anxiety and depression					
Symptoms of anxiety	Not important	1 (11.1)	- -	- -	No consensus
	Important	2 (22.2)	17 (28.8)	5 (35.7)	
	Critical	5 (55.6)	42 (71.2)	9 (64.3)	
Symptoms of depression	Not important	- -	- -	- -	No consensus
	Important	3 (33.3)	23 (39.7)	6 (42.9)	
	Critical	5 (55.6)	35 (60.3)	8 (57.1)	
Symptoms of anxiety and depression	Not important	- -	1 (1.7)	1 (7.1)	No consensus
	Important	3 (33.3)	21 (36.2)	3 (21.4)	
	Critical	5 (55.6)	36 (62.1)	10 (71.4)	
Symptoms of depression, anxiety, and stress	Not important	- -	1 (1.8)	1 (7.1)	No consensus
	Important	3 (33.3)	20 (35.1)	2 (14.3)	
	Critical	6 (66.7)	36 (63.2)	11 (78.6)	
Received newly prescribed psychotropic drugs	Not important	- -	4 (6.7)	2 (14.3)	Out
	Important	4 (44.4)	30 (50.0)	6 (42.9)	
	Critical	3 (33.3)	26 (43.3)	6 (42.9)	
Family Post-intensive care syndrome	Not important	- -	1 (1.7)	- -	No consensus
	Important	3 (33.3)	20 (34.5)	2 (14.3)	
	Critical	5 (55.6)	37 (63.8)	12 (85.7)	

Outcome	Rating	Patient and Family	Health professional	Researcher	Consensus
		N (%)	N (%)	N (%)	
37: Social burden – Stress outcomes					
Distress tolerance	Not important	- -	8 (14.0)	2 (15.4)	Out
	Important	4 (50.0)	22 (38.6)	5 (38.5)	
	Critical	4 (50.0)	27 (47.4)	6 (46.2)	
Symptoms of peritraumatic distress	Not important	- -	4 (6.8)	1 (7.1)	No consensus
	Important	3 (42.9)	24 (40.7)	6 (42.9)	
	Critical	4 (57.1)	31 (52.5)	7 (50.0)	
Symptoms of dissociation	Not important	- -	5 (8.8)	1 (7.7)	No consensus
	Important	2 (28.6)	30 (52.6)	6 (46.2)	
	Critical	5 (71.4)	22 (38.6)	6 (46.2)	
Symptoms of post-traumatic stress disorder (PTSD)	Not important	- -	1 (1.8)	1 (7.1)	No consensus
	Important	2 (22.2)	27 (47.4)	3 (21.4)	
	Critical	7 (77.8)	29 (50.9)	10 (71.4)	
Symptoms of experiential avoidance	Not important	- -	3 (5.4)	2 (16.7)	Out
	Important	2 (40.0)	29 (51.8)	5 (41.7)	
	Critical	3 (60.0)	24 (42.9)	5 (41.7)	
Family general health scores	Not important	1 (12.5)	7 (11.7)	2 (14.3)	Out
	Important	6 (75.0)	30 (50.0)	7 (50.0)	
	Critical	1 (12.5)	23 (38.3)	5 (35.7)	
Emotional and psychological well-being	Not important	- -	4 (6.7)	2 (14.3)	No consensus
	Important	4 (44.4)	17 (28.3)	4 (28.6)	
	Critical	5 (55.6)	39 (65.0)	8 (57.1)	
Lifestyle disruption	Not important	1 (12.5)	6 (10.3)	3 (21.4)	Out
	Important	4 (50.0)	29 (50.0)	4 (28.6)	
	Critical	3 (37.5)	23 (39.7)	7 (50.0)	
Morbidity	Not important	- -	6 (10.3)	1 (7.1)	No consensus
	Important	4 (44.4)	18 (31.0)	4 (28.6)	
	Critical	5 (55.6)	34 (58.6)	9 (64.3)	
37: Social burden – Grief					
Anticipatory grief	Not important	2 (25.0)	1 (1.7)	1 (7.1)	Out
	Important	2 (25.0)	28 (47.5)	6 (42.9)	
	Critical	4 (50.0)	30 (50.8)	7 (50.0)	
Symptoms of prolonged grief	Not important	2 (22.2)	2 (3.4)	1 (7.1)	No consensus
	Important	2 (22.2)	22 (37.3)	3 (21.4)	
	Critical	5 (55.6)	35 (59.3)	10 (71.4)	
Symptoms of complicated grief	Not important	2 (22.2)	2 (3.4)	- -	No consensus
	Important	2 (22.2)	20 (33.9)	4 (28.6)	
	Critical	5 (55.6)	37 (62.7)	10 (71.4)	
37: Social burden – Conflict					
Difficulty in managing family in end-of-life issues	Not important	- -	1 (1.6)	- -	No consensus
	Important	4 (44.4)	18 (29.5)	5 (35.7)	
	Critical	5 (55.6)	42 (68.9)	9 (64.3)	

Outcome	Rating	Patient and Family	Health professional	Researcher	Consensus
		N (%)	N (%)	N (%)	
Decision regret	Not important	1 (12.5)	5 (8.3)	2 (14.3)	No consensus
	Important	3 (37.5)	18 (30.0)	2 (14.3)	
	Critical	4 (50.0)	37 (61.7)	10 (71.4)	
Decision conflict	Not important	1 (12.5)	3 (5.0)	- -	No consensus
	Important	3 (37.5)	16 (26.7)	4 (28.6)	
	Critical	4 (50.0)	41 (68.3)	10 (71.4)	
Clinician burn-out	Not important	1 (11.1)	5 (8.2)	1 (7.1)	No consensus
	Important	3 (33.3)	12 (19.7)	2 (14.3)	
	Critical	5 (55.6)	44 (72.1)	11 (78.6)	
Job strain in staff	Not important	1 (11.1)	5 (8.2)	2 (14.3)	No consensus
	Important	4 (44.4)	14 (23.0)	1 (7.1)	
	Critical	4 (44.4)	42 (68.9)	11 (78.6)	

- = 0

5.11.3 Round One outcomes suggested

Participants proposed 43 outcomes. Only one outcome (communication of dying) met the *a priori* inclusion criteria, while 25 were amended for clarity. All outcome suggestions were discussed, and decisions were agreed with the steering committee prior to implementation in Round Two, as outlined in **Appendix 56**.

5.11.4 Round One free text comments

Overall, 287 comments were entered from 40 participants (comment rate: 47.62%). 196 (68.29%) comments were considered to be related to the outcome description, 68 (23.69%) to reasons why the outcome was critical for inclusion in the COS, and 23 (8.01%) to why the outcome was considered not critical for inclusion. Overall, 21 themes were identified **(Figure 5.15**), with a further 17 subthemes evident in the outcome description matrix. Descriptions and illustrative quotes are provided in **Appendix 57 - Appendix 59.**

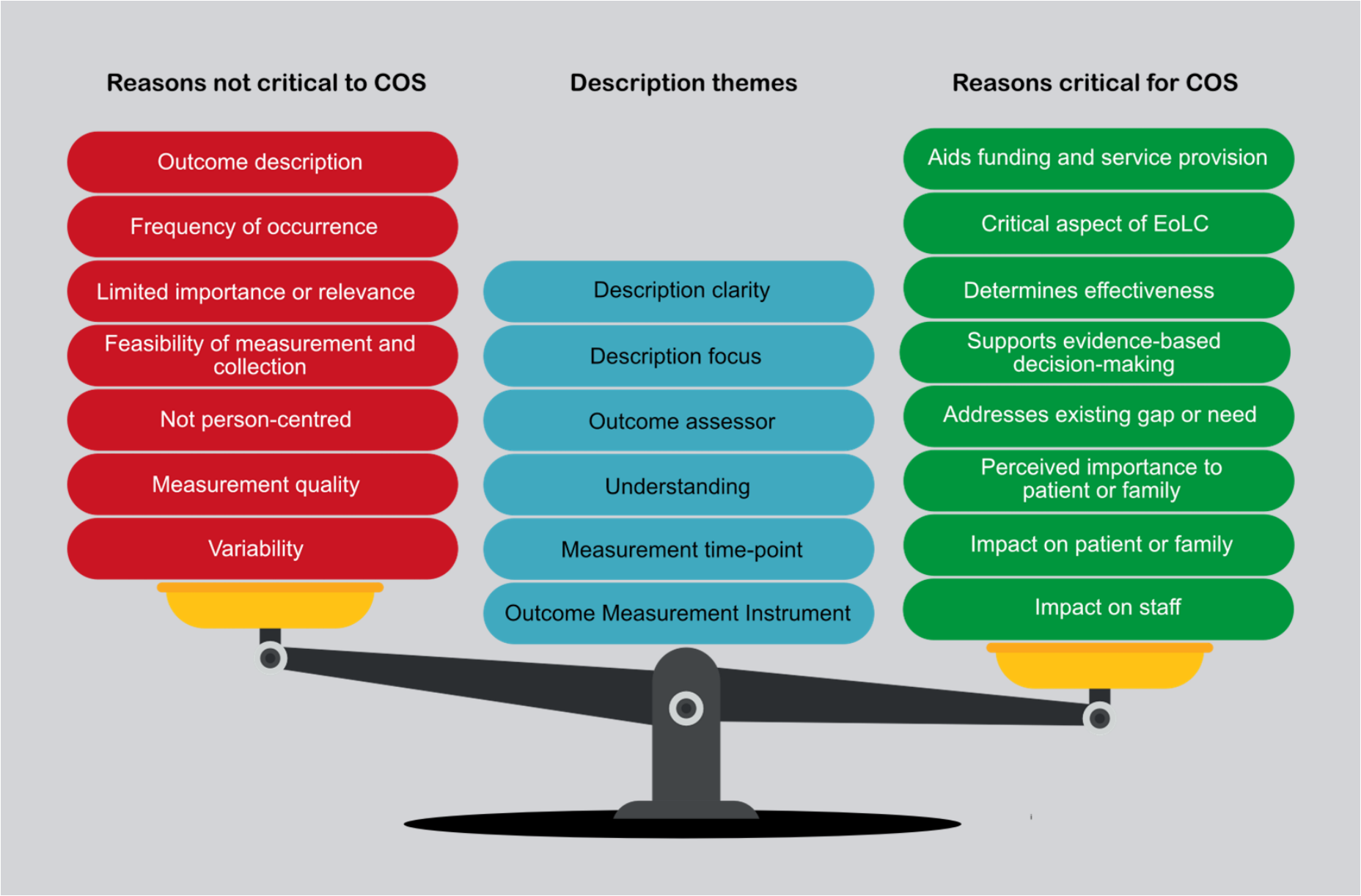


Figure 5.15 Round One comment themes

5.11.5 Description themes

Within the description category, six themes were identified: clarity, focus, assessor, understanding, measurement time point, and outcome measurement instrument (OMI), resulting in amendments to 25 outcome descriptions for Round Two. Although the focus of the COS was on *'what'* to measure, three of the themes (assessor, measurement time point and outcome measurement instrument) pertained to *'how'* an outcome should be measured. They were, however, analysed for context and completeness, as a range of participants considered them a critical component of the COS description, intrinsically linked to what to measure.

Clarity

Although all stakeholder groups commented on the clarity of the outcome descriptions, considering it a vital component in enabling participants to rate outcomes, health professionals felt mortality and withdrawal outcome descriptions lacked *'context'*, advocating for further definitions to be provided. Both health professionals and researchers suggested that the descriptions be *'reworded'* to improve clarity, yet only one patient/family member stated that an outcome description was unclear.

Focus

Health professionals and researchers commented on the focus of the outcome description. Tension was evident both between and within stakeholder groups regarding how tightly an outcome should be defined. Some participants suggested that the outcomes description focus should be *'expanded'* to capture multidimensional aspects of EoL care, while others considered the focus to be too *'granular'*. Researchers predominantly commented on the outcome format, noting the need for consistency across the COS.

Assessor

Health professionals and researchers questioned who was performing the outcome assessment, with comments focusing on assessor subjectivity and the use of proxy assessors. Opinions were divided on the use of patient-reported outcomes, with some health professionals considering them essential and others controversial.

Timepoint

Only health professionals commented on the need for outcome descriptors to capture the timepoint at which an outcome was measured. Participants considered this crucial to research; without it, outcomes could be *'meaningless'*. Questions arose concerning whether a single time point was sufficient or whether repeated measurements across multiple time points should be included to detect meaningful change, identify natural fluctuating patterns in EoL and reduce transient outcomes. Conversely, just one health professional remarked that a baseline measure should be captured.

Understanding

Eight participants across all three stakeholder groups found the outcome description ambiguous or open to multiple interpretations, seeking clarification to improve their analytical understanding. One health professional perceived the term *'palliative care needs'* as a barrier to comprehension for both health professionals and patients/family members, yet no participants in either stakeholder group commented on this specific terminology. Instead, patients/family members found terminology such as *'survival', 'ICU mortality'* and *'non-beneficial interventions'* unfamiliar and hard to interpret. Conversely, comments within the understanding description theme were only observed from UK-based participants.

Outcome measurement instrument

Health professionals expressed a need for outcome measure descriptors to capture and specify an OMI; however, validated OMIs with demonstrated reliability in the critical care population or EoL context were considered underdeveloped or *'unavailable'* by both health professionals and researchers. Nuanced OMIs that distinguished between measurement validity (accurately capturing staff perceptions) and construct validity (whether these perceptions reflect objective reality) were advocated, with one health professional highlighting the current discordance encountered between the two.

The six description themes and 17 subthemes are illustrated in ***Figure 5.16***

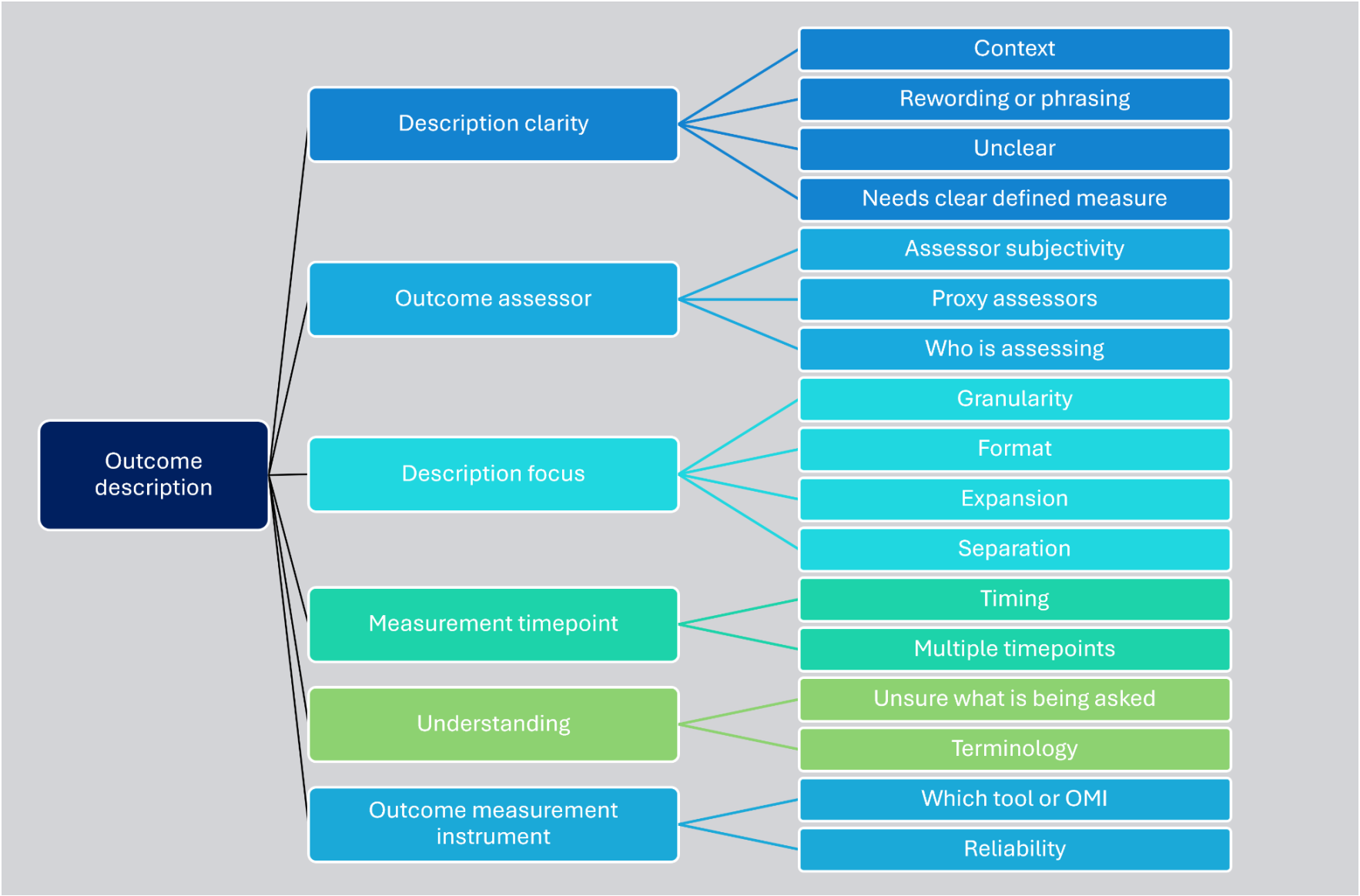


Figure 5.16 Round One description themes and subthemes

5.11.6 Critical for inclusion themes

Eight themes reflected the reasons participants considered outcomes critical for inclusion in the COS.

Aids funding and service provision

Healthcare participants considered outcomes critical for inclusion where they could be translated into economic terms – for example, demonstrating *'areas that are costly and not serving service users or service delivery'* or where outcomes could provide evidence that the current service provision was insufficient to meet a measurable need.

Critical/essential aspect of EoLC

Being a critical or essential aspect of EoLC was considered a critical reason for including an outcome in the COS by all stakeholders. Health professionals emphasised the comparative importance of outcomes, whilst researchers referred to *'gold standards'*, and patients reflected on the determinants of effective care delivery.

Determines effectiveness

Health professionals and researchers considered outcomes critical to include that determined the effectiveness of the intervention in question. Here the emphasis was on providing an evidence base of *'vital data'* for *'efficacy'.* Conversely, no patient/family member commented on effectiveness.

Supports evidence-based decision making

Five participants noted that including mortality outcomes was imperative to facilitate the identification of trends, disparities, and causal relationships, providing health professionals with a transparent evidence-based foundation for future care decisions. Commentary was confined to two stakeholder groups. Here, the evolving evidentiary base was considered central to *'accurate prognostication'* by one researcher, while health professionals considered the inclusion of such outcomes central to strengthening the evidence base for patient-centred decisions, such as the location of death.

Addresses existing gap or need

Patient/family responses revealed gaps and unmet needs, particularly where symptom control was considered insufficient. One health professional specifically commented how delirium outcomes were *'under managed'* while another health professional felt complicated grief was *'unrecognised'*. Conversely, no researchers commented on such gaps or needs.

Perceived importance to patient or family

Descriptive responses from both health professionals and researchers indicated that outcomes should be included in the COS based on their perceived *'vital importance to patients'*. Whilst such statements aligned with patient/family comments concerning pain outcomes, health professionals' and researchers' statements were incongruent with the patient/family perspectives articulated regarding mortality outcomes.

Impact on patient or family

Commentary was represented across all stakeholder groups on the critical importance of including outcomes that highlighted the impact on patients or their families. Differences were evident, however, between stakeholder groups when considering the duration of impact. For patients/family and researchers, the impact was short-lived, confined to EoL symptomology outcomes such as nausea and pain. In contrast, health professionals recognised the lasting psychological impacts extending beyond the EoL processes such as complicated grief.

Impact on staff

Within the impact of staff theme, responses were confined to the health professionals stakeholder group. Nurses commented that providing EoLC was linked to *'burnout'* and the challenges of accessing psychological support while a doctor felt it important to differentiate the impact of clinical work and background status.

5.11.7 Not critical for inclusion themes

Framework analysis of the Round One free-text comments revealed seven distinct themes that encapsulated the reasons participants considered outcomes not critical to include in the COS. Unlike the reasons for inclusion, comments predominantly originated from the health professionals stakeholder group.

Outcome description

Outcomes with descriptors deemed unclear, insufficient or emotive were not considered critical to include by health professionals. One health professional considered quality of death and dying a *'clumsy phrase'* while another considered non-beneficial interventions to be a *'loaded term'.*

Frequency of occurrence

Outcomes that occurred rarely or were considered part of EoLC were not prioritised for inclusion in the COS by health professionals. In such cases, outcomes were thought unlikely to offer additional insights into EoLC or substantively contribute to the research base.

Limited importance or relevance

Both health professionals and researchers cited lack of *'relevance'* or *'limited importance'* as reasons for not including outcomes in the COS. Further analysis, however, indicated that researchers evaluated the comparative importance of outcomes, concluding that they were considered of limited importance when considered alongside other competing priorities or influential factors. An assertion echoed by one patient/family member.

Feasibility of measurement and collection

To both health professionals and researchers, an outcome was not critical to the COS if the conditions necessary for collection were not feasible. The value of outcomes such as depression, preferred place of death, and quality of life was contingent not only on the psychometric properties of the OMI but also on the practical feasibility of collecting these outcomes. In such circumstances, outcomes were considered abstract constructs *'difficult to collect and interpret'*.

Not person-centred

Outcomes pertaining to mortality, length of stay, and costs were perceived by health professionals as not '*person-centred'*, as they impacted *'individualised'* care and were not congruent with the COS scope.

Measurement quality

Measurement quality encompassed concerns about bias, the validity and reliability of the outcomes presented. One health professional commented on how the *'timing'* of assessment could impact the outcome, while another was concerned about the reliability of proxy measures making outcomes not critical for inclusion in the COS.

Variability

Outcomes were considered non-critical for inclusion in the COS by health professionals, where applicability and measurement were contingent upon the research question or study design. For example, outcomes capturing staff symptomology were determined to *'depend on the research study'* which precluded consistent collection. Health professionals were the only stakeholder group mapped to this category of the coding framework.

5.12 Round Two

5.12.1 Participant characteristics

Fifty-four participants completed Round Two (male: female ratio = 11:16, age range [minimum-maximum]:25-68 years, mean 46) with 66.67% (n=36) identifying as health professionals, 20.37% (n=11) identifying as researchers and 12.96% (n=7) identifying as patient or family members. Participants were located in nine countries within five continents (**Figure 5.17**). Health professionals had, on average, 15 years of experience in EoLC (min 2, max 40), while researchers had, on average, 23 years of experience (min 3, max 44) (**Table 5.9**).

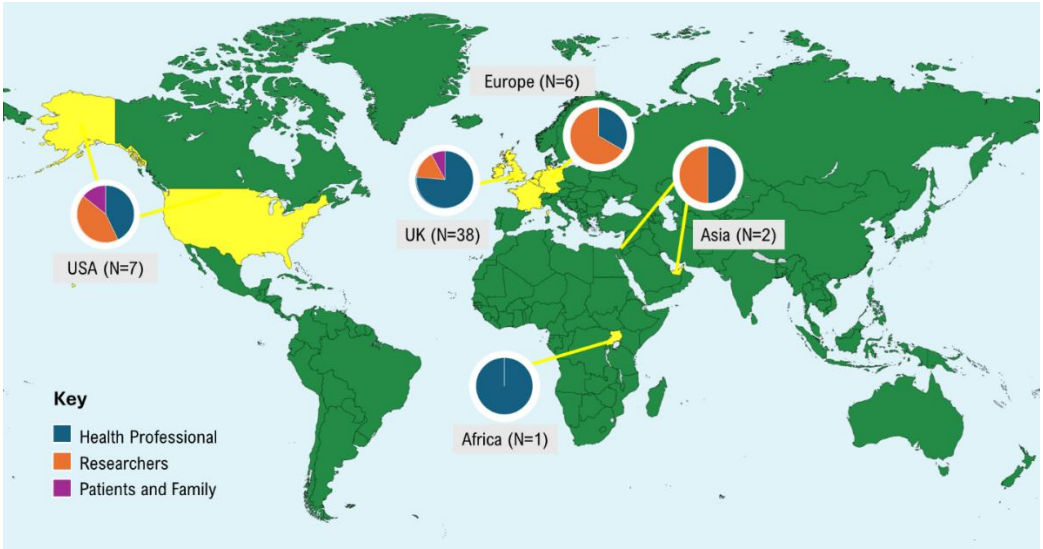


Figure 5.17 Round Two participant location by continent

Table 5.9 Round Two participant characteristics, according to free-text comments

Variable	Free-text comments N=25	(%)	Without free-text comments N=29	(%)	*p*-value
Group					
Patient and family	6	(24.00)	1	(3.49)	
Health professional	15	(60.00)	21	(72.41)	
AHP	-		-		
Doctor	9	(60.00)	11	(52.38)	0.077
Nurse	6	(40.00)	8	(38.10)	
Psychologist	-		1	(4.76)	
Researcher	4	(16.00)	7	(24.13)	
Age in years, mean (standard deviation)	45.56 (10.54)		47.86 (12.35)		0.469
Ethnicity					
African	1	(4.00)	-		
Arabic	-		1	(3.49)	
Chinese	-		1	(3.49)	
Indian	1	(4.00)	3	(10.34)	0.597
Mixed/Multiple - White & Asian	1	(4.00)	-		
Other	4	(16.00)	4	(13.79)	
Prefer not to answer	-		2	(6.91)	
White	18	(72.00)	18	(62.07)	
Location					
Belgium	1	(4.00)	-		
France	1	(4.00)	1	(3.49)	
Germany	-		2	(6.91)	
Ireland	-		-		
Israel	-		-		0.818
Netherlands	-		1	(3.49)	
Uganda	1	(4.00)	-		
UK	19	(76.00)	20	(65.52)	
United Arab Emirates	-		1	(3.49)	
USA	3	(12.00)	4	(13.79)	

AHP = Allied Health Professional

5.12.2 Round Two consensus

Participants rated 69 outcomes with ten (14.49%) meeting the *a priori* criteria for consensus in, five (7.25%) meeting the criteria for consensus out and 54 (78.26%) reaching no consensus (**Figure 5.18**). **Table 5.10** provides a breakdown of the consensus scoring per stakeholder group. Figures within the table are presented to one decimal place to facilitate readability.

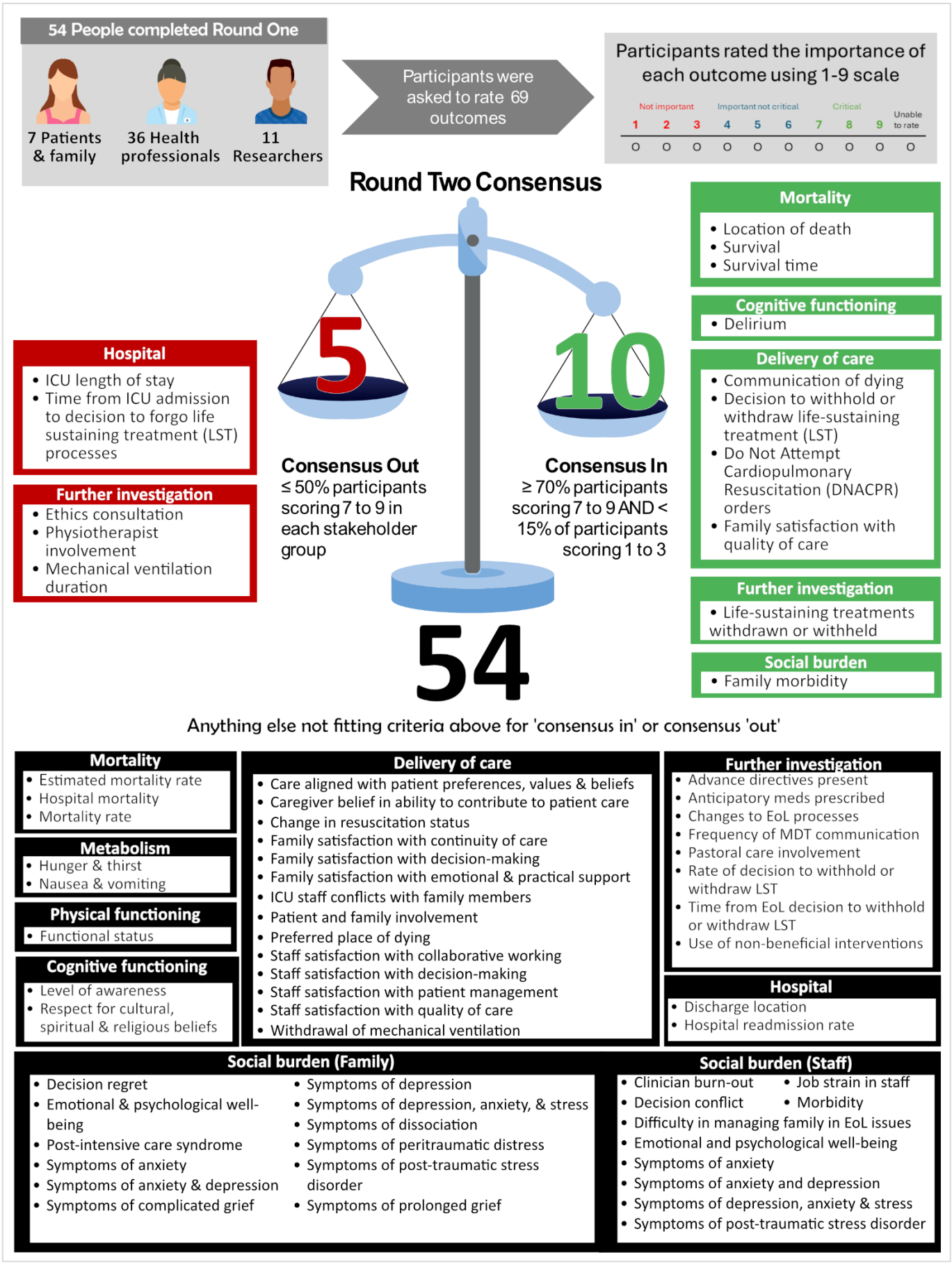


Figure 5.18 Round Two consensus infographic

Table 5.10 Round Two rating by stakeholder group

Outcome	Rating	Patient and Family	Health professional	Researcher	Round Two Consensus
		N (%)	N (%)	N (%)	
01: Mortality outcomes					
Estimate mortality rate	Not important	- -	1 (2.8)	2 (18.2)	No consensus
	Important	2 (28.6)	16 (44.4)	2 (18.2)	
	Critical	5 (71.4)	19 (52.8)	7 (63.6)	
Hospital mortality	Not important	- -	1 (2.9)	2 (18.2)	No consensus
	Important	1 (14.3)	7 (20.0)	3 (27.3)	
	Critical	6 (85.7)	27 (77.1)	6 (54.5)	
Mortality rate	Not important	- -	1 (2.8)	3 (27.3)	No consensus
	Important	2 (33.3)	8 (22.2)	1 (9.1)	
	Critical	4 (66.7)	27 (75)	7 (63.6)	
Survival	Not important	- -	1 (2.9)	2 (18.2)	In
	Important	- -	6 (17.1)	1 (9.1)	
	Critical	7 (100)	28 (80.0)	8 (72.7)	
Survival time	Not important	- -	- -	2 (18.2)	In
	Important	1 (16.7)	8 (22.9)	1 (9.1)	
	Critical	5 (83.3)	27 (77.1)	8 (72.7)	
Location of death	Not important	- -	- -	- -	In
	Important	2 (28.6)	10 (28.6)	- -	
	Critical	5 (71.4)	25 (71.4)	11 (100)	
14: Metabolism and nutrition outcomes					
Hunger and thirst	Not important	- -	- -	1 (9.1)	No consensus
	Important	2 (33.3)	10 (30.3)	1 (9.1)	
	Critical	4 (66.7)	23 (69.7)	9 (81.8)	
Nausea and vomiting	Not important	- -	- -	2 (18.2)	No consensus
	Important	2 (33.3)	7 (21.2)	2 (18.2)	
	Critical	4 (66.7)	26 (78.8)	7 (63.6)	
25: Physical functioning outcomes					
Functional status	Not important	- -	- -	1 (9.1)	No consensus
	Important	2 (40.0)	17 (54.8)	6 (54.5)	
	Critical	3 (60.0)	14 (45.2)	4 (36.4)	
29: Cognitive functioning outcomes					
Respect for cultural, spiritual and religious beliefs	Not important	1 (16.7)	- -	- -	No consensus
	Important	1 (16.7)	8 (25)	- -	
	Critical	4 (66.7)	24 (75)	11 (100)	
Delirium	Not important	- -	- -	1 (9.1)	In
	Important	1 (16.7)	6 (18.8)	2 (18.2)	
	Critical	5 (83.3)	26 (81.3)	8 (72.7)	
Level of awareness	Not important	- -	- -	1 (9.1)	No consensus
	Important	2 (33.3)	10 (32.3)	2 (18.2)	
	Critical	4 (66.7)	21 (67.7)	8 (72.7)	
32: Delivery of care – End-of-Life outcomes					
Preferred place of dying	Not important	- -	1 (3.1)	- -	No consensus
	Important	3 (50.0)	14 (43.8)	1 (9.1)	
	Critical	3 (50.0)	17 (53.1)	10 (90.9)	
32: Delivery of care – Communication outcomes					
Communication of dying	Not important	- -	- -	- -	In
	Important	1 (16.7)	2 (6.3)	- -	
	Critical	5 (83.3)	30 (93.8)	11 (100)	

Outcome	Rating	Patient and Family	Health professional	Researcher	Round Two Consensus
		N (%)	N (%)	N (%)	
32: Delivery of care – Care satisfaction outcomes					
Caregiver belief in ability to contribute to patient care	Not important	- -	- -	- -	No consensus
	Important	3 (50.0)	12 (37.5)	3 (27.3)	
	Critical	3 (50.0)	20 (62.5)	8 (72.7)	
Family satisfaction with continuity of care	Not important	- -	1 (3.1)	- -	No consensus
	Important	2 (33.3)	11 (34.4)	1 (9.1)	
	Critical	4 (66.7)	20 (62.5)	10 (90.9)	
Family satisfaction with quality of care	Not important	- -	- -	- -	In
	Important	1 (16.7)	2 (6.3)	1 (9.1)	
	Critical	5 (83.3)	30 (93.8)	10 (90.9)	
Staff satisfaction with quality of care	Not important	- -	- -	- -	No consensus
	Important	2 (33.3)	5 (15.6)	2 (18.2)	
	Critical	4 (66.7)	27 (84.4)	9 (81.8)	
Family satisfaction with emotional and practical support	Not important	- -	- -	- -	No consensus
	Important	2 (33.3)	5 (15.6)	1 (9.1)	
	Critical	4 (66.7)	27 (84.4)	10 (90.9)	
Staff satisfaction with collaborative working	Not important	- -	1 (3.1)	- -	No consensus
	Important	3 (50.0)	9 (28.1)	2 (18.2)	
	Critical	3 (50.0)	22 (68.8)	9 (81.8)	
Staff satisfaction with patient management	Not important	- -	1 (3.1)	- -	No consensus
	Important	2 (33.3)	6 (18.8)	3 (27.3)	
	Critical	4 (66.7)	25 (78.1)	8 (72.7)	
32: Delivery of care - Decision-making outcomes					
Family satisfaction with decision-making	Not important	- -	- -	- -	No consensus
	Important	2 (33.3)	3 (9.4)	3 (27.3)	
	Critical	4 (66.7)	29 (90.6)	8 (72.7)	
Staff satisfaction with decision-making	Not important	- -	- -	1 (9.1)	No consensus
	Important	3 (50.0)	7 (21.9)	1 (9.1)	
	Critical	3 (50.0)	25 (78.1)	9 (81.8)	
Patient and family involvement	Not important	- -	- -	- -	No consensus
	Important	3 (50.0)	3 (9.4)	1 (9.1)	
	Critical	3 (50.0)	29 (90.6)	10 (90.9)	
Decision to withhold or withdraw life-sustaining therapy	Not important	- -	- -	- -	In
	Important	1 (16.7)	5 (15.6)	- -	
	Critical	5 (83.3)	27 (84.4)	11 (100)	
Care aligned with patient preferences, values and beliefs	Not important	- -	- -	- -	No consensus
	Important	3 (50.0)	6 (18.8)	- -	
	Critical	3 (50.0)	26 (81.3)	11 (100)	

Outcome	Rating	Patient and Family	Health professional	Researcher	Round Two Consensus
		N (%)	N (%)	N (%)	
ICU staff conflicts with family members	Not important	- -	1 (3.1)	- -	No consensus
	Important	3 (50.0)	13 (40.6)	2 (18.2)	
	Critical	3 (50.0)	18 (56.3)	9 (81.8)	
Change in resuscitation status	Not important	- -	3 (9.4)	1 (9.1)	No consensus
	Important	2 (40.0)	10 (31.3)	2 (18.2)	
	Critical	3 (60.0)	19 (59.4)	8 (72.7)	
DNACPR orders	Not important	- -	- -	1 (9.1)	In
	Important	1 (16.7)	6 (18.8)	1 (9.1)	
	Critical	5 (83.3)	26 (81.3)	9 (81.8)	
32: Delivery of care – Withdrawal outcomes					
Withdrawal of mechanical ventilation (terminal wean)	Not important	- -	1 (3.1)	2 (18.2)	No consensus
	Important	2 (33.3)	11 (34.4)	1 (9.1)	
	Critical	4 (66.7)	20 (62.5)	8 (72.7)	
34: Hospital outcomes					
ICU length of stay	Not important	- -	5 (15.6)	1 (9.1)	Out
	Important	5 (83.3)	16 (50)	7 (63.6)	
	Critical	1 (16.7)	11 (34.4)	3 (27.3)	
Time from ICU admission to decision to FLST	Not important	- -	- -	1 (9.1)	Out
	Important	5 (83.3)	17 (53.1)	6 (54.5)	
	Critical	1 (16.7)	15 (46.9)	4 (36.4)	
Discharge location	Not important	- -	3 (9.4)	1 (9.1)	No consensus
	Important	5 (83.3)	14 (43.8)	2 (18.2)	
	Critical	1 (16.7)	15 (46.9)	8 (72.7)	
Hospital readmission rate	Not important	- -	2 (6.3)	1 (9.1)	No consensus
	Important	2 (33.3)	19 (59.4)	4 (36.4)	
	Critical	4 (66.7)	11 (34.4)	6 (54.5)	
36: Further investigation – organ support outcomes					
Mechanical ventilation duration	Not important	- -	2 (6.3)	2 (18.2)	Out
	Important	3 (50.0)	21 (65.6)	4 (36.4)	
	Critical	3 (50.0)	9 (28.1)	5 (45.5)	
Use of nonbeneficial interventions	Not important	- -	1 (3.1)	1 (9.1)	No consensus
	Important	2 (40.0)	9 (28.1)	2 (18.2)	
	Critical	3 (60.0)	22 (68.8)	8 (72.7)	
Life-sustaining treatments withdrawn	Not important	- -	- -	- -	In
	Important	1 (16.7)	9 (28.1)	2 (18.2)	
	Critical	5 (83.3)	23 (71.9)	9 (81.8)	
36: Further investigation – MDT outcomes					
Ethics consultations	Not important	- -	3 (9.4)	1 (9.1)	Out
	Important	4 (66.7)	15 (46.9)	5 (45.5)	
	Critical	2 (33.3)	14 (43.8)	5 (45.5)	
Pastoral care involvement	Not important	- -	- -	1 (9.1)	No consensus
	Important	4 (66.7)	10 (31.3)	2 (18.2)	
	Critical	2 (33.3)	22 (68.8)	8 (72.7)	
Physiotherapist involvement	Not important	- -	- -	3 (27.3)	Out
	Important	3 (50.0)	20 (62.5)	5 (45.5)	
	Critical	3 (50.0)	12 (37.5)	3 (27.3)	
Frequency of multidisciplinary communication	Not important	- -	2 (6.3)	2 (18.2)	No consensus
	Important	2 (33.3)	6 (18.8)	- -	
	Critical	4 (66.7)	24 (75)	9 (81.8)	

Outcome	Rating	Patient and Family	Health professional	Researcher	Round Two Consensus
		N (%)	N (%)	N (%)	
36: Further investigation – Prescribing, procedures and processes					
Anticipatory medication prescribed	Not important	- -	- -	1 (9.1)	No consensus
	Important	3 (50.0)	3 (9.4)	1 (9.1)	
	Critical	3 (50.0)	29 (90.6)	9 (81.8)	
Time to end-of-life decision to withhold or withdraw therapies	Not important	- -	1 (3.1)	1 (9.1)	No consensus
	Important	1 (16.7)	12 (37.5)	1 (9.1)	
	Critical	5 (83.3)	19 (59.4)	9 (81.8)	
Changes to end-of-life processes	Not important	- -	2 (6.7)	1 (9.1)	No consensus
	Important	2 (33.3)	7 (23.3)	3 (27.3)	
	Critical	4 (66.7)	21 (70.0)	7 (63.6)	
Rate of decision to withhold or withdraw life-sustaining therapies	Not important	- -	3 (9.4)	2 (18.2)	No consensus
	Important	2 (40.0)	7 (21.9)	3 (27.3)	
	Critical	3 (60.0)	22 (68.8)	6 (54.5)	
Advance directives present	Not important	- -	1 (3.1)	1 (9.1)	No consensus
	Important	2 (33.3)	13 (40.6)	4 (36.4)	
	Critical	4 (66.7)	18 (56.3)	6 (54.5)	
37: Social burden – Anxiety and depression outcomes					
Family symptoms of anxiety	Not important	- -	- -	- -	No consensus
	Important	3 (50.0)	5 (15.6)	2 (18.2)	
	Critical	3 (50.0)	27 (84.4)	9 (81.8)	
Staff symptoms of anxiety	Not important	- -	- -	1 (9.1)	No consensus
	Important	3 (50.0)	7 (21.9)	5 (45.5)	
	Critical	3 (50.0)	25 (78.1)	5 (45.5)	
Family symptoms of depression	Not important	- -	- -	- -	No consensus
	Important	3 (50.0)	9 (28.1)	3 (27.3)	
	Critical	3 (50.0)	23 (71.9)	8 (72.7)	
Family symptoms of anxiety and depression	Not important	- -	1 (3.1)	- -	No consensus
	Important	3 (50.0)	9 (28.1)	2 (18.2)	
	Critical	3 (50.0)	22 (68.8)	9 (81.8)	
Staff symptoms of anxiety and depression	Not important	- -	1 (3.1)	1 (9.1)	No consensus
	Important	2 (33.3)	9 (28.1)	4 (36.4)	
	Critical	4 (66.7)	22 (68.8)	6 (54.5)	
Family symptoms of depression, anxiety, and stress	Not important	- -	1 (3.2)	- -	No consensus
	Important	3 (50.0)	7 (22.6)	2 (18.2)	
	Critical	3 (50.0)	23 (74.2)	9 (81.8)	
Staff symptoms of depression, anxiety, and stress	Not important	- -	1 (3.1)	1 (9.1)	No consensus
	Important	2 (33.3)	8 (25)	4 (36.4)	
	Critical	4 (66.7)	23 (71.9)	6 (54.5)	
Family Post-intensive care syndrome	Not important	- -	1 (3.1)	- -	No consensus
	Important	2 (33.3)	5 (15.6)	1 (9.1)	
	Critical	4 (66.7)	26 (81.3)	10 (90.9)	

Outcome	Rating	Patient and Family	Health professional	Researcher	Round Two Consensus
		N (%)	N (%)	N (%)	
37: Social burden – Stress outcomes					
Family symptoms of peritraumatic distress	Not important	- -	2 (6.3)	- -	No consensus
	Important	3 (50.0)	9 (28.1)	2 (18.2)	
	Critical	3 (50.0)	21 (65.6)	9 (81.8)	
Family symptoms of dissociation	Not important	- -	3 (9.4)	- -	No consensus
	Important	2 (33.3)	17 (53.1)	4 (36.4)	
	Critical	4 (66.7)	12 (37.5)	7 (63.6)	
Family symptoms of post-traumatic stress disorder (PTSD)	Not important	- -	2 (6.3)	- -	No consensus
	Important	2 (33.3)	10 (31.3)	1 (9.1)	
	Critical	4 (66.7)	20 (62.5)	10 (90.9)	
Staff symptoms of post-traumatic stress disorder (PTSD)	Not important	- -	2 (6.3)	1 (9.1)	No consensus
	Important	2 (33.3)	7 (21.9)	3 (27.3)	
	Critical	4 (66.7)	23 (71.9)	7 (63.6)	
Family emotional and psychological well-being	Not important	- -	- -	- -	No consensus
	Important	3 (50.0)	7 (21.9)	2 (18.2)	
	Critical	3 (50.0)	25 (78.1)	9 (81.8)	
Staff emotional and psychological well-being	Not important	- -	- -	1 (9.1)	No consensus
	Important	2 (33.3)	5 (15.6)	4 (36.4)	
	Critical	4 (66.7)	27 (84.4)	6 (54.5)	
Family morbidity	Not important	- -	1 (3.1)	1 (9.1)	In
	Important	1 (16.7)	6 (18.8)	2 (18.2)	
	Critical	5 (83.3)	25 (78.1)	8 (72.7)	
Staff morbidity	Not important	- -	1 (3.1)	2 (18.2)	No consensus
	Important	4 (66.7)	6 (18.8)	2 (18.2)	
	Critical	2 (33.3)	25 (78.1)	7 (63.6)	
37: Social burden – Grief outcomes					
Family symptoms of complicated grief	Not important	- -	- -	- -	No consensus
	Important	2 (33.3)	5 (15.6)	1 (9.1)	
	Critical	4 (66.7)	27 (84.4)	10 (90.9)	
Family symptoms of prolonged grief	Not important	- -	- -	1 (9.1)	No consensus
	Important	2 (33.3)	4 (12.5)	- -	
	Critical	4 (66.7)	28 (87.5)	10 (90.9)	
37: Social burden – Conflict outcomes					
Staff difficulty in managing family in end-of-life issues	Not important	- -	- -	1 (9.1)	No consensus
	Important	3 (50.0)	7 (21.9)	3 (27.3)	
	Critical	3 (50.0)	25 (78.1)	7 (63.6)	
Family decision regret	Not important	- -	- -	2 (18.2)	No consensus
	Important	3 (50.0)	8 (25)	- -	
	Critical	3 (50.0)	24 (75)	9 (81.8)	
Decision conflict	Not important	- -	- -	- -	No consensus
	Important	3 (50.0)	5 (15.6)	2 (18.2)	
	Critical	3 (50.0)	27 (84.4)	9 (81.8)	

Outcome	Rating	Patient and Family	Health professional	Researcher	Round Two Consensus
		N (%)	N (%)	N (%)	
Clinician burn-out	Not important	- -	- -	1 (9.1)	No consensus
	Important	3 (50.0)	2 (6.3)	1 (9.1)	
	Critical	3 (50.0)	30 (93.8)	9 (81.8)	
Job strain in staff	Not important	- -	- -	1 (9.1)	No consensus
	Important	4 (66.7)	5 (15.6)	2 (18.2)	
	Critical	2 (33.3)	27 (84.4)	8 (72.7)	

- = 0

5.12.3 Scoring changes

Overall, there were 1,165 changes by panellists to their ratings between successive rounds (**Table 5.11**). Only one participant (a health professional) made no modification. Fifty-three (98.15%) participants increased at least one rating (occurrence 1-48 times, rating increase range 1-6) while 50 (92.59%) decreased one or more of their ratings (occurrence 1-27 times, rating reduction range 1-5).

Table 5.11 Round Two number of rating changes

Rating	**Patient and family** **N= 304 (%)**	**Health professionals** **N=1,668 (%)**	**Researchers** **N=568 (%)**
Increased	70 (23.03)	492 (29.50)	153 (26.94)
Decreased	48 (15.79)	276 (16.55)	126 (22.19)
No change	186 (61.18)	900 (53.96)	289 (50.88)

Participant score changes resulted in category changes between rounds, with variations between stakeholder groups (**Table 5.12**). Changes in scores from patients/family showed the least impact on their relationship to the consensus threshold, with 90.13% (274) of score changes remaining within the ‘not important’, ‘important’, or ‘critical’ categories of the rating scale. This suggests patient and family opinions had a greater convergence of opinions without affecting the consensus threshold (**Table 5.13**).

Table 5.12 Round Two: number of rating changes within categories

Rating	Patient and family		Health professionals		Researchers	
	N=304	(%)	N=1668	(%)	N=568	(%)
Increased	24	(7.89)	286	(17.14)	115	(20.25)
Decreased	6	(1.97)	103	(6.18)	46	(8.10)
No change	274	(90.13)	1,279	(76.67)	407	(71.65)

Table 5.13 Round Two: number of rating changes across consensus threshold

Rating	Patient and family		Health professionals		Researchers	
	N=304	(%)	N=1668	(%)	N=568	(%)
Increased	17	(5.59)	242	(14.50)	102	(17.96)
Decreased	6	(1.97)	90	(5.40)	26	(4.58)
No change	281	(92.43)	1,336	(80.10)	440	(77.46)

Free-text boxes requesting a rationale for a score change received 231 comments. A schematic representation of the coding framework is provided in **Figure 5.19**. Ten ‘parent’ codes delineate the overarching themes derived from participants' free-text rationales, which were expanded into 29 ‘child’ codes articulating subthemes within the parent codes. Code descriptions with illustrative quotes are provided in **Appendix 60.**

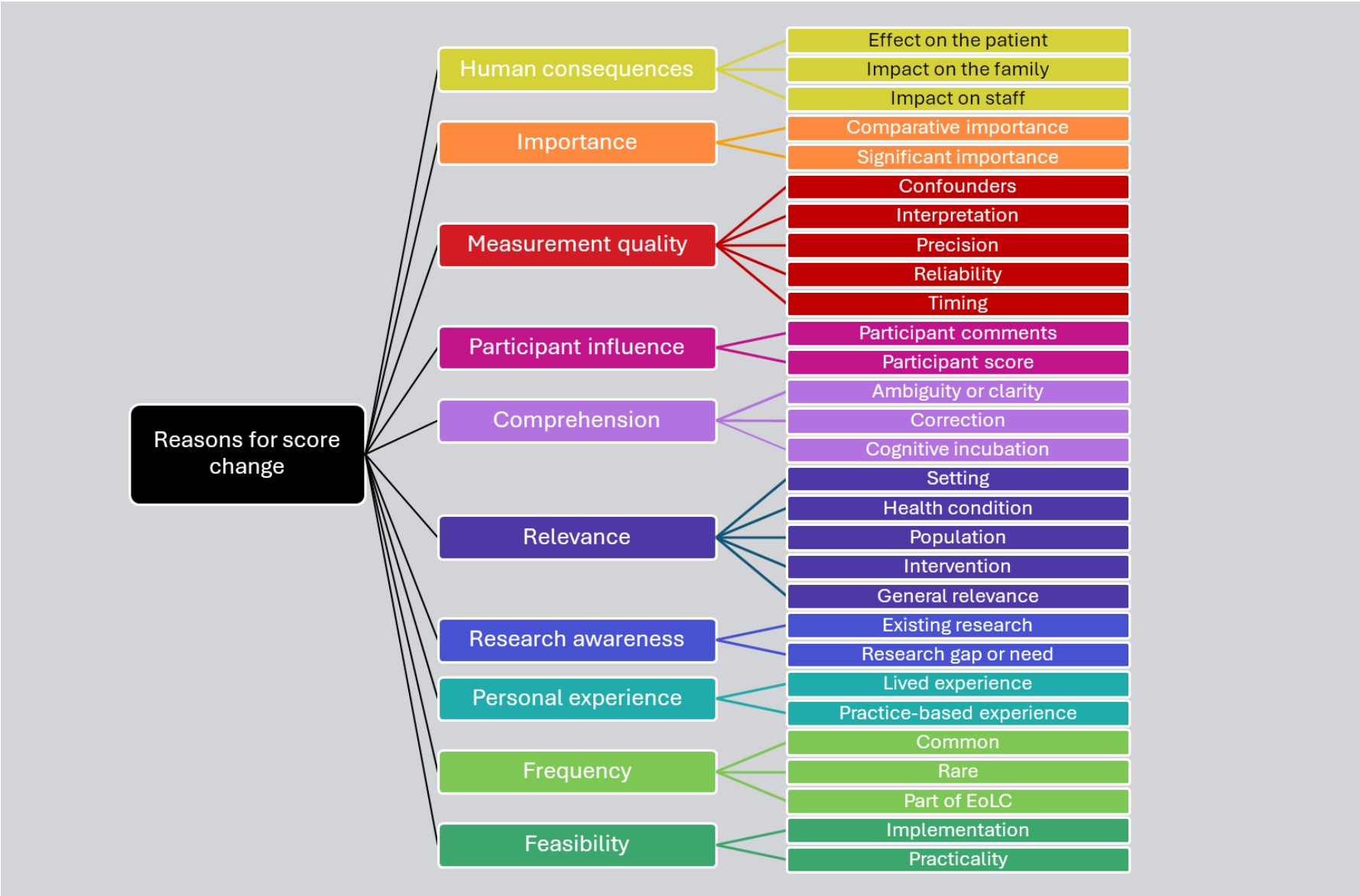


Figure 5.19 Thematic scheme of reasons for score change

Overall, human consequences (52 comments, 22.5%) were the most frequently applied code, followed by importance (46, 19.9%) and measurement quality (24, 10.4%) (**Table 5.14**). Variations, however, were evident between stakeholder groups in the distribution, with researchers citing importance as the second most frequent reason for score change, with no comments attributed to the personal experience code. Similarities were evident between the patient and family and health professionals stakeholder groups.

Table 5.14 Free-text comments reason for score change

Theme	Patient and Family	Health professional	Researcher	All comments
	n %	n %	n %	N %
Human consequences	16 (30.19)	30 (23.08)	6 (12.50)	52 (22.51)
Importance	9 (16.98)	25 (19.23)	12 (25.00)	46 (19.91)
Measurement quality	5 (9.43)	15 (11.54)	4 (8.33)	24 (10.39)
Participant influence	4 (7.55)	12 (9.23)	5 (10.42)	21 (9.09)
Comprehension	3 (5.66)	10 (7.69)	7 (14.58)	20 (8.66)
Relevance	2 (3.77)	13 (10.00)	3 (6.25)	18 (7.79)
Research awareness	3 (5.66)	5 (3.85)	6 (12.50)	14 (6.06)
Personal experience	5 (9.43)	7 (5.39)	- -	12 (5.19)
Frequency	4 (7.55)	5 (3.85)	3 (6.25)	12 (5.19)
Feasibility	2 (3.77)	8 (6.16)	2 (4.17)	12 (5.19)
Total	**53 (100)**	**130 (100)**	**48 (100)**	**231 (100)**

- = 0

Within the human consequence theme, three subthemes were identified: effect on the patient, impact on the family and impact on staff, with only effect on the patient and impact on the family common to all three stakeholder groups. Similarities were evident within the participant influence theme, where all three stakeholder groups described being influenced by the comments of other eDelphi participants yet only patient/family members and health professionals commented about being influenced by the scores of other eDelphi participants.

5.12.4 Critical and not critical for inclusion themes

No novel codes emerged upon application of the coding frameworks developed in Round One to the free-text comments in Round Two. Illustrative quotes can be found in **Appendix 61** and **Appendix 62**.

5.12.5 Attrition analysis

Attrition varied per round between stakeholder groups. Patients and family members had the highest attrition rate during Round One (30.76%), and Health professionals during Round Two (29.41%). The overall attrition rate was 26.03%. Participant flow is illustrated in **Figure 5.20**.

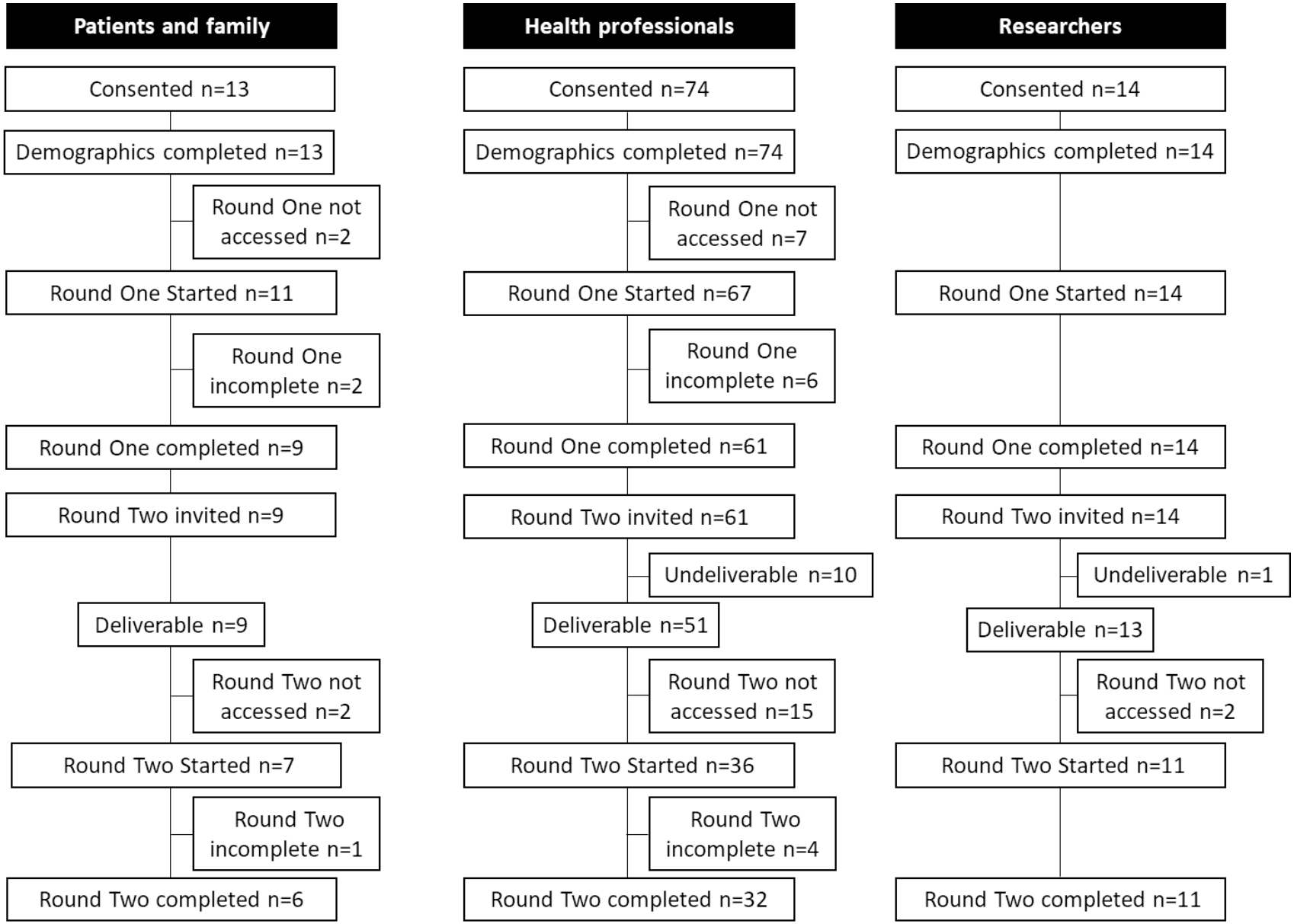


Figure 5.20 Participant flow

5.13 Discussion

Through the international two-round modified eDelphi study, Stage Three of the PEACE-COS study identified 27 outcome measures to assess in all research evaluating EoLC in critical care. International guidelines and recommendations for the development of COS and the conduct and reporting of Delphi studies were followed (Jünger et al., 2017; Kirkham et al., 2017; Williamson et al., 2017).

Person-centred approaches view individuals as whole people rather than a collection of problems, symptoms, or needs, considering physical, emotional, social, spiritual, and environmental dimensions (Byrne et al., 2020). They acknowledge that each individual is inherently unique, shaped by their own experiences, values, preferences, and context. This presented panellists with considerable challenges when trying to achieve consensus around both outcomes and constructs. During both rounds of the eDelphi, all stakeholder groups commented on the challenges encountered in EoL and EoLC. Panellists found it difficult to differentiate between elements essential to all care and outcomes specific to research in EoLC. Comments centred on the context, complexity, multiplicity, interpretation and intersecting relationships with all stakeholder groups, emphasising the importance of understanding a person beyond the standardised domains outlined in the COMET taxonomy.

Communication of dying was the only novel outcome suggested by panellists during Round One that was subsequently included in the Round Two questionnaire. Following Round Two scoring, panellists reached the predefined consensus threshold, resulting in its inclusion for Stage Four of the study. Incorporating the outcome broadened the communication constructs while enhancing content validity, comprehensiveness and relevance of the COS to capture clinically meaningful endpoints not captured in Stages One or Two of the study.

Although no critical care COS have reported the percentage of participants changing score for at least one outcome between Round One and Round Two, results are comparable to those of anal, gastric and prostate cancer COS (97%, 84% and 92%) (Fish et al., 2020). These findings support work by Fish et al., (2020) substantiating the superiority of the eDelphi technique over single-round questionnaires for COS development, when achieving panel consensus is paramount.

In contrast to other critical care COS, panellists received both qualitative and traditional statistical feedback during Round Two. This dual feedback captured the contextual considerations and nuanced perspectives, providing panellists with greater insight into why standpoints were held, facilitating a more informed examination of their own scoring in Round Two. Anonymised comments illuminated divergent rationales and the complexity of EoL, which purely quantitative summaries obscure.

Within COS development, limited evidence exists examining free-text comments to ascertain reasons for score selection or the reasons why participants change in subsequent rounds with only three studies reporting such data that the researcher is aware of. Zambrano et al., (2025) stated that feedback related to personal experience, the outcome description, or the importance of a given outcome in patient care; however, the study failed to report the analytical processes used to generate interpretations, limiting the credibility and dependability of the findings. Outcome description and outcome importance resonate with two themes in this study regarding the reasons for score selection; however, this study identified an additional 12 novel themes that extend the current understanding of the score selection in EoLC outcomes.

Fish et al., (2020) found participants changed scores between rounds due to time to reflect and vicarious thinking (actively considering others' perspectives, especially after viewing numerical group feedback). In contrast, Sautenet et al., (2017) found score change to be attributed to the capacity to control outcomes, debilitating consequences and knowledge gaps, emphasising clinical and experiential reasoning. Conceptual alignment is evident in this study, with some themes from both aforementioned studies. Participant influence broadly aligns with vicarious thinking; however, the score changes observed in this study were attributed to viewing participants' comments rather than numerical group feedback. This distinction is methodologically important, and these findings contribute to a nuanced understanding of consensus formation, highlighting that reassessment of priorities is a dynamic, interactive process. Similarly debilitating consequences are congruent with the subtheme effect on the patient. The most common reason for change in this study was 'human consequences', which reflects the centrality of impact and effects on patients, families, and health professionals beyond those identified by Sautenet et al., (2017).

Comments within this study demonstrated the complex relational nature of EoL, where outcomes and EoLC cannot be separated from the context in which they operate and highlights the importance of developing person-centred outcome measures.

The coding frameworks developed in Round One, for reasons critical and non-critical for inclusion, required minimal refinement in Round Two, demonstrating strong applicability and robustness across successive rounds. Furthermore, the six themes identified in the description matrix enabled the refinement of the outcome descriptors for Round Two.

Several participants self-identified with a stakeholder group different from that anticipated by the researcher. For example, two participants invited as authors on studies included in Stage One self-identified as health professionals rather than researchers. This disparity could have arisen due to individuals holding multiple roles simultaneously or the contextual shift in expertise and responsibility encountered related to the COVID-19 period where non-COVID research activities had to be paused and some researchers returned to clinical roles to meet the unprecedented demand for critical care expertise, resulting in authorship outside the criteria used to define expertise (Bhutkar et al., 2023; Sathian et al., 2020; Thornton, 2020). Whilst authorship in a peer-reviewed publication or clinical experience are frequently employed criteria for defining expertise, no guidelines or selection standards exist (Shang, 2023), resulting in methodological variation in expertise across studies and an area for future research. The post-hoc reallocation of participants within stakeholder groups has been reported by COS developers, arising from both recruitment deficits and discrepancies in participant self-identification, but this risks conflating epistemically distinct perspectives and inflating or suppressing consensus. Furthermore, Khodyakov et al. (2023) suggest that the quality of the Delphi panel results is contingent upon panellists' capacity to express their perspectives coupled with their expertise and experience.

Attrition occurred between eDelphi rounds, which could be attributed to a combination of factors, such as the number of outcomes, and Round Two was open for a shorter time than Round One. The steering committee considered adopting a broader conceptual stance, such as merging a range of symptoms into one ‘symptomology’ construct. Stage Two participants and public research partners, however, consistently emphasised the importance of subtle nuances in EoLC that would have been lost in more aggregated interpretations, thereby affecting participants' understanding of the phenomenon.

5.14 Strengths

The methodology employed throughout the eDelphi study was defined *a priori* and consistent with international consensus recommendations (Kirkham et al., 2017, 2019), enabling important progress to be achieved in developing a core outcome set for EoLC in critical care. The anonymity provided through using REDCap reduced subject bias as each opinion carried the same weight and was afforded equal importance (Keeney et al., 2001). This is imperative in healthcare settings where power differentials are known to exist between stakeholders and evidence suggests that patients/family priorities may not be congruent with those of healthcare professionals. Furthermore, the eDelphi technique ensured the process is not dominated by specific individuals.

5.15 Limitations

Although the study aimed to recruit an equitable number of patient/family and researcher stakeholders, both groups had lower representation compared to the health professionals stakeholder group. Such limitations, however, are not unique to this study. Similar recruitment challenges have been documented in the development of both adult and paediatric critical care COS (Fink et al., 2020). Blackwood et al. (2019) encountered comparable limitations in the number of patient/family participants in the development of a COS for critical care ventilation trials, identifying only two ICU support groups, concluding they were not well established internationally and were difficult to access. Fink et al. (2020) encountered similar challenges with their family stakeholder group when developing a COS for paediatric critical care. This study's findings suggest that the situation remains largely unchanged, providing an area for future research. Defining consensus within individual stakeholder groups, rather than across the aggregate panel, however, mitigated the disproportionate influence of the health professionals stakeholder group. Employing this approach preserved methodological integrity, ensuring equitable representation of all panel members (Brookes et al., 2016; Gargon et al., 2019).

Heterogeneity of expertise was evident throughout, with geographical heterogeneity maintained between Rounds One and Two. Biases in the panel, however, could be present due to the predominance of UK-based experts. Furthermore, only one low/middle-income country (LMIC) (Uganda) were represented (World Bank Country and Lending Groups, 2025). The limited representation of LMIC countries could constrain and compromise the global applicability, reflecting high-income country priorities and

potentially omitting contextually relevant outcomes. Conversely, the geographical distribution of the Delphi panellists broadly reflects the existing research base identified during Stage One of the COS development, with representation concentrated in high rather than LMICs. This alignment could explain the representation of the researcher stakeholder group, in which only those with direct research experience were included to rate the importance of proposed outcomes, in line with the current COS development recommendations (Williamson et al., 2017). Future iterations of this COS's development should therefore prioritise proactive engagement with low- and middle-income countries to ensure that its evolution reflects a more equitable distribution of expertise, thereby increasing global relevance.

Constrained by finance and time, Stage Three of the PEACE-COS study was conducted only in English, potentially excluding linguistically diverse populations and may have contributed to the limited representation of low- and middle-income countries. Despite this, Round One and Two were completed by participants in nine countries, English was not the native language in seven. Throughout the eDelphi, participants completed the free-text boxes, enabling nuanced linguistic and cultural expressions of EoL concepts to be captured. Cross-cultural adaptation of the outcomes and descriptions through forward-backwards translation techniques and cultural validation procedures could have further ensured conceptual equivalence across languages and enhanced the outcomes' representativeness and validity. To minimise data entry errors and facilitate international dissemination, the study was conducted exclusively online, with no provision for participation via non-digital means, limiting participation to those with computer literacy and internet access.

5.16 Conclusion

Through a transparent process 27 outcomes across eight domains of the COMET taxonomy achieved consensus (Dodd et al., 2018). Framework analysis after each round facilitated a transparent and rigorous synthesis of qualitative data, enabled differentiation between misunderstandings and misinterpretations of the outcomes, and accounted for reasons outcomes were not considered critical in Round One and the number of score changes between rounds. Twenty-three themes for score selection and 10 for why participants changed scores between rounds emerged. The findings extend the knowledge base of COS development, but further research is needed to determine whether this

reflects study-specific characteristics or is generalisable across diverse settings, health conditions/populations, and interventions.

5.17 Next chapter

Chapter Five has presented how an eDelphi study led to the identification of 27 outcomes. The following chapter reports Stage Four of the PEACE-COS study: an international consensus meeting to review the outcomes identified in Stage Three and reach a final agreement on those outcomes for inclusion in the COS on ‘what’ to measure.

Chapter 6: An International Consensus Meeting

6.1 Abstract

***Objectives*:** To agree and ratify what person-centred outcomes should be included in the COS for EoLC in critical care.

Methods: Using elements of a modified nominal group technique, a pre-consensus and a final consensus meeting brought together key stakeholders to review potential outcome definitions and finalise the outcomes for inclusion in the COS. Consensus for inclusion in the COS was defined *a priori* as outcomes scoring ≥70% as critical using a three-point Likert scale (not important, important, critical).

***Results*:** Participants (three stakeholder groups combined) agreed and ratified the inclusion of six core outcomes: pain, respiratory distress, delirium, dignity, quality of death and dying, and quality of communication.

Conclusion: This is the first study to identify a core outcome set for research evaluating EoLC in critical care, providing the foundation for standardising outcome reporting, enabling inter-study comparisons, while improving the relevance of research outcomes to patients and family members, health professionals, and researchers. Determining appropriate outcome measurement instruments represents the next critical step to facilitate the synthesis of EoLC critical care research.

Public Researcher Partners Contribution: Study design, public-facing study documents, participant engagement resources, piloting and presentation of findings.

6.2 Introduction

The final stage of developing *'what'* to measure in a core outcome set requires a structured consensus process with key stakeholders to agree and ratify the 'core' set of outcomes identified during Stage Three (Williamson et al., 2017). Through a systematic and transparent approach, a pre-consensus and consensus meeting were convened. Chapter Six presents the design, conduct and analysis of the meetings. Results highlight areas of agreement and divergence in why outcomes were considered 'core'. The final COS is presented.

6.3 Methods

6.3.1 Aims

The primary aim of the pre-consensus meeting was to improve subsequent decision-making by enhancing outcome clarity, patient/family engagement, and meeting efficiency. As a result, voting was formative rather than summative. In contrast, the final consensus meeting aimed to ratify the *'what'* to measure element of the COS. The objectives of both meetings were to review commonalities and differences in the reasons why outcomes were considered core or non-core. Following public research partner (PRP) recommendations, a pre-consensus meeting was convened first with patient/family members and stakeholders representing patient and family support groups/charities to facilitate sensitivity in the discussions.

6.3.2 Study design

Due to the cost of international travel and the geographic dispersion of participants, both meetings were conducted synchronously in English via Microsoft TEAMS video conferencing. The pre-consensus meeting was convened on 29th May 2025, with the main consensus meeting held on 4th September 2025.

6.3.3 Sample identification

Similar to the modified Delphi technique, the modified Nominal Group Technique (mNGT) does not rely on statistical power (Ven & Delbecq, 1974). Instead, a pragmatic decision was made to recruit a small representative group of between 10-15 participants with the aim of a final sample of between 7-10 participants, accounting for attrition. This range has been recommended as the optimal size to facilitate small group discussions (Ven & Delbecq, 1974).

Using stratified purposive sampling, participants from all stakeholder groups who completed all rounds of the eDelphi study and indicated their willingness to participate in a consensus meeting in Stage Three were invited. The aims were to be diverse in terms of age, gender, ethnicity and experience. In addition, representatives from secondary stakeholder groups (such as policy and guideline developers, charities, and support groups) were also invited in line with COMET recommendations (Williamson et al., 2017).

6.3.4 Ethical approval and consent

Ethical approval was granted by the Health Research Authority and Health and Care Research Wales (HCRW), and institutional approval from the University of Hertfordshire Health, Science, Engineering and Technology Committee as outlined in **Chapter 2 2.4**. Prior to the meetings convening, informed e-consent (**Appendix 63**) and demographic details were obtained from each participant using REDCap (**Appendix 64**). Participants were provided with preparatory guidance developed in conjunction with public research partners and in line with COMET and virtual NGT recommendations (Gorst et al., 2021; Smith et al., 2024). This encompassed an introduction to COS, a brief outline of EoLC in critical care, guidance on using Microsoft TEAMS (**Appendix 65**) and, if applicable, a copy of their personal eDelphi scoring from Stage Three. This process allowed participants time to reflect on their previous answers and provided a means of pre-elicitation. Participants were also offered the opportunity to attend a technical familiarisation event to experience the platform before the consensus meetings, together with links to appropriate support services.

6.3.5 Steering committee consultation

Stage Three **(Chapter Five, section 5.13)** identified 27 outcomes for inclusion (rated by each stakeholder group as ‘critical for inclusion’ by >70%, and ‘not important’ by <15%), nearly triple the recommended number of outcomes for a COS (Williamson et al., 2017). Including 27 outcomes in a COS presented significant methodological, logistical and practical challenges. An overly expansive COS could burden both research participants and researchers, compromising the research conduct and data quality. Extensive outcome measurement increases participant fatigue and assessment burden (time, cognitive and emotional), contributing to higher attrition rates and increasing study costs (Calvert et al., 2018; Young & Bagley, 2016). Furthermore, selective, inconsistent outcome reporting could occur, undermining the standardisation that the COS aims to achieve. The need for a concise COS was therefore paramount, necessitating a pragmatic decision to reduce the number of outcomes for discussion and a post hoc deviation from the study protocol.

Members of the steering committee convened on three occasions to discuss, reduce and refine the number of outcomes to be considered during the consensus meeting. Each outcome that achieved consensus during Stage Three was discussed, identifying nine overlapping outcomes that could be merged without compromising construct coverage,

reducing the overall number of outcomes from 27 to 22 (**Table 6.1**). Outcome wording and associated descriptions were reviewed by public researcher partners for clarity.

Table 6.1 Outcomes for consensus meeting

Outcome	**Steering decision**
ICU mortality	Retain - no changes
Survival time	Retain - no changes
Survival	Retain - no changes
Location of death	Retain - no changes
Pain	Retain - no changes
Patient respiratory discomfort	Retain - no changes
Delirium	Retain - no changes
Patient quality of life	Retain - no changes
Quality of death and dying	Merged as quality of death and dying
Clinical compassion	
Personalising dying	Merged as patient-centredness of care
Patient-centredness of care	
Dignity	
Palliative care needs	Retain - no changes
Family preparation for patient dying	Merged as communication of dying
Communication of dying	
Satisfaction with end-of-life communication	Merged as quality of communication
Quality of communication	
Family satisfaction with quality of care	Retain - no changes
Family satisfaction with symptom management	Retain - no changes
Competency in end-of-life care	Retain - no changes
Decision to withhold or withdraw life-sustaining therapy	Retain - no changes
Do Not Attempt Cardiopulmonary Resuscitation orders	Retain - no changes
Satisfaction with withdrawal processes	Retain - no changes
Life-sustaining treatments withdrawn	Retain - no changes
Palliative care involvement	Retain - no changes
Family morbidity	Retain - no changes

6.3.6 Pilot

To assess the suitability and functionality of videoconferencing and online voting platforms, two pilot meetings were held, involving a representative from each stakeholder group (one patient/family member, one researcher, and one health professional). The pilots aimed to systematically evaluate ease of participant access, platform-specific limitations, and ensure the chosen platform was congruent with the study's methodological requirements. Two further pilots were conducted by the researcher with two members of the steering committee (NP, RG) to refine chair/facilitation procedures and mitigate technical issues that could impact participant experience or data quality. In line with virtual NGT recommendations, a facilitator's guide was developed to clarify roles, timing, and content (Smith et al., 2024).

6.3.7 Consensus meeting structure

Conducted in English, and facilitated by a minimum of two members of the steering committee with expertise in critical care and/or qualitative methodology (SKH, NP, RG), the consensus meetings followed a predetermined agenda divided into three sections (**Figure 6.1**). Public research partners contributed to the preparatory guidance, meeting structure, timings and voting techniques. Meeting lengths were determined by the number of outcomes to be considered, with appropriate breaks incorporated. To enhance participant contributions and address any incidents that arose, members of the steering committee held brief catch-ups between breaks (Katiri et al., 2021). The first section included an introduction to the COS, the specific objectives of the meeting and an explanation of how the mNGT would operate.

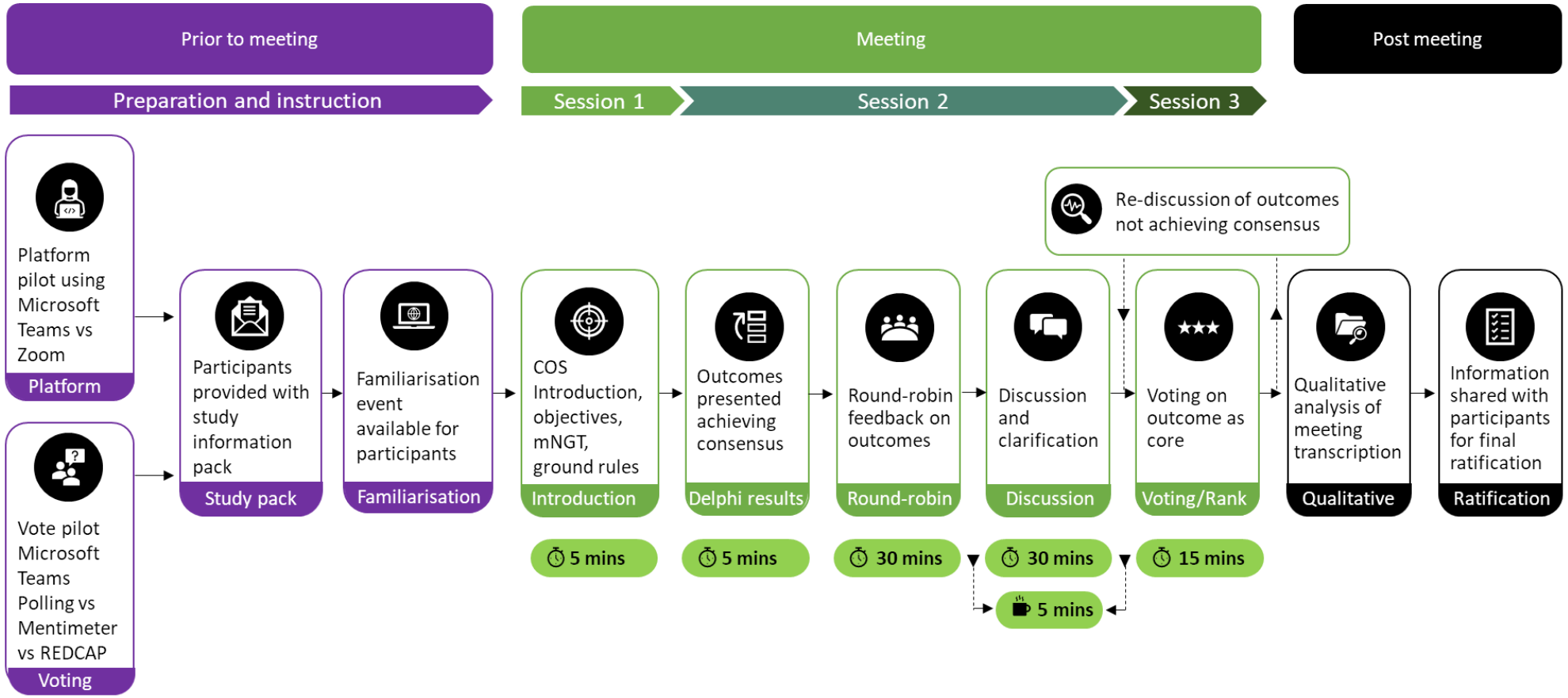
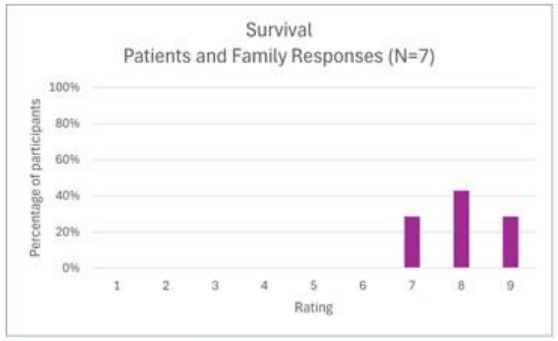


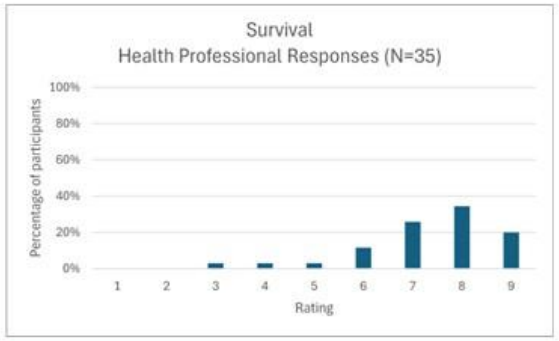
Figure 6.1 Overview of the modified nominal group technique process

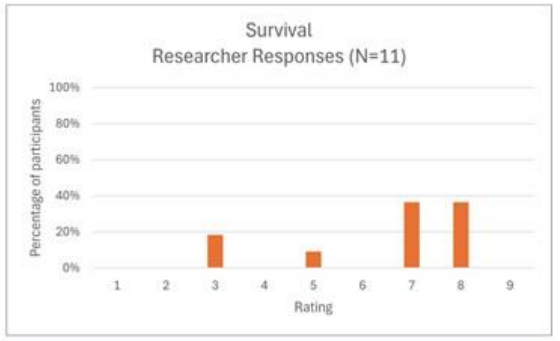
In the second session, feedback was sought from participants on the inclusion and exclusion of outcomes, which achieved consensus during Stage Three. For each outcome, a slide illustrating the results per stakeholder group was presented together with relevant quotes and descriptive statistics (**Figure 6.2).** Wording was shortened with slide information read out by the chair to facilitate accessibility. A standardised script was employed to ensure consistency, reduce ambiguity/variability and promote clear communication when presenting outcomes. Participants were asked, in turn (round robin), to comment on the presented outcome, but not to repeat an idea previously proposed. Verbal clarification was provided by the chair and/or facilitator as needed. Timed discussions were captured through audio-video recordings, and field notes were taken to accurately capture key points. Contrasting views were actively encouraged, with the chairperson ensuring all participants had equal opportunity to contribute before voting commenced in session three on the suitability of each outcome. To reduce anxiety and digital fatigue, participants had autonomy over when to activate their cameras. Gallery view was employed for interactive sessions to enhance engagement, group cohesion and interaction quality, simulating a sense of co-presence in an online environment.

Survival

- Number or percentage of patients who are alive at ICU or hospital discharge.







Median	8	8	7
IQR	[7,9]	[7,8]	[5,8]
"When the patient is in ICU at death's door survival is more important than religion and culture." [R133]		*"Survival: more focus on survival rates to help when survivors inevitably Google. Research often shows worst case scenarios."* [R252] *"Survival in itself is less important in my opinion than how one survives."* [R272]	*"These are all crucial factors, either to epidemiologists/ONS & specialist needs in certain areas."* [R168]

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Figure 6.2 Pre-consensus meeting survival outcome

During the main consensus meeting, breakout rooms in Microsoft TEAMS provided a structured, efficient way to facilitate the online mNGT. Participants were divided *a priori* into two subgroups to enable equitable contribution and enhance engagement (Chalmers et al., 2018), although due to attrition, one group only included one researcher. Two steering committee members (SKH, RG) could open and close rooms, move participants, and broadcast announcements across the two subgroups, ensuring coordination and alignment with the overall session objectives. Following the discussion of all outcomes, participants returned to the main meeting to share insights, promoting synthesis and collaborative reflection before voting in session three.

Slides were updated for the final consensus meeting to encompass the pre-consensus meeting results and discussions (**Figure 6.3).** Following participant feedback, histograms were altered to bar charts to enhance visual clarity and improve data communication for participants on mobile devices.

Survival

- Number or percentage of patients who are alive at ICU or hospital discharge.

	Delphi Results	Delphi Quotes	Patient Family Meeting
Patients and family		*"When the patient is in ICU at death's door survival is more important than religion and culture."* [R133]	
Health Professionals		*"Survival: more focus on survival rates to help when survivors inevitably Google. Research often shows worst case scenarios."* [R252] *"Survival in itself is less important in my opinion than how one survives."* [R272]	**Patient and Family Meeting** *"Is it just a matter of coming out alive at all costs, but also how long are they alive for? Some of them might not cope with whatever they're left with or with their experience in ICU or might have you know other health issues that mean they die soon after, or or take their own life. I mean, there's there's a lot of things to take into account."* [CM123]
Researchers		*"These are all crucial factors, either to epidemiologists/ONS & specialist needs in certain areas."* [R168]	

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Figure 6.3 Consensus meeting survival outcome

Underpinned by elements of Dual-Coding Theory (Mayer, 2024; Mayer et al., 2001) illustrated in **Chapter Five, Figure 5.2**, a study-specific voting and consensus criteria animation was developed and shown before voting. Technical issues during the pre-consensus meeting prevented anonymised voting. Instead, participants physically raised their hands, a method evident in other COS development consensus meetings (Chalmers et al., 2018). Mentimeter was subsequently used in the main consensus meeting to ensure anonymity. Participants could choose not to vote on any outcome they did not consider themselves to have the experience or expertise. Consensus criteria were defined *a priori* using the same 70% critical for inclusion threshold employed in the eDelphi and recommended by COMET (Williamson et al., 2012). The nine-point voting scale was compressed to a three-point scale, while preserving the three foundational categorial distinctions (critical for inclusion, important, not important) to reduce cognitive load and increase procedural accessibility and efficiency. The facilitator (SKH) immediately shared the results in both meetings, once each vote was closed, with visuals provided via Mentimeter during the main consensus meeting (**Figure 6.4**). Outcomes were rediscussed where consensus was not achieved, followed by a revote. Upon conclusion of the consensus meeting, the definitive core outcome set was established on *'what'* to measure.

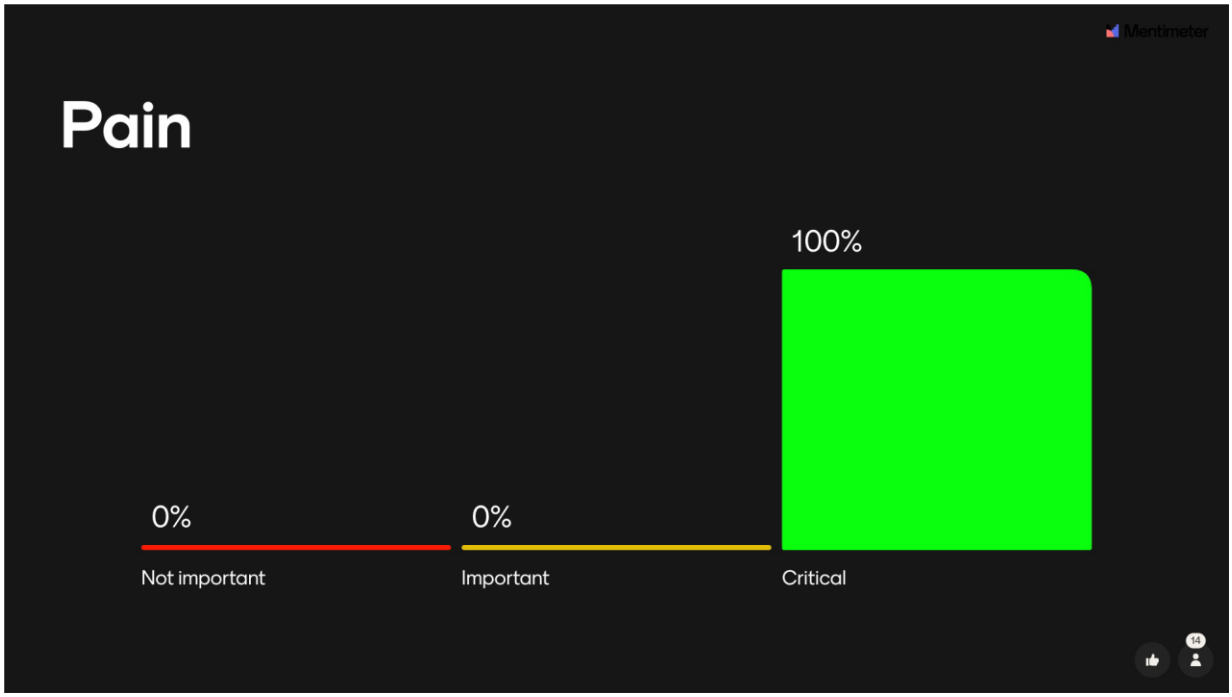


Figure 6.4 Example of consensus meeting voting

Throughout both meetings, all participants utilised the mute function to reduce cross-talk, and improve bandwidth and technical performance (accuracy of the initial transcription,

video/audio quality stability). Transcription automatically commenced using Microsoft TEAMS' artificial speech-recognition technology at the start and was manually initiated by the chairperson (NP, RG) within breakout rooms. Transcripts were available immediately post-meeting to the chairs and researcher, requiring extensive accuracy checking against the audiovisual recordings for context and meaning, facilitating data immersion and robust data analysis. Transcription was influenced by participants' accents, dialects, colloquialisms, pronunciation inflexions, and speaking rates. They were more accurate for participants who spoke slowly. Inconsistencies were evident in the sensitivity of speech fillers (um, er, ah), repetitions and false starts both within and across transcripts, with key words such as breathlessness and intubated being transcribed as briefness and incubated. Prolonged engagement with audiovisual recordings was therefore imperative, necessitating an evolving decision-making process on how to approach the transcriptions. Idiosyncratic elements such as nonverbal and involuntary vocalisations were omitted, resulting in transcripts treated as constructions as opposed to objective accounts of recorded data.

Amendments to the outcome descriptions were discussed during the main consensus meeting; however, due to time constraints, participants were contacted via email to ratify the final descriptions.

6.3.8 Qualitative data analysis

Following the completion of the pre-consensus meeting, a modified framework analysis was employed using a five-stage process previously illustrated in **Chapter Five, Figure 5.9**. The meeting transcript was imported into NVivo (version 14), creating a case per participant. Following a familiarisation process, data were deductively coded according to the themes identified in Stage Three: reasons critical for inclusion, reasons not critical for inclusion, and reasons for score change. Coding categories were therefore specified *a priori,* then merged with others that emerged from inductive analysis to identify reasons outcomes were considered ‘core’ or ‘non-core’ (Dixon-Woods, 2011; Ritchie & Spencer, 1994). Data were initially clustered into the 24 outcomes discussed during the pre-consensus meeting organised under the COMET taxonomy core areas (Dodd et al., 2018). A charting matrix was created in NVivo and a codebook was maintained throughout the process, containing explanatory descriptions. Quotes from the pre-consensus meeting were presented at the main consensus meeting. Transcripts from the main consensus meeting followed the same methodology. Data was subsequently analysed across

outcomes, meetings and stakeholder groups, facilitating the identification of areas of divergence and discordance.

6.4 Results

6.4.1 Pre-consensus meeting

Five patient-survivors, along with two representatives from patient support organisations (ICU Steps and The UK Sepsis Trust) were formally invited to participate in the pre-consensus meeting. Written consent was received from six, yielding a response rate of 86%. No attrition was evident between consent and participation, with all six (100%) participating. The mean age was 54 years (range 34-68), with a male: female ratio of 1:5. The sample was homogeneous, with all participants UK-based and self-reporting White ethnicity.

Twenty-two outcomes were initially discussed; participants did not agree with the steering committee's decision to merge quality of death and dying with clinical compassion, or to merge patient-centredness of care with dignity. Consequently, these two outcomes were discussed separately, creating twenty-four outcomes. Overall, six outcomes met the *a priori* criteria for consensus in, 17 met the criteria for consensus out, with one outcome reaching no consensus (**Figure 6.5**). A breakdown of the voting is provided in **Table 6.2.**

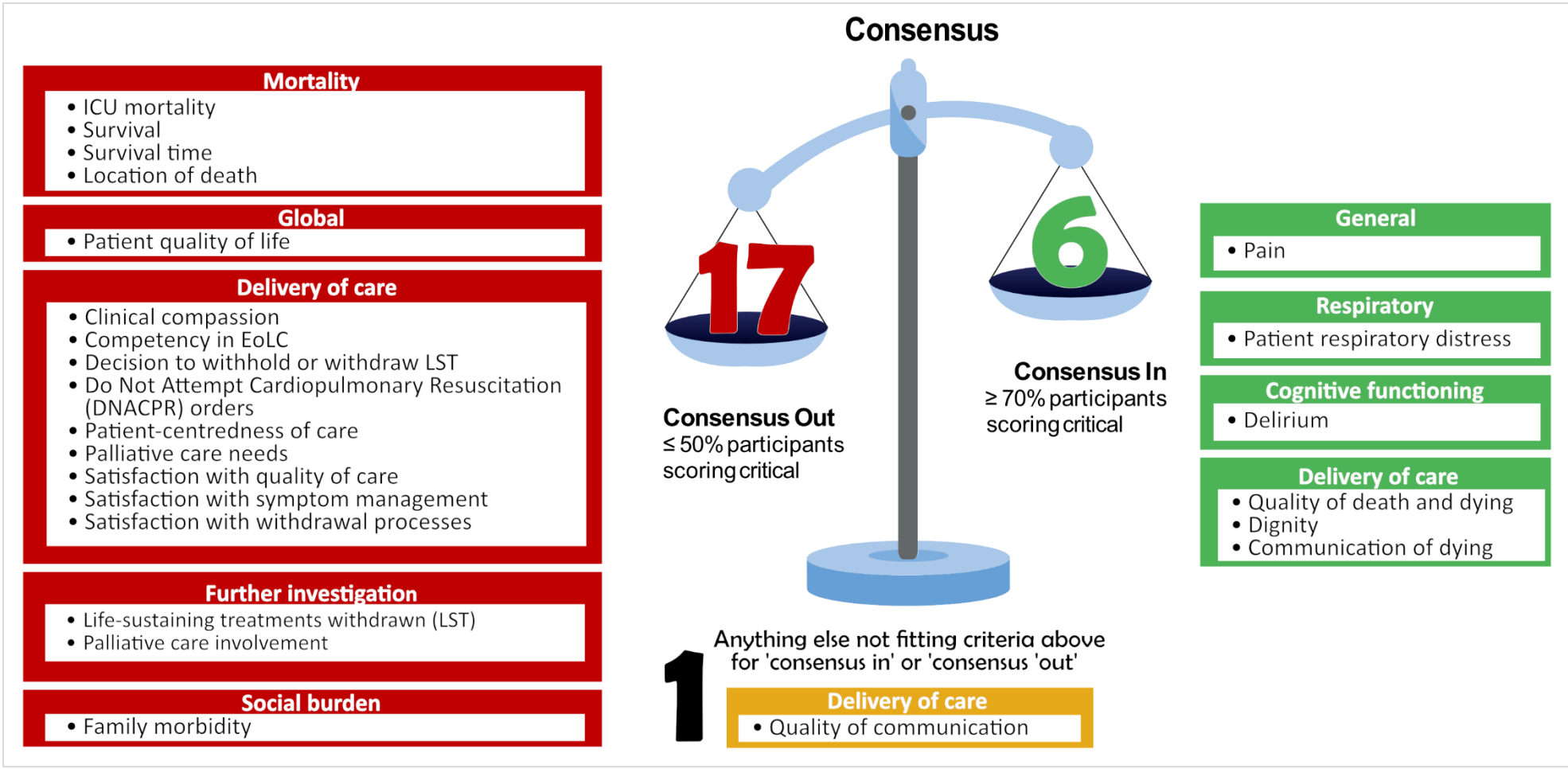


Figure 6.5 Pre-consensus meeting results

Table 6.2 Pre-consensus meeting results

Outcome	Rating	N	(%)	Consensus
1: Mortality				
ICU mortality	Not important	6	(100)	Out
	Important	0	(0)	
	Critical	0	(0)	
Survival	Not important	6	(100)	Out
	Important	0	(0)	
	Critical	0	(0)	
Survival time	Not important	6	(100)	Out
	Important	0	(0)	
	Critical	0	(0)	
Location of death	Not important	6	(100)	Out
	Important	0	(0)	
	Critical	0	(0)	
9: General outcomes				
Pain	Not important	0	(0)	In
	Important	0	(0)	
	Critical	6	(100)	
22: Respiratory, thoracic and mediastinal				
Patient respiratory distress	Not important	0	(0)	In
	Important	0	(0)	
	Critical	6	(100)	
29: Cognitive functioning				
Delirium	Not important	0	(0)	In
	Important	0	(0)	
	Critical	6	(100)	
30: Global quality of life				
Patient quality of life	Not important	6	(100)	Out
	Important	0	(0)	
	Critical	0	(0)	
32: Delivery of care - End-of-life				
Patient centredness	Not important	6	(100)	Out
	Important	0	(0)	
	Critical	0	(0)	
Quality of death and dying	Not important	0	(0)	In
	Important	0	(0)	
	Critical	6	(100)	
Palliative care needs	Not important	4	(80)	Out
	Important	1	(20)	
	Critical	0	(0)	
Dignity	Not important	0	(0)	In
	Important	1	(17)	
	Critical	5	(83)	
Clinical compassion	Not important	6	(100)	Out
	Important	0	(0)	
	Critical	0	(0)	

Outcome	Rating	N	(%)	Consensus
32: Delivery of care - Communication				
Communication of dying	Not important	0	(0)	In
	Important	1	(20)	
	Critical	4	(80)	
Quality of communication	Not important	0	(0)	No consensus
	Important	3	(50)	
	Critical	3	(50)	
32: Delivery of care - Care Satisfaction				
Satisfaction with quality of care	Not important	4	(67)	Out
	Important	1	(17)	
	Critical	1	(17)	
Satisfaction with symptom management	Not important	6	(100)	Out
	Important	0	(0)	
	Critical	0	(0)	
Competency in end-of-life care	Not important	6	(100)	Out
	Important	0	(0)	
	Critical	0	(0)	
32: Delivery of care - Decision making				
Decision to withhold or withdraw life-sustaining therapy	Not important	4	(67)	Out
	Important	1	(17)	
	Critical	1	(17)	
Do Not Attempt Cardiopulmonary Resuscitation (DNR) orders	Not important	4	(67)	Out
	Important	1	(17)	
	Critical	1	(17)	
Satisfaction with withdrawal processes	Not important	6	(100)	Out
	Important	0	(0)	
	Critical	0	(0)	
36: Further investigation - Organ support				
Life-sustaining treatments withdrawn	Not important	4	(67)	Out
	Important	2	(33)	
	Critical	0	(0)	
36: Further investigation - MDT				
Palliative care involvement	Not important	2	(33)	Out
	Important	2	(33)	
	Critical	2	(33)	
37: Social burden – Stress outcomes				
Family morbidity	Not important	6	(100)	Out
	Important	0	(0)	
	Critical	0	(0)	

Note: Not all percentages add to 100% owing to rounding

6.4.2 Consensus meeting

Thirty-six participants who completed both rounds of the eDelphi study were invited to the final consensus meeting, together with eight organisation representatives. Twenty-five (57%) respondents provided written consent to participate (response rate), with fourteen (56%) attending the main consensus meeting. Due to health reasons and clinical commitments, three (12%) participants withdrew on the day of the consensus meeting. Smith et al. (2024) highlighted the impact of attrition when delivering nominal groups;

consequently, deliberate over-recruitment was employed. Response and attrition rates varied across the stakeholder groups (36% overall) (**Figure 6.6**). Statistical tests to determine association were not employed due to the sample size.

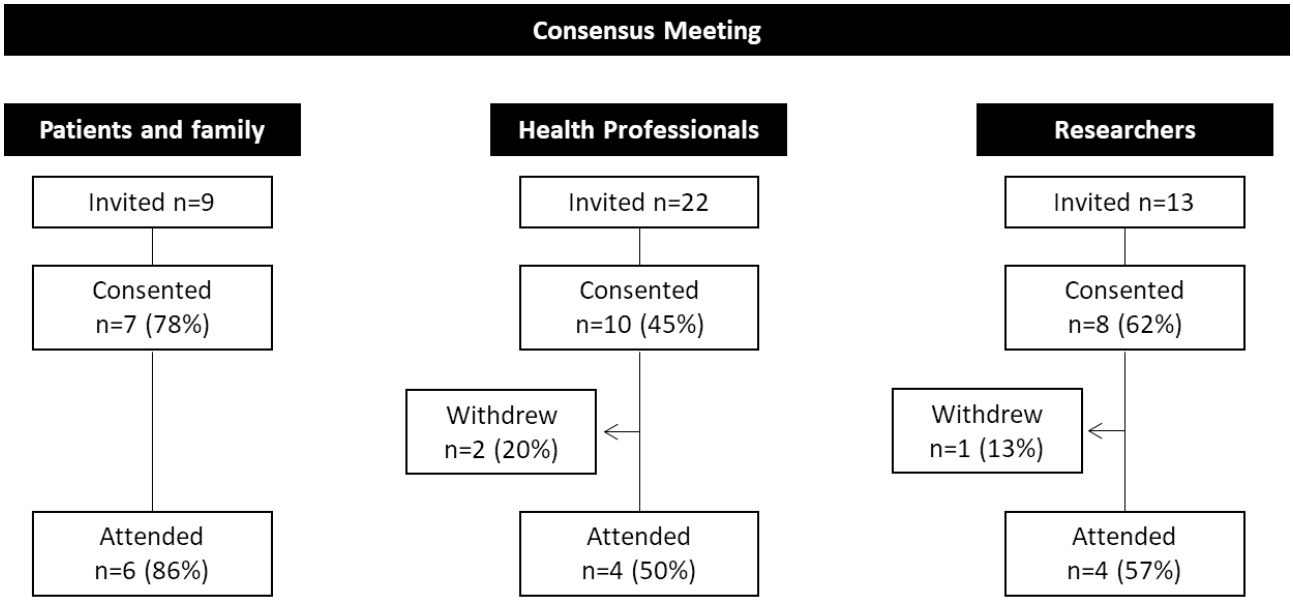


Figure 6.6 Consensus meeting attendance by stakeholder group

6.4.3 Participant characteristics

Fourteen respondents participated in the final consensus meeting, 11 (79%) of participants were female (representing a smaller percentage compared to Stage Three). Participant age ranged between 34-67 years (mean 51 years), with 43% (n=6) participating as patients/family stakeholders, 29% (n=4) as health professionals stakeholders, and 29% (n=4) as researchers. The following organisations were represented: European Society for Intensive Care Medicine (ESICM), Intensive Care and National Audit and Research Centre (ICNARC), The Brain Tumour Charity, The Intensive Care Society (ICS) and The UK Sepsis Trust. Participants were located in three countries on three continents. **Table 6.3** provides a comparative breakdown of participants' characteristics throughout the consensus process.

Table 6.3 Characteristics of participants across the consensus process

Variable	eDelphi study		Consensus meeting	
	Round One N=85 (%)	Round Two N=54 (%)	Pre N=6 (%)	Consensus N=14 (%)
Stakeholder group				
Patient and family	9 (11)	7 (13)	6 (100)	6 (43)
Health professional	61 (73)	36 (67)		4 (29)
Researcher	14 (17)	11 (20)		4 (29)
Gender				
Male	32 (38)	22 (41)	1 (17)	3 (21)
Female	52 (62)	32 (59)	5 (83)	11 (79)
Age group				
18-29 years	7 (8)	4 (7)	0 (0)	0 (0)
30-39 years	20 (24)	12 (22)	1 (17)	3 (21)
40-49 years	23 (27)	17 (31)	1 (17)	4 (29)
50-59 years	25 (30)	12 (22)	2 (33)	5 (26)
60-69 years	9 (11)	9 (17)	2 (33))	2 (14)
Ethnicity				
African	1 (1)	1 (2)	0 (0)	0 (0)
Arabic	1 (1)	1 (2)	0 (0)	0 (0)
Chinese	1 (1)	1 (2)	0 (0)	0 (0)
Indian	4 (5)	4 (7)	0 (0)	0 (0)
Mixed/Multiple	1 (1)	1 (2)	0 (0)	0 (0)
Other	9 (11)	8 (15)	0 (0)	3 (21)
Prefer not to answer	4 (5)	1 (4)	0 (0)	1 (7)
White	63 (75)	36 (67)	6 (100)	10 (71)
Geographical location				
Belgium	1 (1)	1 (1)	0 (0)	1 (7)
France	3 (4)	2 (4)	0 (0)	0 (0)
Germany	2 (2)	2 (4)	0 (0)	0 (0)
Ireland	1 (1)	0 (0)	0 (0)	0 (0)
Israel	1 (1)	1 (2)	0 (0)	1 (7)
Netherlands	1 (1)	1 (2)	0 (0)	0 (0)
Uganda	1 (1)	1 (2)	0 (0)	0 (0)
UK	63 (75)	38 (70)	6 (100)	12 (86)
United Arab Emirates	1 (1)	1 (2)	0 (0)	0 (0)
USA	10 (12)	7 (13)	0 (0)	0 (0)

Note: Not all percentages add to 100% owing to rounding

Table 6.4 outlines the final consensus meeting voting.

Table 6.4 Final consensus meeting voting

Outcome	Rating	First rating	Discussion 2 and re-rating	Discussion 3 and re-rating	Final Consensus
		N (%)	N (%)	N (%)	
1: Mortality					
ICU mortality	Not important	13 (93)	- -	- -	Out
	Important	1 (7)	- -	- -	
	Critical	0 (0)	- -	- -	
Survival	Not important	12 (86)	- -	- -	Out
	Important	1 (7)	- -	- -	
	Critical	1 (7)	- -	- -	
Survival time	Not important	12 (86)	- -	- -	Out
	Important	1 (7)	- -	- -	
	Critical	1 (7)	- -	- -	
Location of death	Not important	10 (71)	- -	- -	Out
	Important	4 (29)	- -	- -	
	Critical	0 (0)	- -	- -	
9: General outcomes					
Pain	Not important	0 (0)	- -	- -	In
	Important	0 (0)	- -	- -	
	Critical	14 (100)	- -	- -	
22: Respiratory					
Patient respiratory distress	Not important	0 (0)	- -	- -	In
	Important	1 (7)	- -	- -	
	Critical	13 (93)	- -	- -	
29: Cognitive functioning					
Delirium	Not important	3 (21)	2 (15)	2 (14)	In
	Important	3 (21)	2 (15)	2 (14)	
	Critical	8 (57)	9 (69)	10 (71)	
30: Global quality of life					
Patient quality of life	Not important	9 (64)	- -	- -	Out
	Important	4 (29)	- -	- -	
	Critical	1 (7)	- -	- -	
32: Delivery of care - End-of-life					
Quality of death and dying	Not important	1 (7)	- -	- -	In
	Important	0 (0)	- -	- -	
	Critical	13 (93)	- -	- -	
Palliative care needs	Not important	6 (43)	- -	- -	Out
	Important	7 (50)	- -	- -	
	Critical	1 (7)	- -	- -	
Dignity	Not important	3 (21)	- -	- -	In
	Important	1 (7)	- -	- -	
	Critical	10 (71)	- -	- -	
Clinical compassion	Not important	4 (31)	- -	- -	Out
	Important	7 (54)	- -	- -	
	Critical	2 (15)	- -	- -	

Outcome	Rating	First rating	Discussion 2 and re-rating	Discussion 3 and re-rating	Final Consensus
		N (%)	N (%)	N (%)	
Patient-centredness of care	Not important	2 (14)	- -	- -	Out
	Important	5 (36)	- -	- -	
	Critical	7 (50)	- -	- -	
32: Delivery of care - Communication					
Satisfaction with end-of-life communication	Not important	3 (21)	Merge into one outcome	0 (0)	In
	Important	2 (14)			
	Critical	9 (64)		3 (21)	
Quality of communication	Not important	3 (21)			
	Important	2 (14)		11 (79)	
	Critical	9 (64)			
32: Delivery of care - Care Satisfaction					
Satisfaction with quality of care	Not important	5 (36)	- -	- -	Out
	Important	5 (36)	- -	- -	
	Critical	4 (29)	- -	- -	
Satisfaction with symptom management	Not important	7 (50)	- -	- -	Out
	Important	4 (29)	- -	- -	
	Critical	3 (21)	- -	- -	
Competency in end-of-life care	Not important	9 (64)	- -	- -	Out
	Important	4 (29)	- -	- -	
	Critical	1 (7)	- -	- -	
32: Delivery of care - Decision making					
Decision to withhold or withdraw life-sustaining therapy	Not important	9 (64)	- -	- -	Out
	Important	4 (29)	- -	- -	
	Critical	1 (7)	- -	- -	
Do Not Attempt Cardiopulmonary Resuscitation (DNR) orders	Not important	12 (86)	- -	- -	Out
	Important	2 (14)	- -	- -	
	Critical	0 (0)	- -	- -	
Satisfaction with withdrawal processes	Not important	11 (79)	- -	- -	Out
	Important	1 (7)	- -	- -	
	Critical	2 (14)	- -	- -	
36: Further investigation - Organ support					
Life-sustaining treatments withdrawn	Not important	10 (71)	- -	- -	Out
	Important	4 (29)	- -	- -	
	Critical	0 (0)	- -	- -	
36: Further investigation - MDT					
Palliative care involvement	Not important	8 (57)	- -	- -	Out
	Important	5 (36)	- -	- -	
	Critical	1 (7)	- -	- -	
37: Social burden – Stress outcomes					
Family morbidity	Not important	12 (86)	- -	- -	Out
	Important	2 (14)	- -	- -	
	Critical	0 (0)	- -	- -	

- = not performed

6.4.4 Coding frameworks

Transcripts from both meetings were analysed to identify reasons outcomes were considered ‘core’ or ‘non-core’. Overall, 305 comments were coded as core reasons, with 513 comments coded as non-core. Five main themes and six subthemes were identified, explaining why outcomes were proposed as core. Seven main themes and eleven subthemes emerged as to why outcomes were considered non-core. **Figure 6.7** provides a thematic scheme of the reasons outcomes were considered core and non-core. Illustrative quotes and descriptions are provided in **Appendix 66** and **Appendix 67**. Minimal refinement was required from the pre-consensus meeting to the main consensus meeting. No additional main themes were identified between meetings, but additional subthemes (setting) emerged as reasons outcomes were considered non-core. Coding definitions were updated during analysis of the main consensus meeting transcripts.

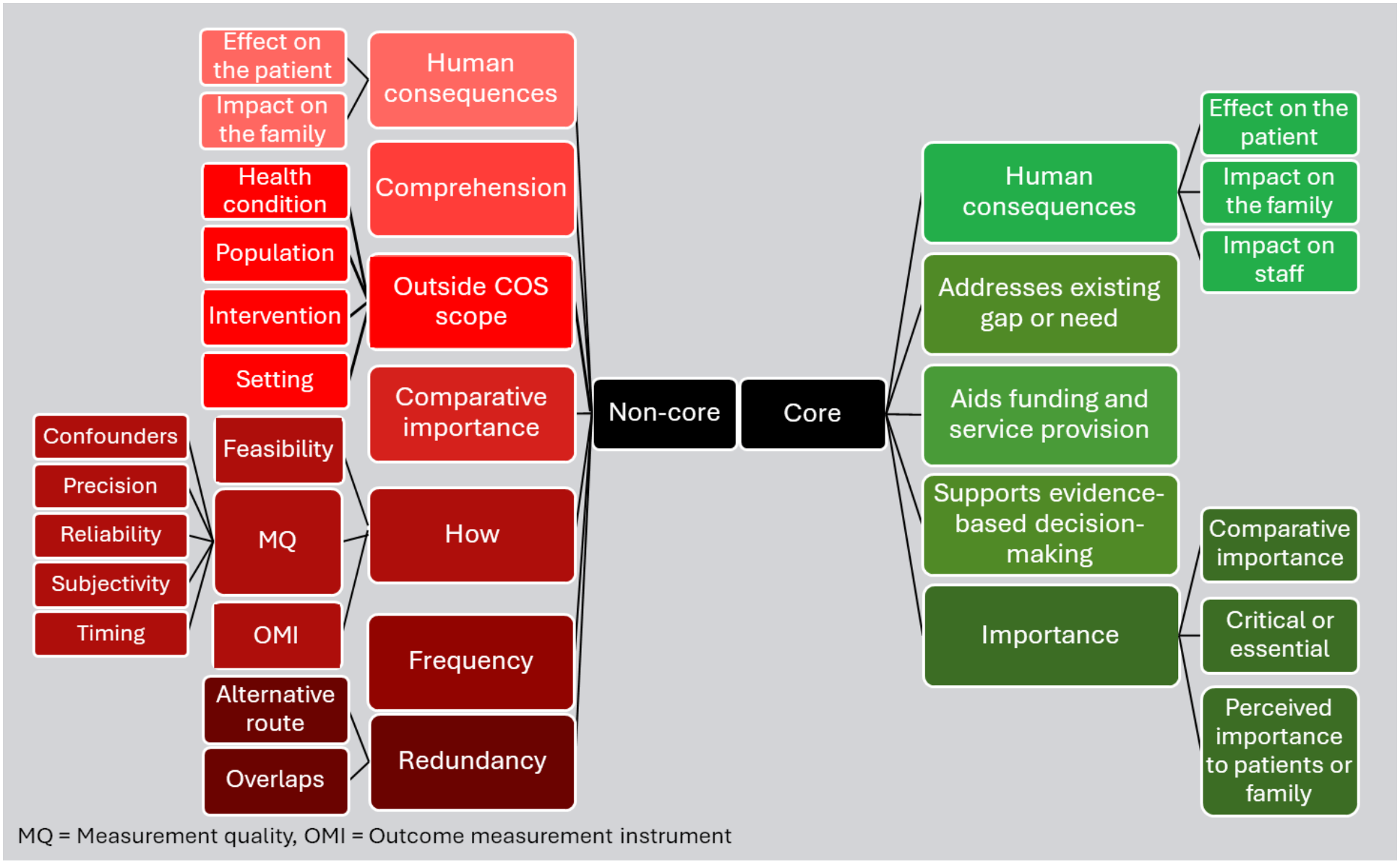


Figure 6.7 Thematic scheme of reasons for core or non-core

Themes for core

Across both meetings, the most frequently applied codes were human consequences (167 comments, 55%) and importance (81 comments, 27%), although variation was evident across stakeholder groups, with no researchers' comments coded to human consequences as a reason for being core (**Table 6.5**).

Table 6.5 Reasons for core

	Pre-consensus Meeting	**Main Consensus Meeting**			
	Patient and Family	Patient and Family	Health Professionals	Researchers	All Participants
Theme	N (%)	n (%)	n (%)	n (%)	N (%)
Address existing gap or need	1 (1)	2 (2)	12 (26)	0 (0)	14(10)
Aids funding and service provision	6 (4)	6 (7)	2 (4)	3 (21)	11(7)
Human consequences	93 (59)	62 (72)	12 (26)	0 (0)	74(50)
Importance	37 (23)	16 (19)	17 (36)	11 (70)	44(30)
Supports evidence-based decision-making	21 (13)	0 (0)	4 (9)	0 (0)	4(3)
Total comments	**158 (100)**	**86 (100)**	**47 (100)**	**14 (100)**	**147 (100)**

Following the systematic indexing and charting stages of framework analysis (**Chapter Five Figure 5.9**) it became apparent that not all themes were evidenced across the dataset. Congruent with the principles of rigorous framework analysis, empty cells are transparently reported in the core charting matrix in **Table 6.6** (Ritchie & Spencer, 1994). Four outcomes (location of death, palliative care needs, satisfaction with quality of care, and satisfaction with withdrawal processes) received no comments supporting their consideration as core.

Table 6.6 Core framework matrix per outcome

Outcome	Address existing gap or need	Aids funding service provision	Human consequences			Importance			Supports evidence-based decision-making
			Effect on patient	Impact on family	Impact on staff	CI	Critical or essential	PI	
ICU mortality		X							
Location of death*									
Survival									X
Survival time									X
Pain			X	X	X	X	X	X	
Respiratory distress	X		X	X	X	X	X		
Delirium	X		X	X		X	X		
Quality of life						X			
Quality of death and dying						X	X		
Palliative care needs*									
Dignity			X	X					
Clinical compassion				X			X		
Patient-centredness of care			X					X	
Quality of communication			X	X		X	X		
Satisfaction with EoL communication				X			X		
Satisfaction with quality of care*									
Satisfaction with symptom management							X		
Competency in EoLC*									
Decision to withhold/withdraw LST		X							X
DNACPR orders	X	X						X	
Satisfaction with withdrawal processes*									
Life-sustaining treatments withdrawn		X							
Palliative care involvement		X	X	X	X	X			
Morbidity		X							

*=No comments, LST=Life Sustaining Treatment, CI=Comparative importance, PI=Perceived importance to patient or family

6.4.4.1.1 Addresses existing gap or need

The need for core outcomes that addressed existing gaps were identified in both meetings. The pre-consensus meeting raised the notion of symptoms being *'underestimated'* or *'unrecognised'*. This resonated with health professionals at the consensus meeting; however, the concept was expanded to focus on the idea that outcomes should be core indicators of progress towards *'achieving'* gaps, which could specify further actions needed to *'make it possible'*.

6.4.4.1.2 Aids funding and service provision

Outcomes that enabled organisations to review funding to facilitate equitable service provision were cited by patients within the pre-consensus meeting and by organisations representing patient and family members in the consensus meeting. A causal link with *'a better death'* and *'quality care'* was presented within both; however, divergence was evident on how outcomes would be operationalised. A patient commented how having an outcome as core could provide *'more resources'* while organisations representing patient and family members focused on the strategic importance of core outcomes for *'good planning and preparation'*. This interpretation also differed from those of health professionals and researchers who suggested *'evidence'* was needed to secure service provision for family members, highlighting a striking degree of thematic convergence between addressing existing gaps or needs and human consequences.

6.4.4.1.3 Human consequences

Within human consequences, three interlinked subthemes were evident, providing a more complex understanding: effect on the patient, impact on the family and impact on the staff. Patients' comments focused on symptomology, recalling instances of experiencing psychological distress, anxiety and pain, which were *'awful'*, *'horrific'*, cyclical and mutually reinforcing. In contrast, patient and family organisational representatives discussed how patients and family had *'difficulty computing everything'* which could generate *'fear'*, *'misplaced hope'* and compromise EoLC. The need to ensure *'continuity for the support of patients'* was espoused by health professionals, combined with *'making sure it is very much patient-centred'*. These reasons were comparable to those found in the subtheme impact on the family. Witnessing EoLC was considered to have a *'profound'* and enduring impact on the family, articulated by patient/family, and health professional stakeholders across both meetings.

In contrast to the aforementioned subthemes, the impact on staff was raised only by the patients and family stakeholder groups as reasons why outcomes should be included as core. During the pre-consensus meeting, patients perceived the impact on staff to correlate to their remit to '*saving lives'* rather than provide EoLC. However, there was discordance between patients and the patient and family organisational representatives. With the latter feeling that the impact on staff correlated with maintaining professionalism and continuity of EoLC. Further divergence was apparent in the main meeting, where witnessing symptoms such as respiratory distress were considered by one patient as *'the most appalling experience',* impacting on health professionals' ability to deliver effective EoLC. Collectively, human consequences provided a rationale for including outcomes as core when EoLC interventions aimed to alleviate symptom severity or associated anxiety or distress.

6.4.4.1.4 Importance

Within the broad category of importance, the subthemes of comparative importance, critical or essential and perceived importance to patients or family captured reasons why outcomes were considered core. Comparative importance indicated the relational significance participants attributed to outcomes, operating through a contextual weighting in which the salience of any outcome was contingent on its relative position to alternative outcomes, as one health professional commented: *'probably not less important than pain'* (FCM_72_HP). The level of comparative importance varied across meetings, stakeholders, and the outcomes of comparisons; however, comparative importance transcended all stakeholder groups as a reason outcomes should be core.

In contrast to comparative importance, outcomes were considered critical or essential based on their intrinsic merit, independent of what they were compared to or the existence of alternative measures. Health professionals and researchers emphasised the critical importance of conceptualising outcomes regardless of the measurement development process, whilst patients reflected on their experiences.

Considering outcomes perceived as important to patients or family was considered essential to person-centredness and reliant on understanding the patients' values and what would be *'palatable'*. Conversely, it was only raised by patient and family stakeholders in the pre-consensus meeting.

6.4.4.1.5 Supports evidence-based decision-making

The need for outcomes that could support evidence-based decision-making emerged as a core theme across both meetings, among both patient and health professional stakeholders, although rationales differed. For patients' decisions made without an evidence-based foundation risked being *'inconsistent'* or *'wrong',* potentially undermining trust, while decisions derived from evidence would provide a defensible rationale for clinical and *'policy'* decisions. In contrast, health professionals proposed that, by understanding the evidence, decisions could be undertaken proactively with greater clarity, simultaneously providing a transparent basis for EoLC decisions for patients, their families, and health professionals.

Themes for non-core

Overall, the most frequently applied codes were how (192 comments, 37%), outside of scope (135 comments, 26%) and redundancy (70 comments, 14%), with variation seen between meetings and stakeholder groups (**Table 6.7**) and across individual outcomes (**Table 6.8**). Three outcomes (pain, quality of death and dying and quality of communication) received no comments supporting their consideration as non-core.

Table 6.7 Reason non-core

	Pre-consensus Meeting	**Main Consensus Meeting**			
	Patient and Family	Patient and Family	Health Professionals	Researchers	All Participants
Theme	N (%)	n (%)	n (%)	n (%)	N (%)
Comprehension	8 (4)	7 (6)	5 (5)	- -	12 (4)
Comparative importance	17 (8)	16 (13)	- -	10 (14)	26 (9)
Frequency	14 (7)	7 (6)	9 (8)	- -	16 (5)
How	60 (28)	51 (41)	60 (56)	21 (30)	132 (44)
Human consequences	21 (10)	2 (2)	- -	- -	2 (1)
Outside scope	66 (31)	24 (19)	12 (11)	33 (47)	69 (23)
Redundancy	25 (12)	18 (14)	21 (20)	6 (9)	45 (15)
Total comments	**211 (100)**	**125 (100)**	**107 (100)**	**70 (100)**	**302 (100)**

- = no comments

Table 6.8 Non-core framework matrix per outcome

Outcome	Theme						
	Comprehension	Comparative importance	Frequency	How	Human consequences	Outside scope	Redundancy
ICU mortality		X		X		X	X
Location of death				X		X	X
Survival		X		X	X	X	X
Survival time				X	X	X	
Pain*							
Respiratory distress		X		X			
Delirium			X	X		X	
Quality of life	X	X		X		X	
Quality of death and dying*							
Palliative care needs	X			X		X	X
Dignity				X			
Clinical compassion				X			X
Patient-centredness of care		X		X			
Quality of communication*							
Satisfaction with EoL communication				X			
Satisfaction with quality of care				X			X
Satisfaction with symptom management				X		X	X
Competency in EoLC			X	X		X	X
Decision to withhold/withdraw LST		X		X		X	
DNACPR orders		X				X	
Satisfaction with withdrawal processes	X	X		X		X	
Life-sustaining treatments withdrawn				X		X	
Palliative care involvement		X		X		X	X
Morbidity				X		X	

*=No comments, LST=Life Sustaining Treatment, DNACPR=Do Not Attempt Cardiopulmonary Resuscitation

6.4.4.1.6 Comprehension

When an outcome or construct employed terms that were *'unclear'*, *'ambiguous'* or *'unfamiliar'*, patients/family stakeholders and health professionals considered the outcome non-core. Although this divergence in interpretation and understanding was more apparent in the pre-consensus main meeting, the term *'palliative'* was considered *'poorly understood'* even by palliative care specialists. Rather than endorsing an outcome they were unsure they had understood accurately, one patient abstained from voting during the pre-consensus meeting on this outcome.

6.4.4.1.7 Comparative importance

Contrary to the comparative importance within the core themes, in the reasons for non-core, comparative importance reflected a judgment in which participants considered the outcome *'less'* or *'not'* important when contrasted with another outcome. Including the outcome was considered to *'detract'* or '*pull it away'* from the core outcomes of the COS.

6.4.4.1.8 Frequency

Patient outcomes in the main consensus meeting were considered non-core by health professionals, which occurred *'rarely'* or because patients frequently *'don't die that way'*. Furthermore, measuring a *'natural'* part of EoL was perceived as *'superfluous'* and provided limited meaningful value. Conversely, frequency was interpreted differently by patient/family stakeholders. In both meetings, frequency pertained only to staff outcome measures with a procedural focus on not being *'research active'* or being part of routine, '*bread and butter'* practice.

6.4.4.1.9 How

Across both meetings, every participant commented on how an outcome was measured, with comments made on 20 (83%) of outcomes. Three subthemes were evident: measurement quality, feasibility and outcome measurement instrument, with five further subthemes identified within measurement quality. Confounders had the potential to distort if the outcome *'related to'* the EoLC, while subjectivity could introduce bias with outcomes considered to mean *'something different'* to *'different people'*. The precision of *'broad'* or *'vague'* outcomes was considered problematic, potentially leading to *'unclear'* or *'inconclusive'* results, which would undermine the aim of the COS. Reliability and the timing of the outcome were consistently questioned, with a causal link to comparative

importance evident in the timing articulated by researchers. In contrast to the other subthemes, health professionals predominantly expressed feasibility concerns, reflecting real-world conditions in which implementation would be *'impossible'* or *'impractical'*. The lack of diagnostic tools and outcome measurement instruments specific to EoL or critical care resonated with all stakeholder groups.

6.4.4.1.10 Human consequences

In both the pre-consensus and consensus meetings, human consequences were isolated to the patient/family stakeholders and applied only to the outcomes of survival and survival time, reflecting the most infrequent theme overall. Two subthemes emerged: the effect on the patient and the impact on the family, with the *'emotional'* effect/impact transcending both. Including such outcomes as core were considered *'damaging',* creating *'fear'* or *'doubt'* in both patients and family. One participant switched between proxy perspectives, representing both proxy-patient and proxy-proxy perspectives, enriching the discussion and ultimately leading to convergence of opinions.

6.4.4.1.11 Outside scope

Throughout both meetings, outcomes deemed outside the scope of the COS were considered non-core. Patients within the pre-consensus group clearly differentiated between *'palliative'* and *'EoLC'* while health professionals considered outcomes to be *'not generic to ICU'* or *'not specific'* to EoL. In contrast, researchers focused on how outcomes were not applicable to *'some countries'* and were incongruent with the international scope. A further divergence was apparent, with outcomes considered *'process measures'* better suited to '*service evaluation'* rather than person-centred research.

6.4.4.1.12 Redundancy

Across both meetings, outcomes were considered redundant by all stakeholder groups where constructs intersected, were '*captured elsewhere'* or were felt *'to overlap'*, diminishing the unique characteristics and value of an outcome.

Figure 6.8 illustrates the relationships between identified themes and subthemes, with the inner areas representing shared characteristics evident in the data. A notable thematic intersection is evident between core and non-core themes within human consequences (effect on patient and impact on family) and importance (comparative importance). With

the aids funding and service provision, it addresses an existing gap or need intersecting with human consequences in the core themes.

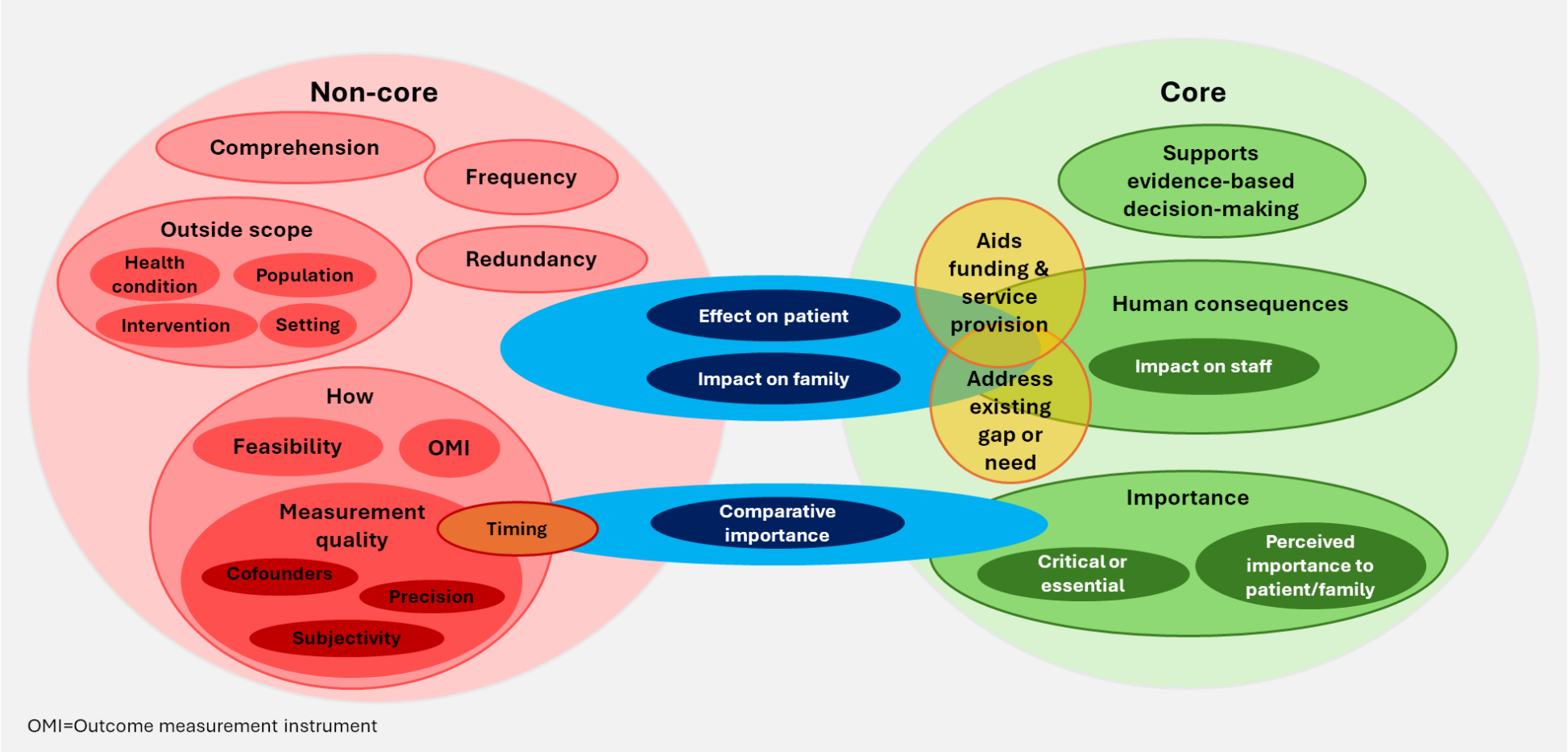


Figure 6.8 Euler diagram of core and non-core themes and subthemes

6.4.5 *Final outcomes included*

Figure 6.9 illustrates the process undertaken to reach the COS.

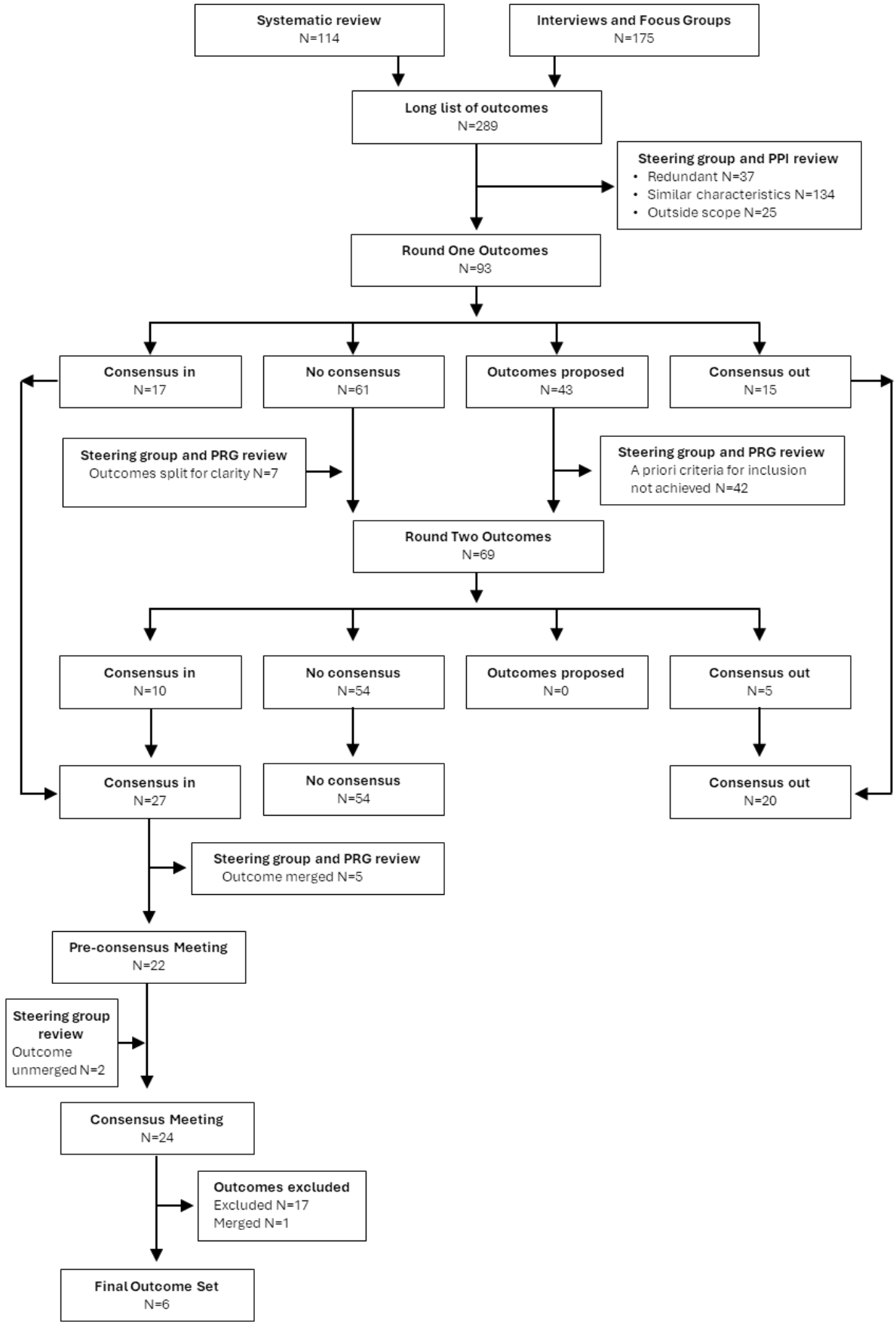


Figure 6.9 Identification and selection of outcomes

At the completion of the main consensus meeting, six outcomes achieved consensus for inclusion and were ratified for the final COS: pain, respiratory distress, delirium, dignity, quality of communication, and quality of death and dying (**Figure 6.10**).

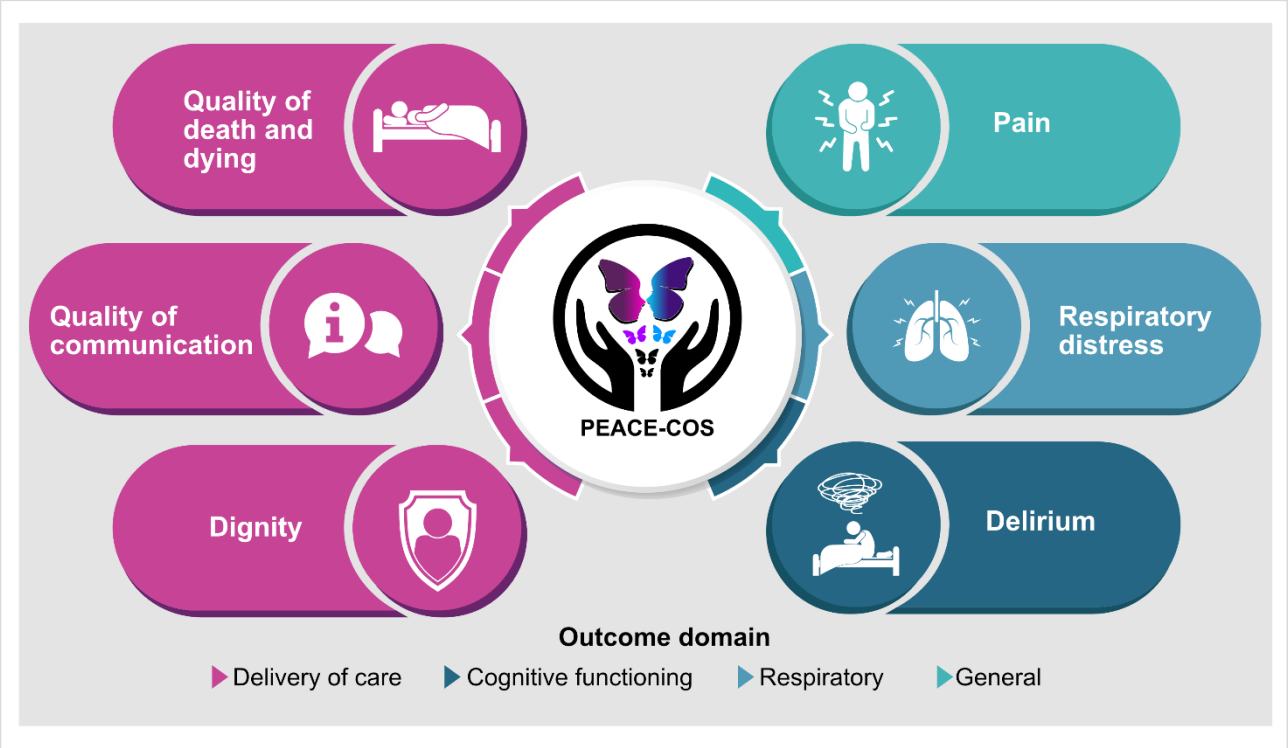


Figure 6.10 Final COS

Pain

Complete concordance was observed across all stakeholder groups, participants and meetings on the voting and ratification of including pain in the COS. Personal reflection was evident across both meetings. Patients recalled the intensity and severity as *'considerable' or 'awful'* with identifying a range of *'types of pain'* while health professionals reflected on the impact on family members of *'seeing'* their loved one *'in'* pain or *'discomfort'*. No comments were provided on why pain outcomes were not considered core, with one participant saying:

> *"I can't imagine there would be a reason that could be justified why pain is not included"*. FCM_33 Patient

Respiratory distress

Respiratory distress was considered *'profoundly distressing'* for patients, their families and health professionals, creating *'anxiety'*, *'panic'*, and a feeling of *'suffocating'* among patients. Accurate measurement was advocated by one health professional to distinguish *'natural'* and *'normal'* physiological changes associated with EoL while another commented:

> *"So putting it out there in the core outcomes set, I think, will demonstrate to researchers, but then also to clinicians, that it is a key thing that we need to be aware of and the fact that it's difficult to measure shouldn't make us or convince us not to include it."* FCM_72 Health professional

Dignity

All participants perceived dignity as a core tenet of EoLC, a multifaceted concept warranting expansion of the original outcome description to include both extrinsic and intrinsic components. Patients, health professionals and researchers articulated the need to maintain extrinsic dignity by protecting the patient's physical privacy, ensuring the confidentiality of the patient's information, and creating a personal space.

> *"When my family was visiting, you know what gets said around them. You know who's in the room when certain procedures are done."* [FCM_52_Patient]

> *"But I can still give them dignity in, as you said, making sure they're covered up, making sure the curtains are closed, speaking in a way that's respectful."* FCM_23 Health professional

Two patients recalled a sense of vulnerability, loss of control and exposure at being *"sat in your mess"* or *"stripped naked and washed"*, emphasising how a lack of dignity eroded person-centred care, creating tension between respect and self-worth. One researcher built on this component, commenting on each individual patient's EoL intrinsic worth. Here, dignity necessitated respect for autonomy, encompassing cognitive and decisional attributes, with the researcher summarising:

> *"… autonomy, independence, self-respect, involvement in decision making is part of dignity as well."* FCM_152 Researcher

Delirium

Delirium was the most contentious of the outcomes included, with three rounds of discussions and voting in the main meeting. Conceptual, definitional and diagnostic instability was evident across all three stakeholder groups. One patient spoke of the need to differentiate delirium and *'delirium mimics'*, considering delirium conceptually distinct from agitation. In contrast, all health professionals perceived delirium to be *'broader'*, encompassing symptoms of *'distress'* and *'agitation'*. A critical tension arose between the clinical diagnosis of delirium and the subjective experience. Variations in international practices across the UK and Europe were felt by one researcher to hinder measurement, with diagnosis reliant on behavioural and cognitive criteria masked by mechanical ventilation and sedation. This assertion was, however contended by a patient:

> *"It doesn't stop just because you're not conscious."* FCM_52 Patient

Ultimately, convergence was achieved on the inclusion as core with a researcher reflecting:

> *"It is so difficult to just go against, I guess, for a lack of a better word, for an actual patient who's experienced that."* FCM_140 Researcher

Quality of death and dying

Measuring quality of death and dying was seen as inseparable from person-centred EoLC and a composite outcome that could systematically measure each person's priorities, preferences and values. One patient considered it *'common sense'* to make it core, while another felt it *'intuitive'*. In contrast, one health professional proposed that it was *'paramount'* to the COS scope, while its comparative importance resonated with both patients/families and health professionals.

Quality of communication

Communicating that the patient was dying or at risk of dying was understood to be clinically and ethically critical to the COS. The clinical challenges of prognostic *'uncertainty'* were raised by two health professionals as specific to the clinician or multidisciplinary team, while a patient felt it was a *'basic decency'* to know their prognosis, reflecting the intersection of autonomy and beneficence. The human consequences of poor-quality

communication were consistently identified across all stakeholder groups, impacting preparation and expectations and potentially compounding grief.

> *"… the legacy that a death leaves on a family and a person. And the lifelong trauma that people can experience if the communication isn't done properly or clearly."*
> FCM_Patient 123

Taking into consideration all the comments across both meetings, outcome descriptions were updated and ratified as outlined in **Table 6.9**.

Table 6.9 Outcome descriptions

Outcome	Description
Pain	Level of pain or discomfort
Respiratory distress	Patients experiencing symptoms of respiratory distress such as dyspnoea or shortness of breath, restlessness, increased respiratory rate (fast breathing)
Delirium	Patients experiencing an acute disturbance in attention and awareness eg confusion, hallucinations, distress, agitation, and restlessness
Dignity	Preservation of personal dignity, privacy, respect and autonomy
Quality of death and dying	Quality of a patient's end-of-life experience in the critical care unit
Quality of communication	Quality of end-of-life communication, including communication around the dying processes.

6.5 Discussion

6.5.1 Main findings

Using rigorous consensus methodology, a core outcome set for *'what'* to measure in EoLC in critical care has been developed with international stakeholders to standardise outcome selection, collection and reporting across future critical care studies. Final consensus was reached on the inclusion of six core outcomes spanning four domains of the COMET taxonomy – general, respiratory, cognitive and delivery of care, with the associated descriptor ratified (Dodd et al., 2018). Key rationales for inclusion were human

consequences (effect on the patient and impact on the family) and importance (critical or comparative). Qualitative analysis of the reasons why outcomes were considered core or non-core showed high levels of convergence between the pre-consensus meeting and consensus meeting. The six outcomes included align and diverge from existing literature, demonstrating key similarities, differences and novel interpretations.

Puntillo et al. (2010) found pain to be multidimensional and under-treated, affecting around 40% of ICU patients at high risk of dying. Evidence from patients and healthcare professionals in this COS development supports these findings that pain is multidimensional, with sensory (intensity) and affective (distress) dimensions captured under the core theme of human consequences. Divergence is, however, evident in the comparability of other symptoms. Puntillo et al. (2010) rated pain the 7th most common symptom by patients, significantly lower than fatigue (75%) or thirst (71%), with the lowest intensity rating among ten symptoms. This COS challenges this. Pain consistently ranked as critical across Stages Three and Four of the study, and the outcome of most importance to include in the COS.

Dyspnoea is highly prevalent in critical care, affecting between 40-55% of patients receiving invasive mechanical ventilation, with 50-55% of patients managed with non-invasive ventilation reporting moderate to severe dyspnoea (Demoule et al., 2022, 2024; Richardson et al., 2024). Exploring the withdrawal of mechanical ventilation at EoL, Mazzu et al. (2023) identified dyspnoea management as the most distressing symptom perceived by staff while Puntillo et al. (2010) found dyspnoea to be the most distressing symptom among patients at high risk of dying. Conversely, Mularski et al. (2005) found only 3% of patients were considered by family members to breathe comfortably at the EoL in ICU. This study extends these findings by framing respiratory distress as an overarching multidimensional construct, extending measures beyond discrete physiological abnormalities to encompass its integrated impact on patient, family, and staff experience. Furthermore, including respiratory distress in this COS addresses a current research gap, as elements such as dyspnoea have been found to be consistently understated and undertreated by critical care clinicians (Richardson et al., 2024).

Dignity is consistently identified as a core tenet of EoLC in critical care (Mergler et al., 2022; Öcalan et al., 2025; Zhuang et al., 2024). Seminal work by Cook & Rocker (2014) frames dignity as an ethical and clinical responsibility of those providing EoLC, recognising

autonomy, respect, preparation and physical comfort as key elements, while qualitative nursing research demonstrates that nurses perceive the use of invasive technologies, loss of autonomy and unrelieved symptoms to be threats to dignity (Su et al., 2018). Recent American, European and Scandinavian practice guidelines on adult EoLC (Darfelt et al., 2025; Kesecioglu et al., 2024; Marshall et al., 2025) operationalise dignity-conserving principles through respect for patient values, shared decision-making, family engagement and avoidance on non-beneficial interventions, synthesising both intrinsic (autonomy, self-esteem, spirituality) and extrinsic (social recognition, relationships, privacy) elements identified within palliative care (Chochinov et al., 2002). The inclusion of dignity in this COS is therefore congruent with existing theoretical and empirical work while creating methodological divergence by situating dignity as a specific composite outcome rather than an implicit principle.

Similarities are evident when compared to the best care for the dying person COS, with the inclusion of *'pain'* mapping *'to address pain'*, *'respiratory distress'* with *'respiratory symptoms'*, *'dignity'* with *'dignity and respect'* and *'quality of death and dying'* with '*to provide quality of death and dying* (Zambrano et al., 2025). This COS, however, diverges by not including *'to address the fear of dying'*, and *'unrestricted access to the patient'*, with neither of these outcomes identified during any stages of the COS development. Instead, delirium and quality of communication were included, which were not included by Zambrano et al. (2025). Contemporary evidence indicates that flexible visiting facilitates timely communication, emotional support, and the alignment of care with patient values are fundamental to person-centred care in critical care and restricting visiting can have devastating effects on patients and their families (Manhas et al., 2025; Nassar et al., 2018). Although variations in practice are evident between critical care units, unrestricted visiting is considered internationally an ethical, compassionate standard of EoLC, enshrined in both quality and clinical guidelines (Kesecioglu et al., 2024; Sprung et al., 2014; Waydhas et al., 2023).

Delirium consistently emerged as a critical outcome for two stakeholder groups (patients/family members and health professionals) across both rounds of the eDelphi and the consensus meetings. Several discussions and voting processes were required to reflect differing ideological positions and the profound intensity with which patients advocated for its inclusion. Although frequently underdiagnosed, delirium is a highly prevalent condition in critical care patients, affecting up to 74% of those receiving

mechanical ventilation and 50% of non-mechanically ventilated patients (Intensive Care Society, 2025; Renzi et al., 2023). Furthermore, the development of a COS for delirium in critical care patients by Rose et al., (2021) and its inclusion in the UK ICS minimum standards for EoLC (Humphreys et al., 2026) simultaneously reinforces its importance as a research and clinical priority. This divergence from Zambrano et al. (2025) reflects why COS need to be setting specific as what is considered core varies substantially between different patient groups and care contexts.

Poor, inconsistent, and fractured EoL communication in critical care has been demonstrated to exacerbate family and staff conflict, compound decision-making and impact on bereavement experiences (Erikson et al., 2025; Janczewski et al., 2024; Jensen et al., 2020; Sanderson et al., 2022). Feldman et al. (2022) examined differences in EoL communication practices in 36 countries, finding considerable variability in different regions. Effective EoL communication is therefore a critical component of high-quality EoLC in critical care and is enshrined in international clinical guidelines (Darfelt et al., 2025; Kesecioglu et al., 2024; Marshall et al., 2025). Findings from this study are consistent with guideline-based recommendations, contributing to the robustness of the EoLC evidence base.

Despite diligent attempts to develop understandable and meaningful outcome descriptions, interpreting and applying the consensus study outcomes internationally proved challenging. Differences in healthcare systems, legislative frameworks, cultural norms, and the scope of practice led participants to view outcomes such as palliative care involvement as non-core. Formalised palliative care teams were considered either non-existent or underdeveloped within ICUs and it was felt their inclusion would constrain the COS. Although there is a paucity of research on such topics, including such outcomes had the potential to limit COS uptake.

6.5.2 Strengths and limitations

In contrast to other critical care COS consensus meetings (Davies et al., 2022), the inclusion threshold (70%) was not altered from that of the eDelphi study, ensuring methodological integrity and uniformity across all consensus processes (Jünger et al., 2017). The iterative refinement achieved through a pre-consensus meeting identified how the steering committee had merged dignity with patient-centredness and personalising

dying, obscuring conceptual distinctions. The unmerging process into separate outcomes yielded refined, standalone discrete outcomes, with dignity subsequently ratified as core.

Overall, the main consensus study meeting attrition rate was 37%, which is lower than other critical care COS (range 42%-78%) (Davies et al., 2022; Freeman-Sanderson et al., 2024; Rose et al., 2023) but higher than other COS in different specialities (Coulman et al., 2016), reflecting the methodological and practical challenges encountered in critical care research. Scheduling constraints coupled with the inclusion of patients who may face health-related barriers align with reasons for attrition in broad COS methodology (Kirkham et al., 2017; Williamson et al., 2017). Such challenges are, however, amplified in critical care research due to the complexity of post-ICU survivorship populations coupled with the multidisciplinary nature of critical care.

Whilst participants were homogeneous in the pre-consensus meeting in terms of geographical location and ethnicity, heterogeneity was evident in the consensus meeting (geographical location, ethnicity, level of expertise, and speciality (palliative and EoLC). Attrition meant there were no representatives from lower-income countries in either meeting, and no explanation for non-attendance was provided. Possible explanations include competing commitments, logistical barriers, personal circumstances or disengagement. Overall, stakeholders from the United Kingdom were overrepresented. A more balanced geographical sample could have yielded different results. Consensus meeting chairs were also members of the steering committee, and there were occasions where the presenter's style may have influenced participant input, with one chair projecting her own perspectives and deviating from the standardised script.

Technical challenges persisted during voting in the pre-consensus meeting when using Microsoft TEAMS voting despite extensive piloting and pre-meeting checks. Timmermans et al. (2022) advocate assigning a designated person to resolve technical concerns for online NGTs. The use of the TEAMS' voting app function was, however, new to the University of Hertfordshire; consequently, the researcher's understanding of its functionality was limited to the pilots and theoretical descriptions and was constrained by the absence of experienced individuals to support the process. Different voting approaches are evident within COS development. Chalmers et al. (2018) employed a real-time, non-anonymous vote via a show of hands. In contrast, Freeman-Sanderson et al. (2024) disseminated discussion summaries post-meeting and requested that participants

vote asynchronously using REDCap. Using physical hand-raising voting may have unintentionally promoted groupthink dynamics and cognitive dissonance in this study, as participants could see others' votes before committing their own. Although asynchronous voting would have allowed participants to vote at their convenience, immediate interactions would have been limited, which were critical for further discussion when consensus was not reached and risked disrupting the richness of participant discussions and the visibility of real-time voting. Discussing 24 outcomes was ambitious within the time constraints. Greater flexibility to discuss important issues that arose would have been beneficial. Methodological choices were therefore shaped by pragmatic considerations and practical constraints.

The lived and professional expertise of three stakeholder groups directly shaped the trajectory of the final COS. Proxies were, however, used in the patient/family group, with only bereaved family members attending the pre-consensus meeting. Little qualitative research is available with ICU patients at high risk of dying, as most patients are sedated or unconscious, rendering them unable to engage in research (Kentish-Barnes et al., 2023). Consequently, assessments and evaluations of EoLC is almost exclusively reliant on retrospective proxy reporting. Although this methodological limitation is unavoidable, it raises concerns about accuracy and bias, introducing epistemic and interpretative constrains (Oldenburger et al., 2023). Proxy assessments represent a socially mediated perception influenced by the proxy's own emotional, cultural and relational context (Oldenburger et al., 2023) and are discussed further in **Chapter 7 7.5.3.**

Despite these limitations, organisations representing two professional ICU societies and three organisations representing patients and family members participated across meetings, demonstrating stakeholder commitment to developing the COS. Further research is warranted to refine the outcome descriptions to incorporate the associated outcome measurement instruments; however, the outcomes within this COS provide a foundation for evaluating EoL research in critical care.

6.6 Conclusion

The PEACE-COS derived from this study is recommended for research studies evaluating EoLC in critical care. Consensus was achieved on six outcomes and descriptors. The six outcomes align and diverge from existing literature, demonstrating key similarities whilst highlighting notable differences in methodology and interpretation.

Chapter 7: Discussion

7.1 Introduction

The PEACE-COS study aimed to develop a core outcome set to be collected and reported in all studies evaluating end-of-life care in critical care. The preceding chapters have presented four distinct stages discussing methodological considerations and findings. This chapter summarises the main findings and discusses the overall implications, strengths and limitations. It outlines how the COS contributes to knowledge both in terms of developing a COS and the COS itself, together with the implications for critical care research and the wider context. Dissemination of the COS and future research are presented.

7.2 Summary of findings

Figure 7.1 illustrates the summary of findings.

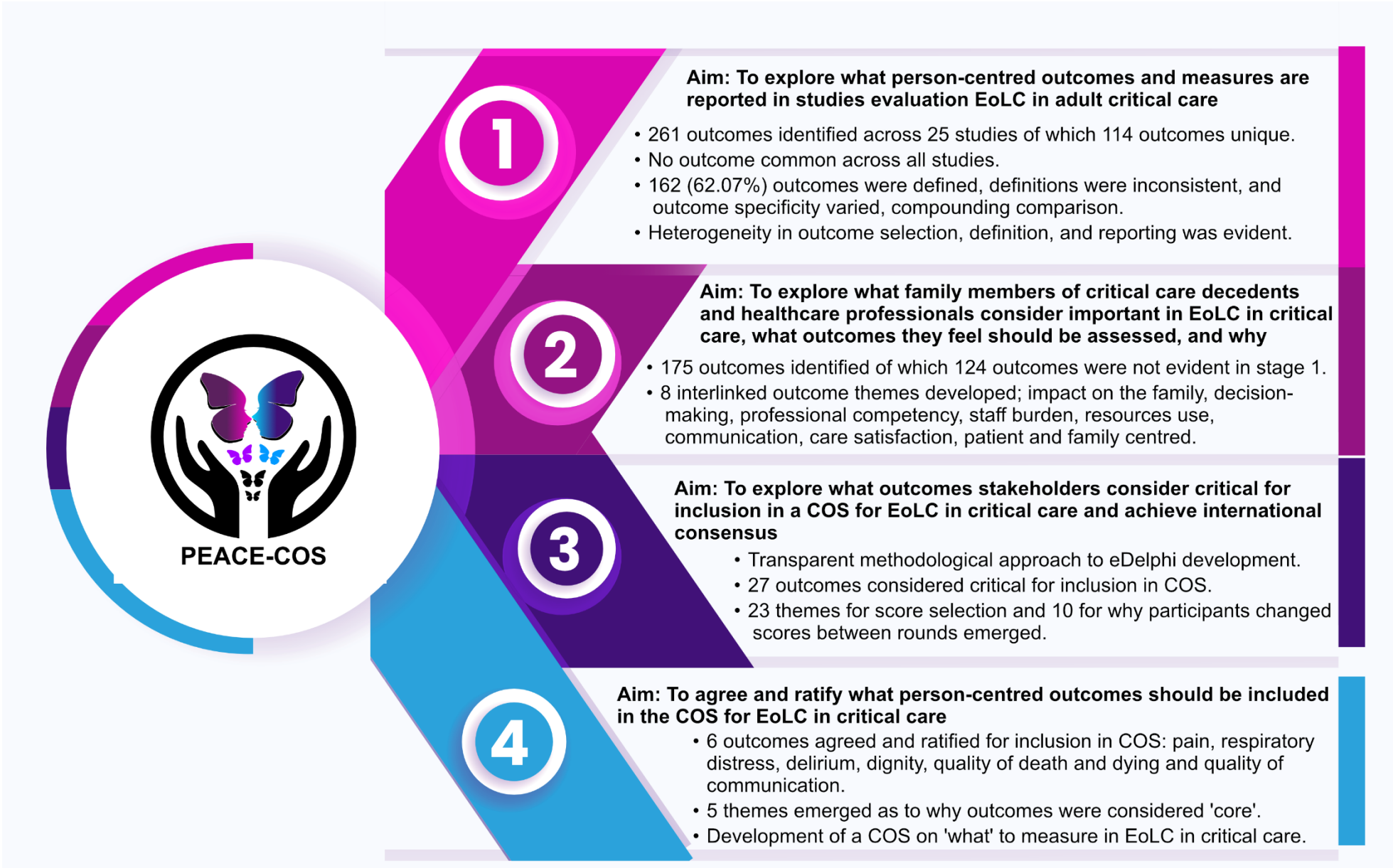


Figure 7.1 Summary of findings

7.3 Implications and impact

This is the first study to develop a COS for EoLC in critical care (Gorst et al., 2025) providing an initial framework for outcome selection in an area where outcome measures have previously been heterogeneous or inconsistently employed. Developed through rigorous consensus methodology, it provides a mechanism for improving comparability across future research studies, systematic reviews, and meta-analyses to reduce research waste and outcome reporting bias (Williamson et al., 2017).

7.3.1 Stage One

Stage One of the study identified extensive heterogeneity in outcome reporting in studies evaluating EoLC in critical care, which significantly constrains the advancement of critical care research and compromises the translational pathway from research to evidence-based care. Inconsistent outcome definitions and specification, coupled with different measurement approaches, currently reduce cross-study comparability, precluding meta-analysis and attenuating the methodological integrity of the evidence base. Although such findings are consistent with other areas of critical care research (Blackwood et al., 2019; Connolly et al., 2024; Rose et al., 2020) Stage One has empirically substantiated this limitation in EoLC research, supporting the need for the COS. Fourteen studies (56%) reported using study-specific OMIs because no available or validated OMI existed, capturing 73 (27.97%) outcomes, of which 46 (40.35%) were unique. The absence of validated OMIs constitutes a key methodological gap, illuminating areas for future research to develop and psychometrically evaluate OMIs that can reliably capture relevant dimensions of EoLC in the critical care population.

Searches were conducted in 2022, and relevant studies may have been published since. Although monthly alerts were established, updating the review mid-COS development would be incongruent with COS methodology recommendations (Beaton et al., 2021; Williamson et al., 2017). Irrespective of whether OMERACT or COMET methodology is utilised, core outcome set development follows a sequential, structured process that focuses on stakeholder consensus rather than evidence synthesis as development progresses (Beaton et al., 2021; Williamson et al., 2017). Updating the review after the COS is published could serve as a basis for future work.

7.3.2 Stage Two

To the researcher's knowledge, this is the first in-depth qualitative study exploring outcomes important to health professionals. It identified 124 outcomes that were not evident in Stage One. The findings illuminate how health professionals' priorities for person-centred outcomes, such as pain, delirium and dignity, diverge from surrogate, or statistically significant outcomes, such as length of stay, costs or mortality, emphasised in published literature. The range of outcomes identified reflects the nuanced nature of EoLC, underscoring the importance of including outcomes beyond those captured in the systematic review in COS development.

The need to clearly differentiate palliative from EoLC resonated with all participants. Failure to do so risks conceptual ambiguity in outcome measurement, potentially obscuring whether outcomes are being evaluated in the context of a patient's life-limiting illness or within the last phases of life and trajectory of dying. Prior literature demonstrates how clear differentiation between these terms supports shared understanding among clinicians, patients and families (Kesecioglu et al., 2024; Nelson et al., 2010). Future research should therefore clearly differentiate between palliative and EoLC to ensure meaningful comparisons across studies.

7.3.3 Stage Three

eDelphis are increasingly being used in COS development and more broadly in health research as an efficient and cost-effective data collection method due to their ability to reach geographically dispersed stakeholders (Shang, 2023), overcoming time zone disparities and affording panellists greater convenience to participate (Hasson et al., 2025). The increased use of Internet-based platforms, however, has introduced new vulnerabilities, with concerns raised over fraudulent responses completed by bots or individuals claiming to be eligible participants (Arundell et al., 2025). Bots are automated software programs able to mimic human behaviour, which can threaten research data quality, distort statistical analyses and reduce the reliability of findings (Hamovitch et al., 2026). In online surveys using rating scales, bot response patterns have a propensity to select responses clustered around the middle of a scale (Hamovitch et al., 2026). Such findings have significant implications for COS developers using rating scales, as they obscure panel agreement and compromise the methodological validity of iterative consensus.

This is the first study within the University of Hertfordshire to implement the Google reCAPTCHA feature in REDCap, providing an initial layer of security against bot detection, and, to the researcher's knowledge, the first COS developed using audio CAPTCHA alternatives. In addition, several methods and strategies were employed throughout the PEACE-COS eDelphi study to identify and mitigate the prevalence of bot and fraudulent responses. A two-step process, separating and screening questionnaire and consent form completion from the Round One questionnaire, was employed. The screening questionnaire used branching and stop logic to prevent ineligible responses from advancing (**Chapter 5, Figure 5.4 and Figure 5.5**), while automated date and time survey fields were added to all questionnaires to identify discrepancies in time zones and completion times (Arundell et al., 2025). The use of digital signatures on the consent form verified that the data were reviewed and affirmed by a specific individual (Lawrence et al., 2020). Furthermore, data was continually reviewed to identify potential bots and fraudulent responses. No participants were found with the same personal details or consecutive responses with similar questionnaire start and end times, with email addresses provided. Guidelines to help identify and limit bot and fraudulent response activity are emerging in the general health care survey literature (Arundell et al., 2025; Ennis et al., 2025; Hamovitch et al., 2026). The combination of multifaceted methods and strategies to enhance research integrity in the PEACE-COS study have not previously been reported in eDelphi studies for COS development. The researcher has subsequently advised other COS developers on the use of REDCAP and has been asked to contribute to the future COMET REDCap eDelphi guidelines. Such advisory roles and invitations extend the study's impact beyond its immediate output as a COS. Research leadership literature highlights how advisory and consultative activities facilitate the dissemination of implicit methodological insights, reflective learning, and practical problem-solving, enabling the synthesis of context-specific insights into generalisable guidance (Flinders, 2022). Additionally, supporting peers through critical dialogue strengthens capacity building and has the potential to influence the co-construction of eDelphi standards.

7.3.4 Stage Four

Six outcomes spanning four domains of the COMET taxonomy – general, respiratory, cognitive and delivery of care (Dodd et al., 2018) were ratified for inclusion in the final COS. Although COMET do not mandate a specific number of outcomes, COS are designed to be used by all studies within a specific condition and therefore need to be

concise to facilitate uptake (Williamson et al., 2017). Maxwell et al. (2019) recommended restricting the number of core outcomes to no more than seven to comprehensively capture the constructs of greatest importance, and a Cochrane Review concluded that the median number of outcomes in systematic reviews using COS was seven (Clarke & Williamson, 2016). The number of outcomes in this COS falls both within the aforementioned recommendations and the observed range reported across published critical care COS (Davies et al., 2022; Rose et al., 2023).

Regulatory bodies and guideline developers increasingly recognise COS as tools for ensuring that clinical recommendations are grounded in outcomes that are significant to both patients and clinicians, enhancing the translation of evidence into practice (Williamson et al., 2017). Throughout the UK, the Guidelines for the Provision of Intensive Care Services (GPICS) are the authoritative minimum standards for planning, commissioning, and the provision of adult intensive care services (Faculty of Intensive Care Medicine & Intensive Care Society, 2026). As a result of the PEACE-COS study the researcher led the EoL section in version 3 (Humphreys et al., 2026). Compared with GPICS 2, GPICS 3 represents a substantive shift towards person-centred outcomes as a core aspect of EoLC, strengthening expectations for pain, symptom and delirium management whilst advocating compassionate communication (Humphreys et al., 2026) encompassing four of the outcomes included in the final COS. Furthermore, the researcher has been invited to contribute to updating the Faculty of Intensive Care Medicine report: Care at the End-of-Life (Faculty of Intensive Care Medicine, 2019).

Empirical data from Stages Two, Three and Four of the study identify the need for a COS to move beyond comprehensiveness to one that ensures outcomes are feasible, evidenced by the exclusion of outcomes from the final set on the grounds that their inclusion would compromise COS uptake due to the challenges associated with collecting. Such findings have implications for researchers developing EoLC outcomes and OMIs. Methodological rigour needs to be balanced against real-world implementability and it is imperative that any burdens on patients, their families, health professionals or researchers are minimised (Klaic et al., 2022).

7.4 Strengths

7.4.1 Methodological peer review and rigour

Peer review of the study methodology constitutes an important strength of the COS development. International formal and informal methodological peer review occurred through the COS development group at the University of Amsterdam COS group, and by presenting the study methodologies at the UK End of Life and Palliative Care in the ICU Research Network, the UK Critical Care Research Group (UKCCRG), and the University of Hertfordshire research conferences. In complex research areas such as EoLC in critical care, these complementary sources strengthened methodological rigour by critically appraising study decisions to mitigate potential methodological weaknesses, and by encouraging the justification of analytic choices, thereby supporting reflexivity. Furthermore, throughout the COS development, engagement with experienced methodological peers at both OMERAC and COMET facilitated an iterative refinement process to enhance coherence and alignment with recognised standards for COS development and reporting (Kirkham et al., 2017; Williamson et al., 2017).

7.4.2 Mixed-methods approach

The development of the COS adhered to established international guidelines and recommendations, employing a mixed-methods approach to outcome generation (Kirkham et al., 2017; Williamson et al., 2017). Stage One provided a transparent, structured means of identifying outcomes that have previously been reported, while also capturing the evolving contemporaneous breadth by including study protocols, ongoing trials, and trial registries. The inclusion of study protocols and ongoing trials is a significant strength, enhancing the rigour and relevance whilst supporting a more nuanced interpretation to contextualise current outcomes. It was, however, constrained by the dominance of researcher-defined priorities that did not reflect health professionals' lived experience. Incorporating qualitative interviews and focus groups in Stage Two is a significant methodological strength, mitigating the epistemological and practical limitations inherent in the COS development if it were to rely solely on published studies. Qualitative interviews and focus groups enabled the elicitation of experiential perspectives, contextualising understandings of the relevance and why outcomes were perceived to be important. This methodological triangulation, coupled with the constant comparison technique, enhanced

the comprehensiveness and credibility of the outcomes, with convergence and divergence facilitating the identification of themes and analytical reflection.

To the researcher's knowledge, this is the first critical care COS to provide direct, verbatim quotes to participants during Round Two of the eDelphi study and in the consensus meetings. Employing this approach enhanced cognitive grounding by situating aggregated stakeholder group ratings within the original context of expert reasoning, enabling panellists to more accurately interpret why divergent views emerged rather than responding solely to decontextualised statistics (Hasson et al., 2025). The strength of providing quotations promoted epistemic reflexivity, encouraging panellists to critically reassess their individual opinions. Qualitative analysis of the reasons why participants changed their scores between rounds has rarely been reported in COS development, yet this substantially enhanced the interpretative depth of the findings. Findings from this study demonstrated that participants were influenced by the provision of quotes rather than by the graphical representation of stakeholder ratings. Consequently, future COS developers should consider incorporating a mixed-methods approach throughout consensus processes.

Throughout all stages of the PEACE-COS study, the researcher has considered her positionality (**Appendix 1**) embracing both an insider (emic) and an outsider (etic) lens (Tashakkori et al., 2021) to achieve a multifaceted and more equitable understanding of outcomes important in EoLC in critical care, thereby creating an impactful and meaningful COS.

7.4.3 Inclusive accessible design

Throughout Stages Two - Four of the PEACE-COS study, the researcher applied inclusive design principles to ensure equitable participation and public communication. The study website, social media posts and the animation were underpinned by the Web Content Accessibility Guidelines (WCAG), an internationally recognised standard (World Wide Web Consortium, 2018). Alternative text for images, sufficient colour contrast, captioned multimedia, and clear, plain language were consistently employed, with accessibility features enabled in REDCap (screen reader compatibility, keyboard navigation, clearly labelled form fields, adjustable text display, and error identification). Similarly, built-in

accessibility features designed to support participants with hearing, visual, motor, and cognitive impairments were activated within Microsoft Teams for interviews, focus groups and consensus meetings (Microsoft, 2026). All participants were invited to disclose their accessibility requirements in advance to accommodate further reasonable adjustments with the study material provided in an alternative format for one participant. The researcher has subsequently taught academic and research organisations together with UK research regulatory bodies how to apply WCAG standards and accessibility features to online meetings, study documents and REDCap. Disseminating the knowledge gained beyond the PEACE-COS study to other COS developers (Humphreys, 2024a) and more broadly to future researchers (Humphreys, 2025b).

7.4.4 Public research partners

The incorporation of multiple public research partners across the research processes, as illustrated in **Chapter Two Figure 2.4**, enhanced the rigour of the study, representing a further methodological strength. This pluralistic approach mitigated the privileging of any one group, broadening and deepening insights, ultimately yielding more meaningful research.

7.4.5 Pre-consensus meeting

Conducting a pre-consensus meeting enabled the identification of outcomes that patient and family representatives felt had been inadequately framed by the eDelphi process and steering group. It provided a safe space for participants to discuss the outcomes and reflect on what should be prioritised as core, without the influence of clinicians or researchers. Notably, participants who attended the pre-consensus meeting appeared more empowered to contribute in the subsequent consensus meeting.

7.5 Limitations

7.5.1 Recruitment challenges

Recruitment challenges were encountered with the patient/family stakeholder group during Stages Two and Three, which could be attributed to several interrelated factors. Despite extensive evidence associating the death of a family member in critical care with

psychological distress and an elevated risk of complicated grief (Sanderson et al., 2022), bereavement follow-up services within Europe exist inconsistently varying both between and within ICUs (Efstathiou et al., 2019), with an absence of structured support groups (Egerod et al., 2019). Furthermore, internationally, support systems are compounded by differing funding mechanisms and delivery structures, limiting recruitment avenues. Similarly, bereavement provision across UK ICUs is inconsistent (Pattison et al., 2020), meaning there is no reliable infrastructure through which researchers can consistently access bereaved relatives. Support organisations such as ICUsteps primarily focus on critical illness recovery, while large-scale bereavement charities such as Cruse adopt a broad, generalised or cause-specific model not tailored to critical care contexts. International critical care organisations were contacted for suggestions or links to critical care support groups, but none were received. The lack of access to established ICU support groups, however, is not unique to this COS development. Similar challenges were encountered in developing a COS for critical care ventilation trials, culminating in a lower-than-anticipated number of patient participants (Blackwood et al., 2019).

Challenges in recruiting bereaved family members in EoL research have previously been reported (Butler et al., 2018; Stiel et al., 2015). A study of bereaved ICU family members was unable to contact 69% of eligible family members due to inaccuracies in the patient record (Downar et al., 2014). Despite the time gap between Downar et al's (2014) research, findings from this study indicate that the challenge of locating and contacting bereaved critical care family members through hospital records remains and compounds both research and bereavement services.

7.5.2 Consideration of proxies

Congruent with COMET and contemporary critical care COS Delphi recommendations, patient representatives (patient survivors and bereaved family members of critical care decedents) were recruited in Stages Three and Four as direct patient participation was unfeasible (Gorst et al., 2025; Williamson et al., 2017). Although the inclusion of proxies was preferable to prevent underrepresented populations from being excluded from the COS development, it raises a critical concern about whose perspective was ultimately captured, potentially introducing outcome bias. The proxy-patient perspectives ask proxies to evaluate outcomes as they believe the patient would react. In contrast, proxy-proxy

perspectives elicit the proxy's own appraisal of the outcomes (Lapin et al., 2023). Using both proxy perspectives provided unique insights into EoLC; however, at times, it was unclear whether participants were providing proxy-patient or proxy-proxy perspectives, as some drew on multiple experiences.

7.5.3 Consideration of critical illness survivors

Surviving critical illness following a period of anticipated mortality may fundamentally alter perceptions, as experiences of care are retrospectively reframed through a different lens due to the reinterpretation of the disease trajectory. In health-related quality-of-life research, Sprangers & Schwartz (1999) found that a response shift can occur, in which individuals readjust their values when confronted with a life-threatening disease, thereby modifying how they assess and evaluate prior experiences. Similarly, Scheunemann et al. (2020) reported how critical illness survivors' priorities in the United Kingdom evolved across different time periods of recovery. These dynamics have important implications for the findings within Stages Three and Four. Although neither study captured the exact time-point in the survivor-based proxy-perspectives, this may have contributed to variability in outcome prioritisation. In Stage Three, a clear divergence emerged, for example, when rating survival and functional outcomes: survivor-based proxy panellists rated outcomes as critical, while family member panellists rated them as not important or important. Conversely, the small sample size limits the ability to conduct meaningful comparative analysis between proxy subgroups. Although the findings from patient survivors and family members could be triangulated in Stage Three, fewer family members participated (1:2 ratio), with only one participating in the pre-consensus meeting and none participating in the consensus meeting. Proxy-proxy perspectives were, however, provided in both consensus meetings within Stage Four by representatives from patient support organisations, maintaining the same proxy-proxy-to-proxy-patient ratio of 1:2. The results derived from both stages, however, disproportionately reflect a reliance on survivor-based proxy perspectives and should be interpreted accordingly.

Results and experience gained from developing the COS highlight the need for disclosing the proxy perspective employed in a transparent manner, as a potential source of inadvertently introducing outcome bias.

7.5.4 Linguistics

Linguistic limitations are evident throughout the development of the core outcome set. Stage One restricted inclusion to studies published in English, with participation in Stages Two–Four confined to those proficient in English. Moher et al. (2000) found no difference in a language-restricted meta-analysis, suggesting the results of the systematic review in Stage One are unlikely to have been affected by the omission of non-English studies; however, the reliance on English-speaking participants in subsequent stages represents a sampling bias excluding linguistically diverse populations whose perspectives and experiences may differ systematically from those represented in the systematic review. As such, the findings reflect a partial and culturally bound understanding of EoLC. Pragmatic decisions were made based on financial and logistical constraints coupled with the complexity of achieving conceptual equivalence of outcomes across languages. Future iterations of the COS may benefit from incorporating multilingual searches (Higgins et al., 2022), with translational and cross-cultural adaptations enabling multilingual participants to participate and mitigating such linguistic limitations. Furthermore, strategies such as expanding the international composition of the study steering committee or adopting collaborative approaches involving multilingual researchers would broaden linguistic and cultural perspectives, strengthening the study design and enhancing global relevance.

7.5.5 Steering committee composition and independence

While the members of the steering committee had previously resided and worked in different countries, all resided in the UK at the time of the study. Consequently, composition may have disproportionately reflected the perspectives of higher-income countries. Additionally, as the steering group was not fully independent from the research team, researcher bias may have influenced the scope and interpretation of the findings.

7.5.6 Inclusion of Low-Middle Income Countries

Throughout the study, there was limited representation of LMICs, with only Uganda (World Bank Country and Lending Groups, 2025) represented in Stage Three. One explanation may be the disparity in critical care provision and development in comparison to high-income countries. In LMIC such as Sub-Saharan Africa, critical care capability remains largely underreported, with many hospitals treating patients on general wards due to the

lack of established public critical care units (Almalki et al., 2024). Furthermore, a scoping review of palliative and EoLC in LMIC found no critical care trials evaluating EoLC interventions or outcomes (Rao et al., 2022). The underrepresentation of LMICs is, however, not unique to this COS. A systematic review of newly published COS on the COMET database concluded that although participation from Asia, South America and Africa was evident, trends did not demonstrate a sustained increase over time (Dodd et al., 2023).

Despite the limited representation of LMIC in this study, observational and qualitative studies conducted in LMIC emphasise the importance of all the core outcomes (pain, respiratory distress, delirium, dignity, quality of death and dying and communication) in EoLC in critical care (Rao et al., 2022). A systematic review of EoLC in Middle Eastern and North African countries indicates both convergence and divergence between EoLC in LMICs and high-income countries (Almalki et al., 2024). Preserving dignity, for example, holds significant importance within Middle Eastern countries, where death is perceived as a sacred transition as opposed to a medical event (Almalki et al., 2024). Critically, the review identifies a disconnect between the importance placed on dignity and the ability to preserve dignity due to open-plan ICUS and insufficient privacy. Such challenges mirror those found in Stage Two and Four of this study with participants in high-income countries, highlighting how dignity is aspirational in both LMIC and high-income countries and the importance of including it in an international COS.

7.6 Dissemination

To ensure research transparency, reduce waste and prevent duplication, the PEACE-COS study was registered *a priori* on the COMET database (Humphreys et al., 2021b) and will be updated to show the study status and links to publications arising from the study. From inception, a systematic, multi-phase dissemination strategy was planned to maximise stakeholder engagement and research impact. Publicly available on the study website (Humphreys, 2023c), participant information sheets throughout the study detailed a commitment to disseminating the research findings through multiple platforms. Findings from Stages One, Two and Three of the study have been presented by the researcher at local, national and international conferences and research meetings (Humphreys, 2022, 2023b, 2023d, 2024c, 2024b, 2024a, 2025a, 2025b) and will be submitted for publication

to relevant peer-reviewed journals. Findings will also be shared with research funders. Plain language summaries will be produced with public research partners. Located in 11 countries, all participants in Stages Two, Three and Four of the study consented to and provided an email address to receive a plain-language summary of the final COS underpinning the researchers' ethical commitments to integrity, transparency and reciprocity. Digital dissemination channels, such as the PEACE-COS website (Humphreys, 2023c), and professional/organisational/study social media platforms, will be used to extend reach. Data arising from the research study will continue to be made available to the scientific community in a timely and responsible manner through careful aggregation and anonymisation of stakeholder contributions to preserve confidentiality and methodological integrity.

7.7 Future work

The development of a COS needs to be followed by decisions and consensus on *'how'* and *'when'* the outcomes should be measured to create a Core Outcome Measurement Set (COMS) (Beaton et al., 2021; Williamson et al., 2017). Although the PEACE-COS study focused on *'what'* should be measured, OMIs and associated time points were identified as part of the process (**Appendix 15**). Wide variation was evident with six different OMIs used to capture the quality of death and dying (**Table 7.1**), while the frequency of measurement was highly variable. Both COS and COMS methodologies recommend that, where possible, each outcome should be linked to a single, validated instrument based on validity, reliability, feasibility and stakeholder relevance (Beaton et al., 2021; Williamson et al., 2017). Not all the OMIs identified in the PEACE-COS study had undergone psychometric or sensitivity/specificity evaluation. Dignity, for example, was identified in both Stages One and Two of the study; however, only a study-specific tool (interview) was identified in Stage One, with none in Stage Two. Similarly, in Stage Two, participants spoke of using visual analogue scales to measure pain but were unable to articulate specific OMIs. As such, outcomes have been included in the COS, where few OMIs were identified in the EoL critical care population. The inclusion of such outcomes in the COS, however, reflects the priorities of multiple stakeholders and is conceptually important. Omitting such outcomes because of an apparent absence of validated OMIs risks conflating measurability with importance (Gorst et al., 2016). The OMIs identified in the PEACE-COS study do not represent an exhaustive account of all available OMIs.

Stage One (systematic review) was constrained by its eligibility criteria. Outcome instrument development studies were excluded, and OMIs reported outside of intervention studies may not have been captured. The apparent paucity of instruments, for example, in delirium and pain, therefore reflects the methodological scope. Going forward, a targeted review is required to identify and appraise OMIs that have been developed or are currently in development, and the development or adaptation of new OMIs may be warranted. The multidimensional nature of the outcomes included in the COS means that, in some cases, more than one OMI may be required if no single OMI adequately captures all the relevant constructs (Gorst et al., 2020). The development of a COMS will form the basis of postdoctoral work.

Table 7.1 Outcome Measurement Instruments

Outcome	**Outcome measurement instrument**	**Source**
Pain	Visual analogue score	Stage 2
Respiratory distress	AOS	Stage 1
	BPS	Stage 1
	RDOS	Stage 1
Dignity	Study-specific questionnaire	Stage 1
Delirium	CAM-ICU	Stage 2
Quality of death and dying	CAESAR	Stage 1
	CEQUEL	Stage 1
	ICUQODD	Stage 1
	QODD	Stage 1
	QODD-1	Stage 1
	QEOLC-10	Stage 1
Quality of communication	QOC	Stage 1

[AOS] Airway Obstruction Scale, [BPS] Behavioural Pain Score, [RDOS] Respiratory, [CAM-ICU] Confusion Assessment Method for the ICU, [CAESAR] Care Assessment of the Experience of Relatives scale, [CEQUEL] Caregiver Evaluation of the Quality of End-of-Life Scales, [ICUQODD] ICU Quality of Death and Dying, [QODD] Quality of Death and Dying Scale, [QODD-1] Quality of Death and Dying Scale 1, [QEOLC-10] Quality of End-of-Life Care–10 instrument, [QOC] Quality of Communication questionnaire

7.8 Conclusion

A COS for evaluating end-of-life care in critical care has been developed and agreed through rigorous methodology and a transparent consensus process involving three key stakeholders: researchers, health professionals and patients/families. A minimum of six outcomes are recommended: pain, respiratory distress, delirium, quality of death and dying, dignity and communication. The study represents the only international COS for EoLC in critical care (Gorst et al., 2025).

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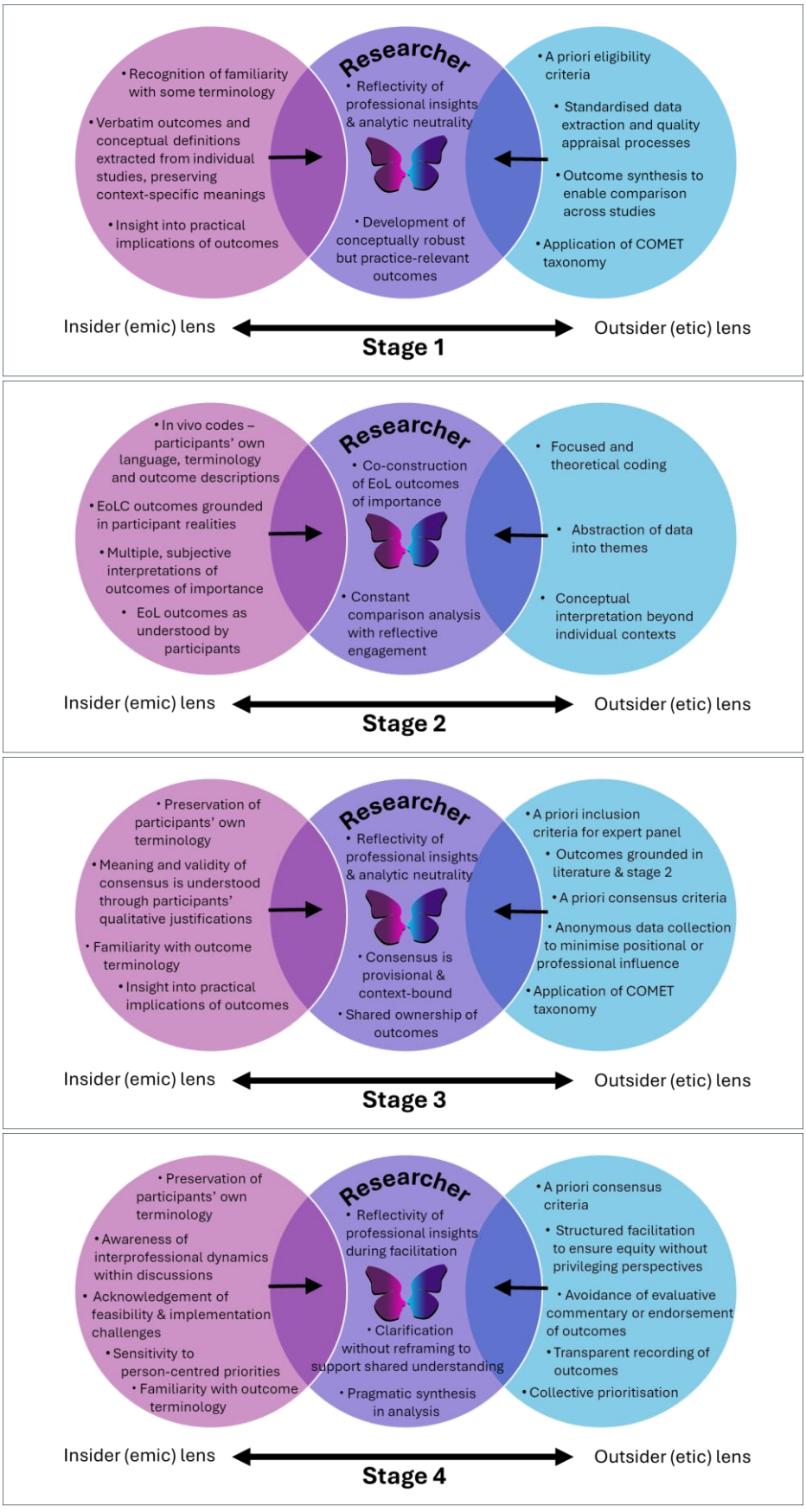
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Appendix 1 The hybrid emic-etic positionality



Appendix 2 Public researcher partners

Name	Affiliation
Patient and Public Involvement Group	East and North Hertfordshire NHS Trust
Health Research Authority	Health Research Authority
Ethnic Minorities Group	National Institute for Health Research
St Nicholas Hospice	St Nicholas Hospice
Public Involvement in Research Group	University of Hertfordshire
Bereaved family member	-
Researcher	-
Health professional	-

Appendix 3 Steering committee

Name	Affiliation	Stakeholder
Rosemary Godbold	University of Hertfordshire	Researcher/nurse
Natalie Hall	University of Hertfordshire	Researcher/REDCap administrator
Sally Humphreys	University of Hertfordshire	Researcher/nurse
Nazir Lone	University of Edinburgh NHS Lothian	Researcher/Intensivist
Natalie Pattison	University of Hertfordshire East and North Hertfordshire NHS Trust	Researcher/nurse
Rebecca Scott	University of Hertfordshire	Information specialist
Alex	University of Hertfordshire	Public research partner

Appendix 4 HRA approvals

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Professor Natalie Pattison
University of Hertfordshire
School of Health and Social Care
Hatfield, Hertfordshire
AL10 9AB

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

06 April 2023

Dear Professor Pattison

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Developing Person-Centred Outcome Measures in End-of-Life Care in Critical Care: a longitudinal qualitative study of bereaved families experience and Delphi exercise to inform a Core Outcome Set**
IRAS project ID:	**306272**
Protocol number:	**To be confirmed**
REC reference:	**23/NE/0057**
Sponsor	**University of Hertfordshire**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **306272**. Please quote this on all correspondence.

Yours sincerely,
Libby Williamson
Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Mrs Sarah Beeley,*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [PEACE-COS Communication Tool Kit - Tracked]	1.1	31 March 2023
Copies of materials calling attention of potential participants to the research [PEACE-COS Communication Tool Kit - Clean]	1.1	31 March 2023
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Uni Hertfordshire Research Insurance]	1.0	02 August 2022
Interview schedules or topic guides for participants [PEACE-COS Stage 2 Interview Guide]	1.0	03 November 2022
IRAS Application Form [IRAS_Form_28022023]		28 February 2023
Letter from funder [No funder letter available]		16 March 2023
Letter from sponsor [Principle Sponsorship Pattison-Humphreys]	1.0	10 February 2023
Letters of invitation to participant [PEACE-COS Stage 2 Approach Letter]	1.0	03 November 2022
Organisation Information Document [OID PEACE-COS]		
Other [PEACE-COS Stage 2 Consent Script]	1.0	03 November 2022
Other [PEACE-COS Bereavement Support Information]	1.0	03 November 2022
Participant consent form [PEACE-COS Consent Form - Tracked]	1.1	31 March 2023
Participant consent form [PEACE-COS Consent Form - Clean]	1.1	31 March 2023
Participant information sheet (PIS) [PEACE-COS Stage 2 PIS - Tracked]	1.1	31 March 2023
Participant information sheet (PIS) [PEACE-COS Stage 2 PIS - Clean]	1.1	31 March 2023
Research protocol or project proposal [PEACE-COS Study Protocol]	1.0	03 November 2022
Schedule of Events or SoECAT [PEACE-COS Schedule of Events]	1.0	12 January 2023
Summary CV for Chief Investigator (CI) [PEACE-COS Summary CV CI N Pattison]	1.0	01 December 2022
Summary CV for student [PEACE-COS Summary CV S Humphreys]	1.0	19 January 2023
Summary CV for supervisor (student research) [PEACE-COS Summary CV R Godbold]	1.0	19 January 2023
Summary CV for supervisor (student research) [PEACE-COS Summary CV N Lone]	1.0	01 November 2022
Summary, synopsis or diagram (flowchart) of protocol in non technical language [PEACE-COS Non-Technical Summary]	1.0	03 November 2022

Health Research Authority

North East - Tyne & Wear South Research Ethics Committee
NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

26 February 2024

Miss Sally Humphreys
University of Hertfordshire
School of Health and Social Care
Hatfield
AL10 9AB

Dear Miss Humphreys

Study title:	**Developing Person-Centred Outcome Measures in End-of-Life Care in Critical Care: a longitudinal qualitative study of bereaved families experience and Delphi exercise to inform a Core Outcome Set**
REC reference:	**23/NE/0057**
Protocol number:	**To be confirmed**
Amendment number:	**Amendment 1**
Amendment date:	**06 February 2024**
IRAS project ID:	**306272**

The above amendment was reviewed at the meeting of the Sub-Committee held on 22 February 2024 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Completed Amendment Tool [Amendment Tool]	1.0	17 January 2024
Letters of invitation to participant [PEACE-COS_Stage_2_FM_Approach_Letter_Version_2.0_2024_01_17_clean.docx]	2.0	17 January 2024
Letters of invitation to participant [PEACE-COS_Stage_2_FM_Approach_Letter_Version_2.0_2024_01_17_clean.docx]	2.0	17 January 2024
Letters of invitation to participant [PEACE-COS_Stage_2_HP_Email_Invite_Version_1.0_2024_01_17.docx]	1.0	17 January 2024
Other [PEACE-COS_Communications_Tool_Kit_Version_2.0_2024_01_17_Tracked.pdf]	2.0	17 January 2024
Participant consent form [PEACE-COS_Stage_2_FM_Consent_Form_Version_2.0_2024_01_17_Clean.pdf]	2.0	17 January 2024
Participant consent form [PEACE-COS_Stage_2_FM_Consent_Form_Version_2.0_2024_01_17_Clean.pdf]	2.0	17 January 2024
Participant consent form [PEACE-COS_Stage_2_HP_FG_Eligibility_Confirmation_Consent_Version_1.0_2024_01_17.pdf]	1.0	17 January 2024
Participant consent form [PEACE-COS_Stage_2_HP_Interview_Eligibilty_Confirmation_Consent_Version_1.0_2024_01_17.pdf]	1.0	17 January 2024
Participant information sheet (PIS) [PEACE-COS_Stage_2_FM_PIS_Version_2.0_2024_01_17_clean.pdf]	2.0	17 January 2024
Participant information sheet (PIS) [PEACE-COS_Stage_2_FM_PIS_Version_2.0_2024_01_17_clean.pdf]	2.0	17 January 2024
Participant information sheet (PIS) [PEACE-COS_Stage_2_HP_FG_PIS_Version_1.0_2024_17_01.pdf]	1.0	17 January 2024
Participant information sheet (PIS) [PEACE-COS_Stage_2_HP_PIS_Interview_Version_1.0_2024_01_17.pdf]	1.0	17 January 2024
Research protocol or project proposal [PEACE-COS_Protocol_Version_2.0_2024_01_23_clean.pdf]	2.0	17 January 2024
Research protocol or project proposal [PEACE-COS_Protocol_Version_2.0_2024_01_23_clean.pdf]	2.0	17 January 2024

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as

possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

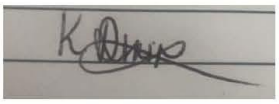
HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS Project ID - 306272:	**Please quote this number on all correspondence**

Yours sincerely

p.p.



Mr Ian Campbell
Chair

E-mail: tyneandwearsouth.rec@hra.nhs.uk

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Miss Sally Humphreys*

Health Research Authority

North East - Tyne & Wear South Research Ethics Committee

NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

17 September 2024

Miss Sally Humphreys
University of Hertfordshire
School of Health and Social Care
Hatfield
AL10 9AB

Dear Miss Humphreys

Study title:	**Developing Person-Centred Outcome Measures in End-of-Life Care in Critical Care: a qualitative study and Delphi exercise to inform a Core Outcome Set.**
REC reference:	**23/NE/0057**
Protocol number:	**To be confirmed**
Amendment number:	**SA-02**
Amendment date:	**04 September 2024**
IRAS project ID:	**306272**

The above amendment was reviewed at the meeting of the Sub-Committee held on 19 September 2024 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Completed Amendment Tool [Amendment Tool]	1	03 September 2024
Copies of advertisement materials for research participants [Delphi Poster A]	1.0	30 August 2024
Copies of advertisement materials for research participants [Delphi Poster B]	1.0	30 August 2024
Copies of advertisement materials for research participants [Delphi Poster C]	1.0	30 August 2024
Copies of advertisement materials for research participants [Social	1.0	30 August 2024

Media Advertisement A]		
Copies of advertisement materials for research participants [Social Media Advertisement B]	1.0	30 August 2024
Copies of advertisement materials for research participants [Social Media Advertisement C]	1.0	30 August 2024
Copies of advertisement materials for research participants [Social Media Advertisement D]	1.0	30 August 2024
Copies of advertisement materials for research participants [Social Media Advertisement E]	1.0	30 August 2024
Copies of advertisement materials for research participants [Email containing the link to the video advertisement]	1.0	30 August 2024
Copies of materials calling attention of potential participants to the research [Study Email Invite]	1.0	30 August 2024
Participant consent form [Online Screening Consent Forms]	1.0	30 August 2024
Participant information sheet (PIS) [Patient Information Sheet]	1.0	30 August 2024
Research protocol or project proposal [Protocol Clean]	3.0	30 August 2024
Research protocol or project proposal [Protocol Tracked]	3.0	30 August 2024
Validated questionnaire [Round 1 Questionnaire]	1.0	30 August 2024

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS Project ID - 306272:	**Please quote this number on all correspondence**

Yours sincerely

p.p.



Mr Ian Campbell
Chair

E-mail: tyneandwearsouth.rec@hra.nhs.uk

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Miss Sally Humphreys*

North East - Tyne & Wear South Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 19 September 2024

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr John Blenkinsopp	Clinical Effectiveness Manager	Yes	
Mr Ian Campbell	Assistant Director of Pharmacy	Yes	Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Katie Atkin	Approvals Administrator

Appendix 5 University of Hertfordshire approvals

University of Hertfordshire UH

University of Hertfordshire
Higher Education Corporation
Hatfield, Hertfordshire
AL10 9AB

Telephone +44 (0) 1707 284000
Fax +44 (0) 1707 284115
Website www.herts.ac.uk

John M Senior
BSc MSc DSc PGCE CEng FIET FRSA FHEA
Professor of Communication Networks
Pro Vice-Chancellor (Research and Enterprise)

Professor N Pattison/Sally Humphreys
CRIPACC
School of Health and Social Work

28 June 2023

Dear Professor Pattison & Ms Sally Humphreys

Re: **UNIVERSITY OF HERTFORDSHIRE SPONSORSHIP IN FULL for the following:**
RESEARCH STUDY TITLE: PEACE-COS: Developing Person-Centred Outcome Measures in End-of-Life Care in Critical Care: a longitudinal qualitative study of bereaved families experience, and Delphi exercise to inform a Core Outcome Set
NAME OF CHIEF INVESTIGATOR (Supervisor): Professor Natalie Pattison
NAME OF INVESTIGATOR (Student): Sally Humphreys
UNIVERSITY OF HERTFORDSHIRE ETHICS PROTOCOL NUMBER: HSK/PGR/NHS/02993
HEALTH RESEARCH AUTHORITY REFERENCE: 23/NE/0057

This letter is to confirm your research study detailed above has been reviewed and accepted and I agree to give full University of Hertfordshire sponsorship, so you may now commence your research.

As a condition of receiving full sponsorship, please note that it is the responsibility of the Chief Investigator to inform the Sponsor at any time of any changes to the duration or funding of the project, changes of investigators, changes to the protocol and any future amendments, or deviations from the protocol, which may require re-evaluation of the sponsorship arrangements.

Permission to seek changes as outlined above should be requested from myself before submission to the Health Research Authority (HRA) Research Ethics Committee (REC) and I must also be notified of the outcome. It is also essential that evidence of any further NHS Trust or other site permissions is sent as soon as they are received. Copies of annual reports and the end of study report as submitted to the HRA also need to be provided. Please do this via email to research-sponsorship@herts.ac.uk

Please note that University Sponsorship of your study is invalidated if this process is not followed.

In the meantime, I wish you well in pursuing this interesting research study.

Yours sincerely



Professor J M Senior
Pro Vice-Chancellor (Research and Enterprise)

University of Hertfordshire Higher Education Corporation is an exempt charity

From: Research Sponsorship <research-sponsorship@herts.ac.uk>
Sent: 27 September 2024 14:12
To: Sally Humphreys [Student-HSK] <s.k.humphreys@herts.ac.uk>
Cc: Natalie Pattison <n.pattison@herts.ac.uk>; Rosemary Godbold <r.godbold@herts.ac.uk>
Subject: RE: IRAS PROJECT ID 306272, REC Reference 23/NE/0057 Confirmation of favourable opinion for substantial amendment

Hi Sally,

Apologies for the delay in responding.

I can confirm continued sponsorship following approval by the HRA of the SA02.

Best wishes,
Sarah

Sarah Beeley (she/her)
Senior Research Governance and Information Coordinator
Research and Enterprise Services
Office of the Vice-Chancellor
University of Hertfordshire
01707 285794 (x5794)

To: Sally Humphreys

Your application for ethics approval for the study listed below has been approved by the Health, Science, Engineering and Technology Ethics Committee with Delegated Authority. **Please read this letter carefully.**

Study Title: Developing Person-Centred Outcome Measures in End-of-Life Care in Critical Care: a qualitative study and Delphi exercise to inform a Core Outcome Set

Your UH protocol number is: **0890 2025 Apr HSET**
This reference must be quoted on all paperwork, including advertisements for participants.

If you wish to use the UH Ethics Committee logo disclaimer in your communications with participants, please find it in our UH Ethics Canvas site under 'Units - Application Forms': UH Ethics Approval (instructure.com.

This ethics approval expires on 01/10/2025

Amending your protocol

Individual protocols will normally be approved for the limited period of time noted above. Application for minor amendments (including time extensions) of a protocol, may be made for a maximum of 4 working weeks after the end date of that protocol.

It is expected that any amendments proposed via the online system will be minor. Should substantial modification be required, it would be necessary to make a fresh application for ethical approval.

Note that you must obtain approval from the relevant UH Ethics Committee with Delegated Authority **prior to implementing any changes**. Failure to do so constitutes a breach of ethics regulations (UPR RE01).

Adverse circumstances
Any adverse circumstances that may arise because of your study/activity must be reported to ethicsadmin@herts.ac.uk as soon as possible.

Permissions
Any necessary permissions for the use of premises/location and accessing participants for your study/activity must be obtained in writing prior to any data collection commencing. Failure to obtain adequate permissions may be considered a breach of this protocol.

Ethics Administration Team

ethicsadmin@herts.ac.uk

Appendix 6 Medline initial search

Ovid MEDLINE(R) ALL <1946 to February 18, 2022>

#	Query
1	(ICU* or intensive care or critical care* or critical* ill or HDU*).ab. or (ICU* or intensive care or critical care* or critical* ill).ti. or (ICU* or intensive care or critical care* or critical* ill or HDU*).hw.
2	critical care/ or critical illness/ or intensive care units/
3	(end of life* or eol* or palliative care* or terminal* ill or terminal patient* or terminal phase or terminal stage or final stages of life or limited survival or comfort care* or supportive care or dying* or (withdrawal adj3 treatment*) or (withdrawal adj3 care) or (treatment adj1 limitation*)).mp.
4	Terminal care/
5	death/ and (good or well or bad or poor).ti.
6	(high risk adj2 death).mp.
7	(person cent*red or patient cent*red or pcom or quality of dying or quality of death or (quality adj3 measure*) or quality indicat* or (outcome* adj3 measure*) or (quality adj2 communication)).mp.
8	(anxiety or depression or PTSD).ti. or (anxiety or depression or PTSD).ab.
9	(symptom management or satisfaction or dignity or compassion or spiritual* or emotional support or continuity of care).mp.
10	Pain/ or Dyspnea/ or Fatigue/ or "Personal Autonomy"/
11	(family* or families* or relative* or significant other or bereav*).mp.
12	family/ or caregivers/
13	1 or 2
14	3 or 4 or 5 or 6
15	7 or 8 or 9 or 10 or 11 or 12
16	13 and 14 and 15
17	randomised controlled trials/ or random allocation/ or double-blind method/ or single-blind method/ or clinical trials/ or prospective studies/ or cross-over studies/ or clinical study/ or evaluation study/ or validation study/ or meta-analysis/ or systematic review/ or exp Epidemiologic Studies/ or observational study/ or comparative study/
18	qualitative research/ or grounded theory/ or focus group/ or interview/ or phenomenology/ or ethnography/ or narrative/ or thematic analysis/ or content analysis/ or epidemiologic/ or observational/ or comparative/ or (qualitative or content analysis or thematic analysis or phenomenology or grounded theory or narrative or ethnography or focus group* or interview* or experience*).mp.
19	17 or 18
20	16 and 19
21	(paediatric or pediatric or children or child or neonat* or baby or infan*).ti.
22	20 not 21
23	limit 22 to english

Appendix 7 PRESS (2015) Guideline evidence-based checklist

Translation of the research question	Yes, No or N/A	Comments
Does the search strategy match the research question/PICO?	Yes	Although addition of exclusion of children not mentioned in research design
Are the search concepts clear?	Yes	
Are there too many or too few PICO elements included?	No	Each element is covered in strategy
Are the search concepts too narrow or too broad?		Some lines could have more terms
Does the search retrieve too many or too few records? (Please show number of hits per line.)		#5 ((good or bad or poor or well) adj2 (death or dying)).af. 3969 or tw. 3950 or ab. 3622
Are unconventional or complex strategies explained?	N/A	
Boolean and proximity operators		
Are Boolean or proximity operators used correctly?	Yes	
Is the use of nesting with brackets appropriate and effective for the search?	Yes	
If NOT is used, is this likely to result in any unintended exclusions?		#21 Children excluded using NOT, however no mention of an age specific cohort in the research description
Could precision be improved by using proximity operators (eg, adjacent, near, within) or phrase searching instead of AND?	Yes	#5
Is the width of proximity operators suitable (eg, might adj5 pick up more variants than adj2)?	Yes	
Subject headings		
Are the subject headings relevant?	Yes	
Are any relevant subject headings missing?		None used in lines #8 or #9
Are any subject headings too broad or too narrow?		Line #12 could have more headings
Are subject headings exploded where necessary and vice versa?	No	Could have exploded lines #2 and #4
Are major headings (“starring” or restrict to focus) used? If so, is there adequate justification?		Not used
Are subheadings missing?		Not used
Are subheadings attached to subject headings?	N/A	
Are floating subheadings relevant and used appropriately?	N/A	
Are both subject headings and terms in free text used for each concept?	No	Line #10 no free text used for pain, dyspnoea or fatigue.
Are the subject headings relevant?	Yes	

Text word searching (free text)	Yes, No or N/A	Comments
Does the search include all spelling variants in free text?	Yes	
Does the search include all synonyms or antonyms (e.g., opposites)?	No	Line #11 could be improved on
Does the search capture relevant truncation (i.e., is truncation at the correct place)?	No	Over use in lines #1 #3 and #11 Line #18 truncate phenomenology and ethnography
Is the truncation too broad or too narrow?	No	
Are acronyms or abbreviations used appropriately? Do they capture irrelevant material? Are the full terms also included?	No	HDU not written in full ITU not included or written in full
Are the keywords specific enough or too broad? Are too many or too few keywords used? Are stop words used?	Yes	No stop words used
Have the appropriate fields been searched; e.g., is the choice of the text word fields (.tw.) or all fields (.af.) appropriate? Are there any other fields to be included or excluded (database-specific)?	No	Variations in fields used in different lines, ti. ab. hw. mp. Lines #3 and #7 mp. used for PICO term, line #8 ti. ab. used for minor term
Should any long strings be broken into several shorter search statements?	No	
Spelling, syntax and line numbers		
Are there any spelling errors?	No	
Are there any errors in system syntax; e.g., the use of a truncation symbol from a different search interface?	No	
Are there incorrect line combinations or orphan lines (i.e., lines that are not referred to in the final summation that could indicate an error in an AND or OR statement)?	No	All lines used, however, I would exclude #11 and #12 from line #15 and combine separately before pulling in all combination lines at the end. Otherwise terms in lines #7 - #10 could not appear at all in final search in favour of terms in lines#11 or #12 and vice versa.
Limits and filters		
Are all limits and filters used appropriately and are they relevant given the research question?		Limited to English only
Are all limits and filters used appropriately and are they relevant for the database?	Yes	
Are any potentially helpful limits or filters missing? Are the limits or filters too broad or too narrow? Can any limits or filters be added or taken away?	No	
Are sources cited for the filters used?	N/A	

Over all, good search strategy, just needs some attention to use of truncation and use of matching subject headings and text words. Exclusion of children needs to be part of study as no mention of it being specifically adults. Review combination in line #15 to improve relevance of search results. Every time you add another term using OR, you are saying I'll take that term in favour of these terms; so each term within an OR string needs to be equal in subject and relevance to the others. By including #11 and #12 with #7 to #10 you are potentially dropping all the other terms in #7 to #10 in favour of #11 or #12, so dropping pain, symptom management, anxiety etc etc, in favour of family.

Appendix 8 Final Medline search

#	Query Medline via Ovid NHS
1	(ICU* or intensive care or critical care or critical* ill* or intensive care unit* or critical care unit*).ti. or (ICU* or intensive care or critical care or critical* ill or intensive care unit* or critical care unit*).ab.
2	critical care/ or critical illness/ or intensive care units/
3	(end of life or eol* or palliative care or terminal* ill or terminal patient* or terminal phase or terminal stage or final stages of life or limited survival or comfort care or supportive care or dying or (withdrawal adj3 treatment*) or (withdrawal adj3 care) or (treatment adj1 limitation*)).ti. or (end of life or eol* or palliative care or terminal* ill or terminal patient* or terminal phase or terminal stage or final stages of life or limited survival or comfort care or supportive care or dying or (withdrawal adj3 treatment*) or (withdrawal adj3 care) or (treatment adj1 limitation*)).ab.
4	Terminal care/ or Palliative care/
5	((good or bad or poor).ti. or (good or bad or poor).ab.) and death/
6	Bereavement/ or Grief/
7	(person cent*red or patient cent*red or pcom or quality of dying or quality of death or (quality adj3 measure*) or quality indicat* or (outcome* adj3 measure*) or (quality adj2 communication)).ti. or (person cent*red or patient cent*red or pcom or quality of dying or quality of death or (quality adj3 measure*) or quality indicat* or (outcome* adj3 measure*) or (quality adj2 communication)).ab.
8	(anxiety or depression or PTSD or post-traumatic stress disorder).ti. or (anxiety or depression or PTSD or post-traumatic stress disorder).ab. or Anxiety/ or Depression/ or ((bereav* or grief or griev*) adj2 (stress* or distress* or complicat* or persist* or complex or patholog* or disorder*)).ti. or ((bereav* or grief or griev*) adj2 (stress* or distress* or complicat* or persist* or complex or patholog* or disorder*)).ab.
9	(symptom management or satisfaction or dignity or compassion or spiritual* or emotional support or continuity of care).ti. or (symptom management or satisfaction or dignity or compassion or spiritual* or emotional support or continuity of care).ab. or "Continuity of Patient Care"/ or Symptom Assessment/ or Respect/ or Empathy/ or Spirituality/
10	(pain or dyspnea or fatigue or personal autonomy).ti. or (pain or dyspnea or fatigue or personal autonomy).ab. or Pain/ or Dyspnea/ or Fatigue/ or "Personal Autonomy"/
11	1 or 2
12	3 or 4 or 5 or 6
13	7 or 8 or 9 or 10
14	11 and 12 and 13
15	randomised controlled trials/ or random allocation/ or double-blind method/ or single-blind method/ or clinical trials/ or prospective studies/ or cross-over studies/ or clinical study/ or evaluation study/ or validation study/ or meta-analysis/ or systematic review/ or exp Epidemiologic Studies/ or observational study/ or comparative study/
16	qualitative research/ or grounded theory/ or focus group/ or interview/ or phenomenology/ or ethnography/ or narrative/ or thematic analysis/ or content analysis/ or epidemiologic/ or observational/ or comparative/ or (qualitative or content analysis or thematic analysis or phenomenolog* or grounded theory or narrative or ethnograph* or focus group* or interview* or experience*).ti. or (qualitative or content analysis or thematic analysis or phenomenolog* or grounded theory or narrative or ethnograph* or focus group* or interview* or experience*).ab.
17	15 or 16
18	14 and 17
19	(paediatric* or pediatric* or children or child or neonat* or baby or infan* or newborn* or adolescent*).ti. or (paediatric* or pediatric* or children or child or neonat* or baby or infan* or newborn* or adolescent*).ab. or Infant/ or Child, Preschool/ or Pediatrics/ or Adolescent/ or Infant, Premature/ or Child/ or Infant, Extremely Premature/
20	((adult adj1 child*) or grown-up child*).ti. or ((adult adj1 child*) or grown-up child*).ab.
21	19 not 20
22	18 not 21
23	limit 22 to English

Appendix 9 Database search strategies

Cochrane database search translation

#	Cochrane Query
1	(ICU*:ti OR "intensive care":ti OR "critical care":ti OR (critical* NEXT ill*):ti OR ("intensive care" NEXT unit*):ti OR ("critical care" NEXT unit*):ti) OR (ICU*:ab OR "intensive care":ab OR "critical care":ab OR (critical* NEXT "ill"):ab OR ("intensive care" NEXT unit*):ab OR ("critical care" NEXT unit*):ab)
2	[mh ^"critical care"] OR [mh ^"critical illness"] OR [mh ^"intensive care units"]
3	("end of life":ti OR eol*:ti OR "palliative care”:ti OR (terminal* NEXT “ill”): ti OR OR ("terminal" NEXT patient*):ti OR "terminal phase":ti OR "terminal stage”: ti OR "final stages of life":ti OR "limited survival":ti OR "comfort care":ti OR "supportive care":ti OR dying:ti OR (withdrawal:ti NEAR/3 treatment*:ti) OR (withdrawal:ti NEAR/3 care: ti) OR (treatment:ti NEAR/1 limitation*:ti)) OR ("end of life":ab OR eol*:ab OR "palliative care”:ab OR (terminal* NEXT “ill”): ab OR ("terminal" NEXT patient*):ab OR "terminal phase":ab OR "terminal stage”:ab OR OR "final stages of life":ab OR "limited survival":ab OR "comfort care”: ab OR “supportive care”:ab OR dying:ab OR (withdrawal:ab NEAR/3 treatment*: ab) OR (withdrawal:ab NEAR/3 care:ab) OR (treatment:ab NEAR/1 limitation*:ab))
4	MeSH descriptor: [Intensive Care Units] this term only
5	#2 or #3 or #4
6	((end of life or EOL* or palliative care or terminal* ill or terminal patient* or terminal phase or terminal stage or final stages of life or limited survival or comfort care or supportive care or dying)):ti,ab, OR ((withdrawal NEAR/3 treatment*)):ti,ab, OR ((withdrawal NEAR/3 care)):ti,ab, OR ((treatment NEAR/1 limitation*)):ti,ab,
7	MeSH descriptor: [Terminal Care] this term only
8	MeSH descriptor: [Palliative Care] this term only
9	#S7 OR #S8
10	MeSH descriptor: [Death] this term only
11	(good or bad or poor):ti
12	#S10 AND #S11
13	MeSH descriptor: [Bereavement] this term only
14	MeSH descriptor: [Grief] this term only
15	#13 OR #14
16	((person cent*red or patient cent*red or pcom or quality of dying or quality of death or quality indicat*)):ti,ab, OR ((quality NEAR/3 measure*)):ti,ab, OR ((outcome* NEAR/3 measure)):ti,ab, OR ((quality NEAR/2 communication)):ti,ab,
17	(anxiety OR depression OR PTSD OR post-traumatic stress disorder OR (bereav* OR grief OR griev*) NEAR/2 (stress* OR distress* OR complicat* OR persist* OR complex OR patholog* OR disorder*)):ti OR (anxiety OR depression OR PTSD OR post-traumatic stress disorder OR (bereav* OR grief OR griev*) NEAR/2 (stress* OR distress* OR complicat* OR persist* OR complex OR patholog* OR disorder*)):ab
18	MeSH descriptor: [Anxiety] this term only
19	MeSH descriptor: [Depression] this term only
20	#S17 OR #18 OR #S19
21	((symptom management OR satisfaction OR dignity OR compassion OR spiritual* OR emotional support OR continuity of care OR symptoms severity)):ti,ab,
22	MeSH descriptor: [Continuity of Patient Care] this term only
23	MeSH descriptor: [Symptom Assessment] this term only
24	MeSH descriptor: [Respect] this term only
25	MeSH descriptor: [Respect] this term only

#	Cochrane Query
26	MeSH descriptor: [Spirituality] this term only
27	#21 OR #22 OR #23 OR #24 OR #25 OR #26
28	(Pain OR Dyspnea OR Fatigue OR "personal autonomy"):ti,ab
29	MeSH descriptor: [Pain] this term only
30	MeSH descriptor: [Dyspnea] this term only
31	MeSH descriptor: [Dyspnea] this term only
32	#28 OR #29 OR #30 OR #31
33	#S1 or #S5
34	#S6 OR #S9 OR #S12 OR #S15
35	#S16 OR #S20 OR #S27 OR #S32
36	#33 AND #34 AND #35
37	MeSH descriptor: [Clinical Trial] explode all trees
38	MeSH descriptor: [Randomized Controlled Trial] explode all trees
39	MeSH descriptor: [Systematic Reviews as Topic] explode all trees
40	#S37 OR #S38 OR #S39
41	MeSH descriptor: [Qualitative Research] explode all trees
42	MeSH descriptor: [Interviews as Topic] explode all trees
43	MeSH descriptor: [Observational Study] explode all trees
44	#S41 OR #S42 OR#S43
45	#S40 OR #S44
46	#S36 AND #S45
47	(paediatric or pediatric or children or child or neonat* or baby or infan* or adolescent):ti,ab
48	MeSH descriptor: [Infant] this term only
49	MeSH descriptor: [Child] this term only
50	MeSH descriptor: [Infant, Newborn] this term only
51	MeSH descriptor: [Adolescent] this term only
52	#S47 OR #S48 OR #S49 OR #S50 OR #51
53	((adult NEAR/1 child*) or grown-up child):ti,ab
54	#S52 NOT #S53
55	#S46 NOT #S54
56	limit 22 to English

CINAHL Plus (Ebsco) database search translation

#	EBSCO CINAHL Plus Query
1	(TI ICU* OR TI "intensive care" OR TI "critical care" OR TI "critical* ill*" OR TI "intensive care unit*" OR TI "critical care unit*") OR (AB ICU* OR AB "intensive care" OR AB "critical care" OR AB "critical* ill" OR AB "intensive care unit*" OR AB "critical care unit*")
2	(MH "critical care") OR (MH "critical illness") OR (MH "intensive care units")
3	(TI "end of life" OR TI eol* OR TI "palliative care" OR TI "terminal* ill" OR TI "terminal patient*" OR TI "terminal phase" OR TI "terminal stage" OR TI "final stages of life" OR TI "limited survival" OR TI "comfort care" OR TI "supportive care" OR TI dying OR (TI withdrawal N3 TI treatment*) OR (TI withdrawal N3 TI care) OR (TI treatment N1 TI limitation*)) OR (AB "end of life" OR AB eol* OR AB "palliative care" OR AB "terminal* ill" OR AB "terminal patient*" OR AB "terminal phase" OR AB "terminal stage" OR AB "final stages of life" OR AB "limited survival" OR AB "comfort care" OR AB "supportive care" OR AB dying OR (AB withdrawal N3 AB treatment*) OR (AB withdrawal N3 AB care) OR (AB treatment N1 AB limitation*))
4	(MH "Terminal care") OR (MH "Palliative care")
5	((TI good OR TI bad OR TI poor) OR (AB good OR AB bad OR AB poor)) AND (MH death)
6	(MH Bereavement) OR (MH Grief)
7	(TI "person cent*red" OR TI "patient cent*red" OR TI pcom OR TI "quality of dying" OR TI "quality of death" OR (TI quality N3 TI measure*) OR TI "quality indicat*" OR (TI outcome* N3 TI measure*) OR (TI quality N2 TI communication)) OR (AB "person cent*red" OR AB "patient cent*red" OR AB pcom OR AB "quality of dying" OR AB "quality of death" OR (AB quality N3 AB measure*) OR AB "quality indicat*" OR (AB outcome* N3 AB measure*) OR (AB quality N2 AB communication))
8	(TI anxiety OR TI depression OR TI PTSD OR TI "post-traumatic stress disorder") OR (AB anxiety OR AB depression OR AB PTSD OR AB "post-traumatic stress disorder") OR (MH Anxiety) OR (MH Depression) OR ((TI bereav* OR TI grief OR TI griev*) N2 (TI stress* OR TI distress* OR TI complicat* OR TI persist* OR TI complex OR TI patholog* OR TI disorder*)) OR ((AB bereav* OR AB grief OR AB griev*) N2 (AB stress* OR AB distress* OR AB complicat* OR AB persist* OR AB complex OR AB patholog* OR AB disorder*))
9	(TI "symptom management" OR TI satisfaction OR TI dignity OR TI compassion OR TI spiritual* OR TI "emotional support" OR TI "continuity of care") OR (AB "symptom management" OR AB satisfaction OR AB dignity OR AB compassion OR AB spiritual* OR AB "emotional support" OR AB "continuity of care") OR (MH "Symptoms") AND (MH "Patient Assessment") OR (MH "Respect") (MH "Empathy") (MH "Spirituality")
10	(TI pain OR TI dyspnea OR TI fatigue OR TI "personal autonomy") OR (AB pain OR AB dyspnea OR AB fatigue OR AB "personal autonomy") OR (MH Pain) OR (MH Dyspnea) OR (MH Fatigue) OR (MH "Personal Autonomy")
11	S1 or S2
12	S3 or S4 or S5 or S6
13	S7 or S8 or S9 or S10
14	S11 and S12 and S13
15	(MH "Randomized Controlled Trials") OR (MH "Random Assignment") OR (MH "Double-Blind Studies") OR (MH "Single-Blind Studies") OR (MH "Clinical Trials") OR (MH "Prospective Studies") OR (MH "Crossover Design") OR (MH "Evaluation Research") OR (MH "Validation Studies") OR (MH "Meta Analysis") OR (MH "Systematic Review") OR (MH "Epidemiological Research") OR (MH "Nonexperimental Studies") OR (MH "Comparative Studies")
16	(MH "Qualitative Studies") OR (MH "Grounded Theory") OR (MH "Focus Groups") OR (MH "Interviews") OR (MH "Phenomenological Research") OR (MH "Ethnographic Research") OR (MH "Narratives") OR (MH "Thematic Analysis") OR (TI qualitative OR TI "content analysis" OR TI "thematic analysis" OR TI phenomenolog* OR TI "grounded theory" OR TI narrative OR TI ethnograph* OR TI "focus group*" OR TI interview* OR TI experience*) OR (AB qualitative OR AB "content analysis" OR AB "thematic analysis" OR AB phenomenolog* OR AB "grounded theory" OR AB narrative OR AB ethnograph* OR AB "focus group*" OR AB interview* OR AB experience*)
17	S15 or S16

#	EBSCO CINAHL Plus Query
18	S14 and S17
19	(TI paediatric* OR TI pediatric* OR TI children OR TI child OR TI neonat* OR TI baby OR TI infan* OR TI newborn* OR TI adolescent*) OR (AB paediatric* OR AB pediatric* OR AB children OR AB child OR AB neonat* OR AB baby OR AB infan* OR AB newborn* OR AB adolescent*) OR (MH "Infant") OR (MH "Child, Preschool") OR (MH "Pediatrics") OR (MH "Adolescence") OR (MH "Infant, Newborn") OR (MH "Infant, Premature") OR (MH "Child")
20	((TI adult N1 TI child*) OR TI "grown-up child*") OR ((AB adult N1 AB child*) OR AB "grown-up child*")
21	S19 not S20
22	S18 not 21
23	LA English AND S22

Embase (Ovid) database search translation

#	Embase Query
1	(ICU* or "intensive care" or "critical care" or "critical* ill*" or "intensive care unit*" or "critical care unit*").ti. or (ICU* or "intensive care" or "critical care" or "critical* ill*" or "intensive care unit*" or "critical care unit*").ab.
2	critical illness/ OR intensive care unit/ OR intensive care/
3	("end of life" OR eol* OR "palliative care" OR "terminal* ill" OR "terminal patient*" OR "terminal phase" OR "terminal stage" OR "final stages of life" OR "limited survival" OR "comfort care" OR "supportive care" OR dying OR (withdrawal ADJ3 treatment*) OR (withdrawal ADJ3 care) OR (treatment ADJ1 limitation*)).ti. OR ("end of life" OR eol* OR "palliative care" OR "terminal* ill" OR "terminal patient*" OR "terminal phase" OR "terminal stage" OR "final stages of life" OR "limited survival" OR "comfort care" OR "supportive care" OR dying OR (withdrawal ADJ3 treatment*) OR (withdrawal ADJ3 care) OR (treatment ADJ1 limitation*)).ab.
4	terminal care/ or palliative therapy/
5	((good OR bad OR poor).ti. OR (good OR bad OR poor).ab.) AND death/
6	Bereavement/ OR Grief/
7	("person cent*red" OR "patient cent*red" OR pcom OR "quality of dying" OR "quality of death" OR (quality ADJ3 measure*) OR "quality indicat*" OR (outcome* ADJ3 measure*) OR (quality ADJ2 communication)).ti. OR ("person cent*red" OR "patient cent*red" OR pcom OR "quality of dying" OR "quality of death" OR (quality ADJ3 measure*) OR "quality indicat*" OR (outcome* ADJ3 measure*) OR (quality ADJ2 communication)).ab.
8	(anxiety OR depression OR PTSD OR "post-traumatic stress disorder").ti. OR (anxiety OR depression OR PTSD OR "post-traumatic stress disorder").ab. OR Anxiety/ OR Depression/ OR ((bereav* OR grief OR griev*) ADJ2 (stress* OR distress* OR complicat* OR persist* OR complex OR patholog* OR disorder*)).ti. OR ((bereav* OR grief OR griev*) ADJ2 (stress* OR distress* OR complicat* OR persist* OR complex OR patholog* OR disorder*)).ab.
9	("symptom management" OR satisfaction OR dignity OR compassion OR spiritual* OR "emotional support" OR "continuity of care").ti. OR ("symptom management" OR satisfaction OR dignity OR compassion OR spiritual* OR "emotional support" OR "continuity of care").ab. OR "Symptom Assessment"/ OR Respect/ OR Empathy/ OR Spiritual care/
10	(pain OR dyspnea OR fatigue OR "personal autonomy").ti. OR (pain OR dyspnea OR fatigue OR "personal autonomy").ab. OR Pain/ OR Dyspnea/ OR Fatigue/ OR "Personal Autonomy"/
11	1 or 2
12	3 or 4 or 5 or 6
13	7 or 8 or 9 or 10
14	11 and 12 and 13
15	randomized controlled trial/ or randomization/ or double blind procedure/ or single blind procedure/ or clinical trial/ or prospective study/ or crossover procedure/ or clinical study/ or evaluation study/ or validation study/ or meta analysis/ or "systematic review"/ or epidemiology/ or observational study/ or comparative study/
16	qualitative research/ or grounded theory/ or interview/ or phenomenology/ or ethnography/ or narrative/ or thematic analysis/ or content analysis/ or observational method/ or constant comparative method/ or ("qualitative OR content analysis OR thematic analysis OR phenomenolog* OR grounded theory OR narrative OR ethnograph* OR focus group* OR interview* OR experience).ti. OR (qualitative" or "content analysis" or "thematic analysis" or phenomenolog* or "grounded theory" or narrative or ethnograph* or "focus group*" or interview* or experience).ab.
17	15 or 16
18	14 and 17
19	(paediatric* or pediatric* or children or child or neonat* or baby or infan* or newborn* or adolescent*).ti. or (paediatric* or pediatric* or children or child or neonat* or baby or infan* or newborn* or adolescent*).ab. or Infant/ or preschool child/ or Pediatrics/ or Adolescent/ or Newborn/ or Child/ or Prematurity/
20	((adult ADJ1 child*) OR "grown-up child*").ti. OR ((adult ADJ1 child*) OR "grown-up child*").ab.
21	19 not 20
22	18 not 21
23	"limit 22 to English"

Pubmed database search translation

#	Pubmed Query
1	"ICU"[Title/Abstract] OR "intensive care"[Title/Abstract] OR "critical care"[Title/Abstract] OR ("critical*"[All Fields] AND "ill"[Title/Abstract]) OR "intensive care unit*"[Title/Abstract] OR "critical care unit*"[Title/Abstract]
2	"Critical Care"[MeSH Terms] OR "Critical Illness"[MeSH Terms] OR "Intensive Care Units"[MeSH Terms]
3	("end of life"[Title/Abstract] OR "eol"[Title/Abstract] OR "palliative care"[Title/Abstract] OR "terminally ill"[Title/Abstract] OR "terminal patient*"[Title/Abstract] OR "terminal phase"[Title/Abstract] OR "terminal stage"[Title/Abstract] OR "limited survival"[Title/Abstract] OR "comfort care"[Title/Abstract] OR "supportive care"[Title/Abstract] OR "dying"[Title/Abstract] OR "treatment limitation*"[Title/Abstract] OR (("withdrawal"[Title/Abstract] AND "treatment"[Title/Abstract]) OR "withdrawal"[Title/Abstract])) AND "care"[Title/Abstract]
4	(terminal care[MeSH Terms]) OR (palliative care[MeSH Terms])
5	((good[Title/Abstract] OR bad[Title/Abstract] OR poor[Title/Abstract])) AND (death[MeSH Terms])
6	(bereavement[MeSH Terms]) OR (grief[MeSH Terms])
7	person centred[Title/Abstract] OR "person centered"[Title/Abstract] OR "patient centred"[Title/Abstract] OR "patient centered"[Title/Abstract] OR "pcom"[Title/Abstract] OR "quality of dying"[Title/Abstract] OR "quality of death"[Title/Abstract] OR "quality measure"[Title/Abstract] OR "quality measurement"[Title/Abstract] OR "quality indicator"[Title/Abstract] OR "quality indicators"[Title/Abstract] OR "outcome measure"[Title/Abstract] OR "outcome measures"[Title/Abstract] OR "quality communication"[Title/Abstract] OR "quality of communication"[Title/Abstract]
8	((((bereav*[Title/Abstract] OR grief[Title/Abstract] OR griev*[Title/Abstract]) AND (stress*[Title/Abstract] OR distress*[Title/Abstract] OR complicat*[Title/Abstract] OR persist*[Title/Abstract] OR complex[Title/Abstract] OR patholog*[Title/Abstract] OR disorder*[Title/Abstract])) OR (anxiety[Title/Abstract] OR depression[Title/Abstract] OR PTSD[Title/Abstract] OR "post-traumatic stress disorder"[Title/Abstract])) OR (Anxiety[MeSH Terms])) OR (Depression[MeSH Terms])
9	(((((("symptom management"[Title/Abstract] OR "satisfaction"[Title/Abstract] OR "dignity"[Title/Abstract] OR "compassion"[Title/Abstract] OR "spiritual*"[Title/Abstract] OR "emotional support"[Title/Abstract] OR "continuity of care"[Title/Abstract]) OR ("Continuity of Patient Care"[MeSH Terms])) OR ("symptom assessment"[MeSH Terms])) OR ("Respect"[MeSH Terms])) OR ("Empathy"[MeSH Terms])) OR ("Spirituality"[MeSH Terms])
10	((((pain[Title/Abstract] OR dyspnea[Title/Abstract] OR fatigue[Title/Abstract] OR "personal autonomy"[Title/Abstract]) OR (" "[MeSH Terms])) OR ("Dyspnea"[MeSH Terms])) OR ("Fatigue"[MeSH Terms])) OR ("Personal autonomy"[MeSH Terms])
11	#1 or #2
12	#3 or #4 or #5 or #6
13	#7 or #8 or #9 or #10
14	#11 and #12 and #13
15	Randomized Controlled Trials as Topic[Mesh] OR "Random Allocation"[Mesh] OR "Double-Blind Method"[Mesh] OR "Clinical Trials as Topic"[Mesh] OR "Prospective Studies"[Mesh] OR "Cross-Over Studies"[Mesh] OR "Clinical Studies as Topic"[Mesh] OR "Evaluation Studies as Topic"[Mesh] OR "Validation Studies as Topic"[Mesh] OR "Meta-Analysis as Topic"[Mesh] OR Systematic Reviews as Topic[Mesh] OR "Epidemiologic Studies"[Mesh] OR "Observational Studies as Topic"[Mesh] OR "Comparative Effectiveness Research"[Mesh]
16	("Qualitative Research"[MeSH Terms] OR "Grounded Theory"[MeSH Terms] OR "Focus Groups"[MeSH Terms] OR "Interviews as Topic"[MeSH Terms] OR "anthropology, cultural"[MeSH Terms] OR "Narration"[MeSH Terms] OR "Epidemiology"[MeSH Terms] OR "Observational Studies as Topic"[MeSH Terms] OR "Comparative Effectiveness Research"[MeSH Terms]) OR (qualitative[Title/Abstract] OR "content analysis"[Title/Abstract] OR "thematic analysis"[Title/Abstract] OR phenomenolog*[Title/Abstract] OR "grounded theory"[Title/Abstract] OR narrative[Title/Abstract] OR ethnograph*[Title/Abstract] OR "focus group*"[Title/Abstract] OR interview*[Title/Abstract] OR experience*[Title/Abstract])
17	#15 or #16
18	#14 and #17

#	Pubmed Query
19	((((((((paediatric*[Title/Abstract] OR pediatric*[Title/Abstract] OR children[Title/Abstract] OR child[Title/Abstract] OR neonat*[Title/Abstract] OR baby[Title/Abstract] OR infan*[Title/Abstract] OR newborn*[Title/Abstract] OR adolescent*[Title/Abstract]) OR ("Infant"[MeSH Terms])) OR ("child, preschool"[MeSH Terms])) OR ("Pediatrics"[MeSH Terms])) OR ("Adolescent"[MeSH Terms])) OR ("Infant, Newborn"[MeSH Terms])) OR ("Infant, Premature"[MeSH Terms])) OR ("Child"[MeSH Terms])) OR ("Infant, Extremely Premature"[MeSH Terms])
20	((Adult[Title/Abstract] AND child*[Title/Abstract]) OR ("adult child"[Title/Abstract])) OR ("grown-up child*"[Title/Abstract])
21	#19 not #20
22	#18 not #21
23	(English[Language]) AND (#22)

PyschInfo database search translation

#	Query PyschInfo
1	(TI(ICU*) OR TI("intensive care") OR TI("critical care") OR TI("critical* ill*") OR TI("intensive care unit*") OR TI("critical care unit*")) OR (AB(ICU*) OR AB("intensive care") OR AB("critical care") OR AB("critical* ill") OR AB("intensive care unit*") OR AB("critical care unit*"))
2	MAINSUBJECT.EXACT("Intensive Care")
3	(TI("end of life") OR TI(eol*) OR TI("palliative care") OR TI("terminal* ill") OR TI("terminal patient*") OR TI("terminal phase") OR TI("terminal stage") OR TI("final stages of life") OR TI("limited survival") OR TI("comfort care") OR TI("supportive care") OR TI(dying) OR (TI(withdrawal) NEAR/3 TI(treatment*)) OR (TI(withdrawal) NEAR/3 TI(care)) OR (TI(treatment) NEAR/1 TI(limitation*))) OR (AB("end of life") OR AB(eol*) OR AB("palliative care") OR AB("terminal* ill") OR AB("terminal patient*") OR AB("terminal phase") OR AB("terminal stage") OR AB("final stages of life") OR AB("limited survival") OR AB("comfort care") OR AB("supportive care") OR AB(dying) OR (AB(withdrawal) NEAR/3 AB(treatment*)) OR (AB(withdrawal) NEAR/3 AB(care)) OR (AB(treatment) NEAR/1 AB(limitation*)))
4	MAINSUBJECT.EXACT("Terminally Ill Patients") OR MAINSUBJECT.EXACT("Palliative Care")
5	((TI(good) OR TI(bad) OR TI(poor)) OR (AB(good) OR AB(bad) OR AB(poor))) AND MAINSUBJECT.EXACT("Death and Dying")
6	MAINSUBJECT.EXACT("Bereavement") OR MAINSUBJECT.EXACT("Grief")
7	(TI("person cent*red") OR TI("patient cent*red") OR TI(pcom) OR TI("quality of dying") OR TI("quality of death") OR (TI(quality) NEAR/3 TI(measure*)) OR TI("quality indicat*") OR (TI(outcome*) NEAR/3 TI(measure*)) OR (TI(quality) NEAR/2 TI(communication))) OR (AB("person cent*red") OR AB("patient cent*red") OR AB(pcom) OR AB("quality of dying") OR AB("quality of death") OR (AB(quality) NEAR/3 AB(measure*)) OR AB("quality indicat*") OR (AB(outcome*) NEAR/3 AB(measure*)) OR (AB(quality) NEAR/2 AB(communication)))
8	(TI(anxiety) OR TI(depression) OR TI(PTSD) OR TI("post-traumatic stress disorder")) OR (AB(anxiety) OR AB(depression) OR AB(PTSD) OR AB("post-traumatic stress disorder")) OR MAINSUBJECT.EXACT("Anxiety") OR MAINSUBJECT.EXACT("Reactive Depression") OR ((TI(bereav*) OR TI(grief) OR TI(griev*)) NEAR/2 (TI(stress*) OR TI(distress*) OR TI(complicat*) OR TI(persist*) OR TI(complex) OR TI(patholog*) OR TI(disorder*))) OR ((AB(bereav*) OR AB(grief) OR AB(griev*)) NEAR/2 (AB(stress*) OR AB(distress*) OR AB(complicat*) OR AB(persist*) OR AB(complex) OR AB(patholog*) OR AB(disorder*)))
9	(TI("symptom management") OR TI(satisfaction) OR TI(dignity) OR TI(compassion) OR TI(spiritual*) OR TI("emotional support") OR TI("continuity of care")) OR (AB("symptom management") OR AB(satisfaction) OR AB(dignity) OR AB(compassion) OR AB(spiritual*) OR AB("emotional support") OR AB("continuity of care")) OR MAINSUBJECT.EXACT("Continuum of Care") OR MAINSUBJECT.EXACT("Symptom Checklists") OR MAINSUBJECT.EXACT("Respect") OR MAINSUBJECT.EXACT("Empathy") OR MAINSUBJECT.EXACT("Spirituality")
10	(TI(pain) OR TI(dyspnea) OR TI(fatigue) OR TI("personal autonomy")) OR (AB(pain) OR AB(dyspnea) OR AB(fatigue) OR AB("personal autonomy")) OR MAINSUBJECT.EXACT("Pain") OR MAINSUBJECT.EXACT("Dyspnea") OR MAINSUBJECT.EXACT("Fatigue") OR MAINSUBJECT.EXACT("Independence (Personality)")
11	1 or 2
12	3 or 4 or 5 or 6
13	7 or 8 or 9 or 10
14	11 and 12 and 13
15	MAINSUBJECT.EXACT("Randomized Clinical Trials") OR MAINSUBJECT.EXACT("Random Sampling") OR MAINSUBJECT.EXACT("Clinical Trials") OR MAINSUBJECT.EXACT("Prospective Studies") OR MAINSUBJECT.EXACT("Meta Analysis") OR MAINSUBJECT.EXACT("Systematic Review") OR MAINSUBJECT.EXACT("Epidemiology") OR MAINSUBJECT.EXACT("Observation Methods") OR MAINSUBJECT.EXACT("Quantitative Methods")

#	Query PyschInfo
16	MAINSUBJECT.EXACT("Qualitative Methods") OR MAINSUBJECT.EXACT("Grounded Theory") OR MAINSUBJECT.EXACT("Focus Group") OR MAINSUBJECT.EXACT("Interviews") OR MAINSUBJECT.EXACT("Interpretative Phenomenological Analysis") OR MAINSUBJECT.EXACT("Ethnography") OR MAINSUBJECT.EXACT("Narrative Analysis") OR MAINSUBJECT.EXACT("Thematic Analysis") OR MAINSUBJECT.EXACT("Epidemiology") OR MAINSUBJECT.EXACT("Observation Methods") OR (TI(qualitative) OR TI("content analysis") OR TI("thematic analysis") OR TI(phenomenolog*) OR TI("grounded theory") OR TI(narrative) OR TI(ethnograph*) OR TI("focus group*") OR TI(interview*) OR TI(experience*)) OR (AB(qualitative) OR AB("content analysis") OR AB("thematic analysis") OR AB(phenomenolog*) OR AB("grounded theory") OR AB(narrative) OR AB(ethnograph*) OR AB("focus group*") OR AB(interview*) OR AB(experience*))
17	15 or 16
18	14 and 17
19	(TI(paediatric) OR TI(pediatric) OR TI(children) OR TI(child) OR TI(neonat*) OR TI(baby) OR TI(infan*) OR TI(newborn*) OR TI(adolescent)) OR (AB(paediatric) OR AB(pediatric) OR AB(children) OR AB(child) OR AB(neonat*) OR AB(baby) OR AB(infan*) OR AB(newborn) OR AB(adolescent)) OR MAINSUBJECT.EXACT("Pediatrics")
20	((TI(adult) NEAR/1 TI(child*)) OR TI("grown-up child*")) OR ((AB(adult) NEAR/1 AB(child*)) OR AB("grown-up child*"))
21	19 NOT 20
22	18 NOT 21

Scopus database search translation

Query Number	Scopus Query
1	TITLE(ICU* OR "intensive care" OR "critical care" OR "critical* ill*" OR "intensive care unit*" OR "critical care unit*") OR ABS(ICU* OR "intensive care" OR "critical care" OR "critical* ill" OR "intensive care unit*" OR "critical care unit*")
2	KEY ("critical care" OR "critical illness" OR "intensive care units")
3	TITLE("end of life" OR eol* OR "palliative care" OR "terminal* ill" OR "terminal patient*" OR "terminal phase" OR "terminal stage" OR "final stages of life" OR "limited survival" OR "comfort care" OR "supportive care" OR dying OR (withdrawal W/3 treatment*) OR (withdrawal W/3 care) OR (treatment W/1 limitation*)) OR ABS("end of life" OR eol* OR "palliative care" OR "terminal* ill" OR "terminal patient*" OR "terminal phase" OR "terminal stage" OR "final stages of life" OR "limited survival" OR "comfort care" OR "supportive care" OR dying OR (withdrawal W/3 treatment*) OR (withdrawal W/3 care) OR (treatment W/1 limitation*))
4	KEY ("terminal care" OR "palliative care")
5	TITLE-ABS (good OR bad OR poor) AND KEY (death)
6	KEY (bereavement OR grief)
7	TITLE("person cent*red" OR "patient cent*red" OR pcom OR "quality of dying" OR "quality of death" OR (quality W/3 measure*) OR "quality indicat*" OR (outcome* W/3 measure*) OR (quality W/2 communication)) OR ABS("person cent*red" OR "patient cent*red" OR pcom OR "quality of dying" OR "quality of death" OR (quality W/3 measure*) OR "quality indicat*" OR (outcome* W/3 measure*) OR (quality W/2 communication))
8	TITLE(anxiety OR depression OR PTSD OR "post-traumatic stress disorder") OR ABS(anxiety OR depression OR PTSD OR "post-traumatic stress disorder") OR KEY(Anxiety) OR KEY(Depression) OR TITLE((bereav* OR grief OR griev*) W/2 (stress* OR distress* OR complicat* OR persist* OR complex OR patholog* OR disorder*)) OR ABS((bereav* OR grief OR griev*) W/2 (stress* OR distress* OR complicat* OR persist* OR complex OR patholog* OR disorder*))
9	TITLE-ABS ("symptom management" OR satisfaction OR dignity OR compassion OR spiritual* OR "emotional support" OR "continuity of care") OR KEY ("Continuity of Patient Care" OR "Symptom Assessment" OR "Respect" OR "Empathy" OR "Spirituality")
10	TITLE-ABS-KEY (pain OR dyspnea OR fatigue OR "personal autonomy")
11	#1 OR #2
12	#3 OR #4 OR #5 OR #6
13	#7 OR #8 OR # 9 OR #10
14	#11 AND #12 AND #13
15	KEY ("randomised controlled trials" OR "random allocation" OR "double-blind method" OR "single-blind method" OR "clinical trials" OR "prospective studies" OR "cross-over studies" OR "clinical study" OR "evaluation study" OR "validation study" OR "meta-analysis" OR "systematic review" OR "Epidemiologic* Studies" OR "observational study" OR "comparative study")
16	TITLE-ABS (qualitative OR "content analysis" OR "thematic analysis" OR "phenomenolog*" OR "grounded theory" OR narrative OR "ethnograph*" OR "focus group*" OR "interview*" OR "experience" *) OR KEY ("qualitative research" OR "grounded theory" OR "focus group" OR interview OR phenomenology OR ethnography OR narrative OR "thematic analysis" OR "content analysis" OR epidemiologic OR observational OR comparative)
17	#15 or #16
18	#14 AND #17
19	TITLE-ABS (paediatric OR pediatric OR children OR child OR neonat* OR baby OR infan* OR newborn OR adolescent) OR KEY (infant OR "Child Preschool" OR pediatrics OR adolescent OR "Infant Newborn")
20	TITLE-ABS ("adult W/1 child" OR "grown-up child")
21	#19 AND NOT #20
22	#18 AND NOT #21
23	#22 AND LIMIT-TO (LANGUAGE , "English"

Appendix 10 Data extraction form fields

The data extraction form is comprised of several sections to aid data flow. Branching is active depending on the response. The form allows for 4 interventions/comparators to be entered per study and 3 outcomes. Additional outcomes will need to be captured on an additional form. The additional form will only capture Section 1, 2 and outcomes. The inclusion of section 1 and 2 is to ensure data linkage and reviewer details when using additional forms.

The location of each data point source should be recorded and where applicable the page number, paragraph, line, table, figure, box, and/or headline number documented. Whist this is displayed in a separate column on paper or word forms it is not able to be replicated in a column format in Microsoft forms. Data sources have therefore added as an additional question to align with best practice recommendations.

Instructions

• Please complete one data-extraction form per study.

• Complete every field. If data is missing please code this as **not reported**.

• If data is unclear please code this as **unclear**.

• Data should be extracted verbatim from the study source.

• Each data point source should be recorded and where applicable the page number, table, figure and or box documented.

• Only use the PDF of the study provided for the data extraction. Different copies might place data on different locations on the same page and/or on different page numbers.

• If there are more than 3 study outcome measures please complete this form plus the additional outcome measures form.

• Quality and risk of bias is captured on a separate form.

Section 1 Review details

Question No	Question	Data Field	Pre-defined options	Extra option	Rules	Branching
1	Reviewer ID	Drop down list	NP; RG; SMD; SKH	No	Max 1	Next question
2	Data Type	Drop down list	Conference abstract; Journal full text article; Thesis; Trial registry; Systematic review; Other (please state)	Yes	Max 1	Section 2

Section 2 Study characteristics

Question No	Question	Data Field	Pre-defined options	Extra option	Rules	Branching
3	Publication Year	Free-text	None	No	Number	Next question
4	First Author	Drop down list	Pre-defined list of all authors included	No	Max 1	Next question
5	Title	Drop down list	Pre-defined list of all titles included	No	Max 1	Next question
6	Trial registration numbers	Free-text	None	No	None	Next question
7	Trial registration description location in text	Free-text short	None	No	None	Next question
8	Study Type	Drop down list	Qualitative; Quantitative; Mixed-methods	No	Max 1	Next question
9	Sponsor for the study and sponsor identifiers	Free-text long	None	No	None	Next question
10	Sponsor description location in text	Free-text short	None	No	None	Next question
11	Study design	Drop down list	Cohort; Non randomised; Before and after intervention (pre/post); Randomised controlled trial; Randomised cross-over; Quasi-randomised; Qualitative interview; Other	Yes	Max 1	Next question
12	Country (select all that are appropriate)	Checkbox	Australia; Canada; France; Germany; United Kingdom; United States of America; Not reported; Unclear; Other	Yes	Allow multiple answers	Next question
13	If USA, which State (s)?	Free-text	None	No	None	Next question
14	Data collection period	Free-text	None	No	Number	Next question
15	Duration of the study	Free-text	None	No	None	Next question
16	Duration of the study description location in text	Free-text short	None	No	None	Next question
17	Length of follow-up	Free-text long	None	No	None	Next question
18	Length of follow-up description location in text	Free-text short	None	No	None	Next question
19	Ethical approval needed/obtained for study	Free-text long	None	No	None	Section 3

Section 3 Population and setting

Question No	Question	Data Field	Pre-defined options	Extra option	Rules	Branching
20	Population description (from which study participants are drawn)	Free-text long	None	No	None	Next question
21	Population description location in text	Free-text short	None	No	None	Next question
22	Population - Inclusion criteria reported in the study	Free-text long	None	No	None	Next question
23	Population inclusion criteria location in text	Free-text short	None	No	None	Next question
24	Population - Exclusion criteria	Free-text long	None	No	None	Next question
25	Population exclusion criteria location in text	Free-text short	None	No	None	Next question
26	Severity of illness category and description	Free-text long	None	No	None	Next question
27	Severity of illness location in text	Free-text short	None	No	None	Next question
28	Total number of participants	Free-text	None	No	Number	Next question
29	Total number of participants location in text	Free-text short	None	No	None	Next question
30	Number of participants (patients)	Free-text	None	No	Number	Next question
31	Number of participants (patients) location in text	Free-text short	None	No	None	Next question
32	Number of participants (family members)	Free-text	None	No	Number	Next question
33	Number of participants (family members) location in text	Free-text short	None	No	None	Next question
34	Number of participants (staff)	Free-text	None	No	Number	Next question
35	Number of participants (staff) location in text	Free-text short	None	No	None	Next question
36	Informed consent obtained?	Drop down list	Yes; No; Unclear	No	Max 1	Next question
37	Sites	Drop down list	Singel centre; Multi-centre	No	Max 1	Next question
38	Number of sites	Free-text	None	No	Number	Next question

Question No	Question	Data Field	Pre-defined options	Extra option	Rules	Branching
39	Number of sites location in text	Free-text short	None	No	None	Next question
40	Location (if institutions, such as hospitals, are named)	Free-text long	None	No	None	Next question
41	Location of sites location in text	Free-text short	None	No	None	Next question
42	Critical care type	Checkbox	Burns; Cancer; Cardiac; General; Neuro; Medical; Mixed; Surgical; Trauma; Unclear; Not reported; Other	Yes	Allow multiple answers	Next question
43	Critical care type location in text	Free-text short	None	No	None	Section 4

Section 4 Study definitions

Question No	Question	Data Field	Pre-defined options	Extra option	Rules	Branching
44	End-of-life defined?	Checkbox	Yes; No	No	None	Y = EoL definition N = Palliative care defined
45	End-of-life definition	Free-text long	None	No	None	Next question
46	End-of-life definition location in text	Free-text short	None	No	None	Next question
47	Palliative care defined?	Checkbox	Yes; No	No	None	Y = Palliative care definition N = Section 5 Investigation under investigation – Investigation 1
48	Palliative care definition	Free-text long	None	No	None	Next question
49	Palliative care definition location in text	Free-text short	None	No	None	Next question

Section 5 Intervention under investigation – intervention 1

Question No	Question	Data Field	Pre-defined options	Extra option	Rules	Branching
50	Experimental Intervention 1 Description (with diagnostic criteria if relevant)	Free-text long	None	No	None	Next question
51	Intervention 1 description location in text	Free-text short	None	No	None	Next question
52	Intervention 1 Type	Drop down list	Communication intervention(s); Ethics consultation(s); Educational interventions(s); Palliative care team involvement; Advanced care planning	No	Max 1	Next question
53	Intervention 1 provided/delivered by	Checkbox	Clinical team (Dr, nurse, allied health professional); Family member or Surrogate; Patient; Research team; Unclear; Not reported; Other	Yes	Allow multiple answers	Next question
54	Intervention provided/delivered by description location in text	Free-text short	None	No	None	Next question
55	Intervention 1 assessed/reported by	Checkbox	Clinical team (Dr, nurse, allied health professional); Family member or Surrogate; Patient; Research team; Unclear; Not reported; Other	Yes	Allow multiple answers	Next question
56	Intervention assessed/reported by description location in text	Free-text short	None	No	None	Next question
57	Number of participants in intervention 1 group	Free-text	None	No	Number	Next question
58	Number of participants in intervention 1 group location in text	Free-text short	None	No	None	Next question
59	Comparator for experimental intervention 1	Free-text long	None	No	None	Next question
60	Comparator for intervention 1 group location in text	Free-text short	None	No	None	Next question
61	Number of participants in comparator for intervention 1	Free-text	None	No	Number	Next question

Question No	Question	Data Field	Pre-defined options	Extra option	Rules	Branching
62	Number of participants in comparator for intervention 1 group location in text	Free-text short	None	No	None	Next question
63	Is there another intervention	Checkbox	Yes; No	No	None	Y = Section 6 N = Section 9

Section 6 Intervention under investigation – intervention 2

This repeats all of section 5 questions if question 63 is Yes.

Section 7 Intervention under investigation – intervention 3

This repeats all of section 5 questions if question 77 is Yes.

Section 8 Intervention under investigation – intervention 4

This repeats all of section 5 questions if question 91 is Yes.

Section 9 Study outcomes – outcomes 1

Question No	Question	Data Field	Pre-defined options	Extra option	Rules	Branching
105	Outcome	Free-text long	None	No	None	Next question
106	Outcome 1 category	Drop down list	Primary; Primary Composite; Secondary; Secondary Composite; Composite; Unclear; Not reported; Other	Yes	Max 1	Primary, Secondary or Composite = Next Unclear or Not reported = outcome definition
107	Outcome 1 category location in text	Free-text short	None	No	None	Next question
108	Is a definition provided for outcome 1?	Checkbox	Yes; No	No	Max 1	Y = Next question N = Rational provided
109	Outcome 1 definition	Free-text long	None	No	None	Next question
110	Outcome 1 definition location in text	Free-text short	None	No	None	Next question
111	Is the rationale provided for outcome 1?	Checkbox	Yes; No	No	Max 1	Y = Next question N = Outcome 1 measure/instrument
112	Rationale for outcome 1?	Free-text long	None	No	None	Next question
113	Rational for outcome 1 location in text	Free-text short	None	No	None	Next question
114	Outcome 1 measure/instrument	Free-text long	None	No	None	Next question
115	Outcome 1 measure/instrument location in text	Free-text short	None	No	None	Next question
116	Is outcome/tool/instrument validated?	Checkbox	Yes; No; Not reported; Unclear	No	Max 1	Y = Next question N, Not reported or unclear = unit of measurement
117	Outcome 1 tool/instrument validated location in text	Free-text short	None	No	None	Next question
118	Unit of measurement (if relevant)	Free-text short	None	No	None	Next question
119	Unit of measurement located in text	Free-text short	None	No	None	Next question

Question No	Question	Data Field	Pre-defined options	Extra option	Rules	Branching
120	Scales: upper and lower limits (indicate whether high or log score is good)	Free-text long	None	No	None	Next question
121	Scales location in text	Free-text short	None	No	None	Next question
122	Outcome 1 Robert Wood Foundation Classification	Drop down list	Patient/Family centred decision-making interventions and outcomes; Communication Interventions and outcomes; Continuity of care; Emotional and practical support for patients and families, and outcomes; Symptom management and comfort care; Spiritual support; Support for ICU clinicians and outcomes; No relevant category	No	Max 1	Next question
123	Outcome 1 COMET outcome taxonomy core area	Checkbox	Death; Physical/Clinical; Life impact (Functioning); Resources use; Adverse events/effects	No	Max 1	Death = Outcome 1 measure commenced Physiological/clinical = Outcome 1 COMET Physical/clinical Life impact = Outcome 1 COMET Life Impact Resource use = Outcome 1 COMET resource use Adverse events/effects = Outcome 1 measure commenced

Question No	Question	Data Field	Pre-defined options	Extra option	Rules	Branching
124	Outcome 1 COMET Physiological/clinical outcome domain	Checkbox	2. Blood and lymphatic system outcomes; 3. Cardiac outcomes; 4. Congenital, familial and genetic outcomes; 5. Endocrine outcomes; 6. Ear and labyrinth outcomes; 7. Eye outcomes; 8. Gastrointestinal outcomes; 9. General outcomes; 10. Hepatobiliary outcomes; 11. Immune system outcomes; 12. Infection and infestation outcomes; 13. Injury and poisoning outcomes; 14. Metabolism and nutrition outcomes;15. Musculoskeletal and connective tissue outcomes; 16. Outcomes relating to neoplasms: benign, malignant and unspecified (including cysts and polyps); 17. Nervous system outcomes; 18. Pregnancy, puerperium and perinatal outcomes; 19. Renal and urinary outcomes; 20. Reproductive system and breast outcomes; 21. Psychiatric outcomes; 22. Respiratory, thoracic and mediastinal outcomes; 23. Skin and subcutaneous tissue outcomes; 24. Vascular outcomes	No	Max 1	All = Outcome 1 measurement commenced
125	Outcome 1 COMET Life impact outcome domain	Checkbox	25. Physical functioning; 26. Social functioning; 27. Role functioning; 28. Emotional functioning/wellbeing; 29. Cognitive functioning; 30. Global quality of life; 31. Perceived health status; 32. Delivery of care; 33. Personal circumstances	No	Max 1	All = Outcome 1 measurement commenced
126	Outcome 1 COMET Resource use outcome domain	Checkbox	34. Economic; 35. Hospital; 36. Need for further intervention; 37. Societal/carer burden; 38. Adverse events/effects	No	Max 1	Next question

Question No	Question	Data Field	Pre-defined options	Extra option	Rules	Branching
127	Outcome 1 measure commenced	Checkbox	Critical care admission; Randomisation; Unclear; Not reported; Other	Yes	Max 1	Unclear = measure discontinued
128	Outcome 1 commenced location in text	Free-text short	None	No	None	Next question
129	Outcome 1 measure discontinued	Checkbox	Critical care admission; Randomisation; Unclear; Not reported; Other	Yes	Max 1	Unclear or not reported = frequency
130	Outcome 1 discontinued location in text	Free-text short	None	No	None	Next question
131	Outcome 1 frequency	Drop down list	One, twice, three, four, five, six, Provide description	Yes	Max 1	Unclear or not reported = outcome assessor
132	Outcome 1 frequency location in text	Free-text short	None	No	None	Next question
133	Outcome 1 assessor	Checkbox	Clinical team; Family/Surrogate; Patient; Research team; Unclear Not reported; Other	Yes	Multiple answers	Next question
134	Outcome 1 assessor location in text	Free-text short	None	No	None	Next question
135	Is there another study outcome measure?	Checkbox	Yes; No	No	Max 1	Y = Section 10 N = End of form Submit

Section 10 Study outcomes – outcomes 2

This repeats all of section 9 questions if question 135 is Yes.

Section 11 Study outcomes – outcomes 3

This repeats all of section 9 questions.

Additional study outcomes form

This repeats all of section 9 questions. Section 11 is the maximum form limit. All data extraction guidance agrees that additional forms should be used.

Appendix 11 Included studies

Author and Year	Design	Country	Site	ICU speciality	Participants	Intervention classification	Intervention Description
Braus et al 2016	Non-randomised, before and after intervention	USA	1 ICU 1 hospital	Medical	118 FM of 203 ICU patients	PC team involvement	PC clinician participation in morning interdisciplinary bedside round
Campbell 2017	Randomised controlled trial	USA	5 ICUs 5 hospitals	Medical	NCT registry estimated enrolment 265 ICU patients	Educational intervention (s)	Ventilator withdrawal algorithm
Chen et al 2021	Non-randomised, before and after intervention	USA	4 ICUs 1 hospital	Cardiac; Medical; Neuro; Surgical	41 S of 41 ICU patients	Communication intervention (s)	Daily telephone call with content based on the COMFORT communication model
Cheung et al 2010	Randomised controlled trial	Australia	1 ICU 1hospital	General	9 FM of 20 ICU patients, 35 clinicians	PC team involvement	PC team consultation and management
Cook et al 2015	Cohort	Canada;	1 ICU 1 hospital	Mixed	50 FM of 40 ICU patients, 120 clinicians	Advanced care planning	Elicitation and implementation of wishes from patients, families and clinicians
Cox et al 2018	Non-randomised, before and after intervention	USA	4 ICUs 1 hospital	Cardiac; Medical; Neuro; Surgical; Trauma	67 FM of 78 ICU patients, 10 clinicians	Communication intervention (s) PC team involvement	PC planner mobile app PC family meeting
Cox et al 2020	Randomised controlled trial	USA	3 ICU 3 hospitals	Cardiac; Medical; Neuro; Surgical	Protocol aim 150 ICU patient-family member dyads	Communication Intervention (s) PC team involvement	PC planner mobile app PC family meeting
Curtis et al 2016	Randomised controlled trial	USA	5 ICUs 2 hospitals	Not reported	268 FM of 168 ICU patients	Communication intervention (s)	Communication facilitator and provision of emotional support

Author and Year	Design	Country	Site	ICU speciality	Participants	Intervention classification	Intervention Description
Kaufer et al 2008	Non-randomised, before and after intervention	USA	1 ICU 1 hospital	Medical	88 FM of 88 ICU patients	Communication intervention (s) PC team involvement Educational intervention (s)	Family support team and palliative care team involvement Family meetings and follow up Staff education
Kentish-Barnes et al 2022	Randomised controlled trial	France	34 ICUs 34 hospitals	Medical; Mixed; Surgical	875 FM of ICU patients	Communication intervention (s)	Three family meetings; a family conference to prepare the relatives for the imminent death, an ICU-room visit to provide active support, and a meeting after the patient's death to offer condolences and closure
Kirchhoff et al 2008	Randomised controlled trial	USA	1 ICU 1 hospital	Not reported	20 NoK of 20 ICU patients	Communication intervention (s)	4 tailored messages to prepare families of patients having a planned withdrawal of life support
Lautrette et al., 2007	Randomised controlled trial	France	22 ICUs 22 hospitals	Medical; Mixed; Surgical	108 FM of 126 ICU patients	Communication intervention (s)	End-of-life family conference Bereavement brochure
Lichtenthal et al 2022	Cohort	USA	1 ICU 1 hospital	Medical	10 S of 9 ICU patients	Educational intervention (s)	Brief manualised cognitive-behavioural therapy
Lincoln et al 2020	Randomised controlled trial	USA	5 ICUs 4 hospitals	Cardiac; Medical; Surgical	Protocol aim 690 S of 690 ICU patients	Communication intervention (s) Educational intervention (s) PC team involvement	Staff communication skills training Clinician-family communication Structured family support pathway Emotional and decisional support for families Collaboration between ICU and PC team
Liu et al 2022	Randomised controlled trial	China	6 ICUs 6 hospitals	Not reported	548 FM of 548 ICU patients, 387 clinicians	Communication intervention (s)	Family-clinician shared decision making family conference
Lustbader et al 2011	Cohort	USA	1 ICU 1 hospital	Medical	1208 ICU patients	PC team involvement	Palliative consultation

Author and Year	Design	Country	Site	ICU speciality	Participants	Intervention classification	Intervention Description
McDonagh et al 2004	Cross-sectional	USA	4 ICUs 4 hospitals	Not reported	169 FM of 51 ICU patients, 35 clinicians	Communication intervention (s)	Family conference
O'Mahony et al 2010	Case-control	USA	2 ICUs 2 hospitals	Cardiac; Medical; Surgical	10 FM, 203 ICU patients, 9 nurses	PC team involvement Educational intervention (s	Interdisciplinary palliative consultative service Case-based teaching
Prigerson et al 2019	Randomised controlled trial	USA	3 ICUs 3 hospitals	Not reported	Protocol aim 60 S of 60 ICU patients	Educational intervention (s)	Brief manualized cognitive-behavioral therapy
Robert et al 2017	Cohort	USA	43 ICUs 43 hospitals	Not reported	402 relatives of 458 ICU patients, 1617 clinicians	Educational intervention (s)	Terminal weaning or immediate extubation for withdrawing mechanical ventilation
Robin et al 2021	Randomised controlled trial	France	3 ICUs 1 hospital	Cardiac; Neuro; Trauma	90 relatives of 90 ICU patients	Communication intervention (s) Advanced care planning	Oral information relating to witholding or withdrawing therapies Information pamphlet
Robley and Denton 2006	Cohort	France	1 ICU 1 hospital	Not reported	22 FM of 22 ICU patients	Communication intervention (s)	EoL Critical Care Nurse Liaison
Schart et al 2021	Randomised controlled trial	USA	1 ICU 1 hospital	Medical	29 FM of 22 ICU patients	Educational intervention (s) Communication intervention (s)	Educational booklet Items from a comfort cart Psychological support
Swinton et al 2017	Qualitative interview	USA	1 ICU 1 hospital	Mixed	76 FM of 70 ICU patients, 150 clinicians	Advanced care planning	Elicitation and implementation of wishes from patients, families and clinicians
Tabibian et al 2019	Cohort	Canada	1 ICU 1 hospital	Neuro	149 ICU patients	PC team involvement	Palliative care service involvement

Appendix 12 Supplementary study data sources

Author and date	Title	Source	Identifier
Assistance Publique Hôpitaux de Paris, 2016	Guiding ICU Physicians' Communication and Behavior Towards Bereaved Relatives: a Randomized Controlled Trial (COSMIC - EOL)	TR	NCT02955992
Centre Hospiitalier Departemental Vendee, 2013	Terminal Weaning of Mechanical Ventilation or Extubation in Anticipation of Death in the Intensive Care Unit: Impact on Relatives, Care Givers and the Dying Process - A Prospective, Multicenter, Observational Study.	TR	NCT01818895
Chen, 2017	Using a Nurse-Led Communication Strategy to Improve Surrogates' Perception of Communication in the Intensive Care Unit	TR	NCT03770481
Cheung, 2006	The effect of the Palliative Care Team on quality indicators for end-of-life care in the intensive care unit: A randomised, controlled trial	TR	ACTRN12606000110583
Curtis, 2008	A Randomized Trial of an Interdisciplinary Communication Intervention to Improve Patient and Family Outcomes in the Intensive Care Unit	TR	NCT00720200
Curtis et al., 2012	Development and evaluation of an interprofessional communication intervention to improve family outcomes in the ICU	P	
Duke University, 2020	Operationalizing PCplanner, a Needs-focused Palliative Care for Older Adults in Intensive Care Units: a Randomized Clinical Trial	TR	NCT04414787
Famirea Study Group, 2006	A Proactive Communication Strategy for Family Members of Patients Dying in the ICU: A Multicenter Randomized Controlled	TR	NCT00331877
Liu, 2020	The Effects of Family-Clinician Shared Decision-Making Model on Patient-Centered Care in Advanced Critical Illness: A Multicenter Randomized Control Trial	TR	ChiCTR2000035040
University Hospital Grenoble, 2014	Impact of a Written Document on Post Traumatic Stress Disorder (PTSD) Diagnosed in Family Members After Withholding and Withdrawing Life-sustaining Therapies in the Intensive Care	TR	NCT02329418
Weill Medical College of Cornell University, 2017	Enhancing & Mobilizing the POtential for Wellness & Emotional Resilience Among Surrogate Decision-Makers of ICU Patients	TR	NCT03276559
White, 2015	Stepped Wedge Trial of an Intervention to Support Proxy Decision Makers in ICUs	TR	NCT02445937

TR = Trial registry P= Publication

Appendix 13 All outcomes extracted

Core area: Death

Core outcome domain: 1: Mortality/survival

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Mortality rates estimates	-	-	1	-		1	1	Lustbader et., 2011
ICU mortality	-	2	-	-	1	1	2	Braus et al., 2016; Cheung et al., 2010
In hospital mortality	-	2	-	-	1	1	2	Braus et al., 2016; Lincoln et al., 2020
90 day mortality	-	1	-	-		1	1	Braus et al., 2016
Hospital mortality	-	1	-	-	1	-	1	Cheung et al., 2010
Patient mortality in ICU	-	1	-	-	1	-	1	Curtis et al., 2016
Patient mortality during hospital stay	-	1	-	-	1	-	1	Curtis et al., 2016
All cause 6 month mortality	-	1	-	-	1	-	1	Lincoln et al., 2020
Time from change to comfort care–do-not-resuscitate (CC-DNR) to death	-	-	1	-	-	1	1	Tabibian et al., 2019
Median survival time	-	-	1	-	-	1	1	O'Mahoney et al., 2010
Location of death	-	-	1	-	-	1	1	Lustbader et al., 2011

- = 0

Core area: Physiological/clinical

Core outcome domain: 9: General outcomes

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Illness severity	-	-	1	-	1	-	1	Cox et al., 2020

Core area: Functioning

Core outcome domain: 22: Respiratory, thoracic and mediastinal outcomes

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Patient respiratory comfort	1	-	-	-	1	-	1	Campbell, 2017
Comfort of patients during the dying process	-	1	-	-	-	1	1	Robert et al., 2017

Core outcome domain: 25: Physical functioning

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Functional status at 6 months	-	1	-	-	1	-	1	Lincoln et al., 2020

Core outcome domain: 29: Cognitive function

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Dying as a Spiritual Event	-	-	-	1	-	1	1	Cook et al., 2015
Spiritual Experiences in Wish Solicitation	-	-	-	1	-	1	1	Cook et al., 2015
Spiritual Dimensions of the Wishes Themselves	-	-	-	1	-	1	1	Cook et al., 2015

Core outcome domain: 30: Global quality of life

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Patients' life quality	-	1	-	-	1	-	1	Liu et al., 2022
Surrogate reported quality of life	-	-	1	-	1	-	1	Prigerson et al., 2019

Core outcome domain: 32: Delivery of care – end-of-life care

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Quality of death and dying	-	2	-	-	2	1	2	Curtis et al., 2012; Kentish-Barnes et al., 2022
Family satisfaction with care in the ICU	-	1[C]	-	-	-	1	1	Braus et al., 2016
Family-related quality of death and dying	-	1	-	-	-	1	1	Braus et al., 2016
Surrogate-assessed patient quality of death	-	-	1	-	1		1	Prigerson et al., 2019
Quality of end-of-life care	-	-	1	-	-	1	1	Cook et al., 2015
Quality of end-of-life care in the ICU	-	-	1	-	-	1	1	O'Mahoney et al., 2010
Relative experience	-	1	-	-	-	1	1	Kentish-Barnes et al 2022
Family satisfaction with end-of-life care	-	-	1	-	-	1	1	Kaufer et al., 2008
Relative's satisfaction with the end of life of the patient	-	1	-	-	-	1	1	Robert et al., 2017
Family satisfaction with care in the ICU	-	1[C]	-	-	-	-		Braus et al., 2016
Family satisfaction	1[C]	-	-	-	-	1	1	McDonagh et al., 2004
Family satisfaction with care	-	-	1	-	1	-	1	Shart et al., 2021

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Family composite scores for satisfaction with quality of care	1[C]	-	-	-	-	1	1	Cheung et al., 2010
Family changes in domain scores: Satisfaction with patient care	-	1	-	-	-	1	1	Cheung et al., 2010
Informed about the possibility that their loved one would die from the illness during the last hospitalization	-	-	1	-	-	1	1	Robley & Denton, 2006
Preparation and support of family members before and during the dying process of their loved one	-	-	1	-	1	-	1	Scharf et al., 2021
Family outcomes: palliative care needs	-	-	1	-	-	1	1	Cox et al., 2018
Palliative care needs	-	-	1	-	-	1	1	Cox et al., 2018
Change in unmet palliative care need	1	-	-	-	1	-	1	Cox et al., 2020
Personalising dying	-	-	-	1	-	1	1	Cook et al., 2015
Patient-centeredness of care	-	2	-	-	2	-	2	Cox et al., 2020; Lincoln et al., 2020
Dignifying the Patient	-	-	-	1	-	1	1	Cook et al., 2015
Fostering clinician compassion	-	-	-	1	-	1	1	Cook et al., 2015
Respect for cultural and spiritual beliefs	-	-	1	-	-	1	1	Robley & Denton, 2006

C=composite

Core outcome domain: 32: Delivery of care – communication

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Preliminary efficacy (QOC)	-	1[C]	-	-	-	1	1	Chen et al., 2022
Family Changes in domain scores: Satisfaction with communication	-	1	-	-	1	-	1	Cheung et al., 2010
Pre- and post-intervention scores of the Quality of Communication (QOC) questionnaire between intervention group and control group	1	-	-	-	-	1	1	Chen et al., 2022
Quality of communication	-	1	-	-	1	-	1	Cox et al., 2020
Families' ratings of the quality of communication generally and specifically in the family conference	-	-	1	-	1	-	1	Curtis et al., 2016
Satisfaction with EOL communication	-	1	-	-	1	-	1	Kentish-Barnes et al., 2022
Effectiveness of overall information provided	-		1	-	1	-	1	Lautrette et al., 2007
Quality of communication during the ICU stay	1	-	-	-	1	-	1	Lincoln et al., 2020
Provision of information about the condition	-	-	1	-	-	1	1	Robley & Denton, 2006
Satisfaction with the communication and support	-	-	-	1	-	1	1	Robley & Denton, 2006
Giving the Family a Voice	-	-	-	1	-	1	1	Cook et al., 2015
Clinicians' ratings of the quality of clinician-family in the family conference	-	1	-	-	1	-	1	Curtis et al., 2016

Core outcome domain: 32: Delivery of care – care satisfaction

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Caregiver Self-Efficacy in the ICU	-	-	1	-	1	-	1	Prigerson et al., 2019
Family changes in domain scores: Satisfaction with continuity of care	-	1	-	-	-	1	1	Cheung et al., 2010
Family changes in domain scores: Satisfaction with emotional and practical support	-	1	-	-	-	1	1	Cheung et al., 2010
Family changes in domain scores: Satisfaction with spiritual support	-	1	-	-	-	1	1	Cheung et al., 2010
Family changes in domain scores: Satisfaction with symptom management and comfort care	-	1	-	-	-	1	1	Cheung et al., 2010
Clinicians' ratings of nurse-physician collaboration	-	1	-	-	1	-	1	Curtis et al., 2016
Attentive to the distress of the family members	-	-	-	1	-	1	1	Robley & Denton, 2006

C=composite

Core outcome domain: 32: Delivery of care – decision-making

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Family Changes in domain scores: Satisfaction with patient and family-centred decision making	-	1	-	-	-	1	1	Chen et al., 2022
Families' satisfaction on shared decision making	1	-	-	-	1	-	1	Liu et al., 2022
Family Satisfaction with Decision Making	-	-	1	-	1	-	1	Scharf et al., 2021

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Surrogates reported feelings towards the medical team regarding medical decisions in the ICU	-	-	1	-	1	-	1	Prigerson et al., 2019
Theme Decision making	-	-	-	1	-	1	1	O'Mahony et al., 2010
ICU clinicians Collaboration and Satisfaction about Care Decisions	-	1	-	-	1	-	1	Liu et al., 2022
Decision to forgo life-sustaining treatments	-	-	1	-	1	-	1	Lautrette et al., 2007
To what extent the patient's treatment is aligned with their values	-	1	-	-	1	-	1	Cox et al., 2020
Receipt of goal concordant care	-	1	-	-	1	-	1	Cox et al., 2020
Frequency of goal concordant treatment	-	-	1	-	-	1	1	Cox et al., 2018
Rates of value-concordant care	-	-	1	-	-	1	1	Prigerson et al., 2019
Conflicts with family members reported by ICU staff	-	-	1	-	1	-	1	Lautrette et al., 2007
Being on the breathing machine despite stated wishes of the patient to the contrary	-	-	-	1	-	1	1	Robley & Denton, 2006
CPR change after palliative care consult	-	-	1	-	-	1	1	Cox et al., 2018
Cardiopulmonary resuscitation (CPR) for full care	-	-	1	-	-	1	1	Cox et al., 2018
CC-DNR ordered	-	-	1	-	1	-	1	Tabibian et al., 2019
Do Not Resuscitate (DNR)	-	-	1	1	-	-	1	Robley & Denton, 2006
Direct or graduated change of code status	-	-	1	-	1	-	1	Tabibian et al., 2019
Allow Natural Death (AND) orders	-	-	1	-	-	1	1	Robley & Denton, 2006
Respectfulness of the law regarding withholding and withdrawing life-sustaining therapies	-	1	-	-	1	-	1	Robin et al., 2021

Core outcome domain: 32: Delivery of care – withdrawal

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Evaluation of the Experience of Withdrawal	-	-	2	-	-	1	1	Kirchhoff et al., 2008
Withdrawal of mechanical ventilation (terminal wean)	-	-	1	-	-	1	1	Lustbader et al., 2011

Core area: Resource use

Core outcome domain: 34: Economic

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Number of medical teams caring or consulting for the patient	-	1	-	-	1	-	1	Cheung et al., 2010
Cost of care	-	1	-	-	1	-	1	Curtis et al., 2012
ICU costs all patients	-	1	-	-	1	-	1	Curtis et al., 2016
ICU costs survivors	-	1	-	-	1	-	1	Curtis et al., 2016
ICU costs decedents	-	1	-	-	1	-	1	Curtis et al., 2016
Medical cost in ICU	1	-	-	-	1	-	1	Liu et al., 2022
Average daily ICU cost	-	1	-	-	1	-	1	Curtis et al., 2016
All hospital costs all patients	-	1	-	-	1	-	1	Curtis et al., 2016
All hospital costs survivors	-	1	-	-	1	-	1	Curtis et al., 2016
Hospital costs decedents	-	1	-	-	1	-	1	Curtis et al., 2016
Payer perspective Index hospitalisation cost	-	1	-	-	1	-	1	Lincoln et al., 2020
Total hospitalisation costs	-	1	-	-	1	-	1	Lincoln et al., 2020
Length of stay charges	-	-	1	-	-	1	1	O'Mahony et al., 2010

Core outcome domain: 35: Hospital

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
ICU length of stay	1	5	1	-	4	2	6	Braus et al., 2016; Cheung et al., 2010; Cox et al., 2018; Curtis et al., 2012; Curtis et al., 2016; Lincoln et al., 2020; Liu et al., 2022
ICU length of stay before palliative care consultation	-	-	1	-	-	1	1	Cox et al., 2018
ICU length of stay after palliative care consultation	-	-	1	-	-	1	1	Cox et al., 2018
Post-randomization intensive care unit length of stay	-	1		-	-	1	1	Cox et al., 2018
MICU length of stay	-	-	1	-	-	1	1	Lustbader et al., 2011
Number of days in ICU	-	-	1	-	1	-	1	Lautrette et al., 2007
Duration in the ICU	-	1	-	-	1	-	1	Robin et al., 2021
Number of days from decision to forgo life-sustaining treatments to death	-	-	1	-	1	-	1	Lautrette et al., 2007
Duration of end-of-life processes	-	1	-	-	1	-	1	Robin et al., 2021b
Hospital length of stay	1	3	2	-	3	3	6	Braus et al., 2016; Cheung et al., 2010; Cox et al., 2018; Curtis et al., 2012; Curtis et al., 2016; Lincoln et al., 2020; Lustbader et al., 2011
Length of hospital stay	-	-	1	-	-	1	1	O'Mahony et al., 2010
Post-randomization hospital length of stay	-	1	-	-	1	-	1	Cox et al., 2020
Hospital length of stay before palliative care consultation	-	-	1[CI]	-	-	1	1	Cox et al., 2018
Hospital length of stay after palliative care consultation	-	-	1[CI]	-	-	1	1	Cox et al., 2018
Patient time until death	-	-	1	-	-	1	1	Lustbader et al., 2011

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Proportion of patients for whom an interdisciplinary family meeting was documented while in the ICU	1	-	-	-	-	1	1	Braus et al., 2016
Time between ICU admission and the occurrence of an interdisciplinary family meeting	-	1	-	-	-	1	1	Braus et al., 2016
Number of days from ICU admission to decision to forgo life-sustaining treatment	-	-	1	-	1	-	1	Lautrette et al., 2007
Time from code status change to PC consultation	-	-	1	-	-	1	1	Tabibian et al., 2019
DNR designation at death	-	-	1	-	-	1	1	Lustbader et al., 2011
ICU discharge disposition	-	1	-	-	1	-	1	Liu et al., 2022
Discharge destination of survivors	-	1	-	-	-	1	1	Braus et al., 2016
Discharge disposition	-	-	1	-	1	-	1	Cox et al., 2020
Discharge disposition (including in hospital mortality)	-	1	-	-	1	-	1	Lincoln et al., 2020
Hospital discharge disposition	-	-	1	-	-	1	1	Cox et al., 2018
Hospital readmission rates	-	1	-	-	1	-	1	Lincoln et al., 2020

Core outcome domain: 36: Further intervention – organ support

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Mechanical ventilation duration	-	-	1	-	-	1	1	Cox et al., 2018)
Duration of ventilation	-	-	1	-	1	-	1	Cox et al., 2020
Mechanical ventilation duration before palliative care consult	-	-	1	-	-	1	1	Cox et al., 2018
Mechanical ventilation duration after palliative care consult	-	-	1	-	-	1	1	Cox et al., 2018
Respiratory failure requiring mechanical ventilation	-	-	1	-	-	1	1	Cox et al., 2018
Tracheotomy	-	-	1	-	-	1	1	Cox et al., 2018
Number of nonbeneficial interventions provided after decision to forgo life-sustaining treatments	-	-	1	-	1	-	1	Lautrette et al., 2007
Nonbeneficial interventions after end-of-life conference - mechanical ventilation	-	-	1	-	1	-	1	Lautrette et al., 2007
Life-sustaining treatments withdrawn - mechanical ventilation	-	-	1	-	1	-	1	Lautrette et al., 2007
Use of specific non-beneficial life-prolonging treatments in persons at the end-of-life - ventilator	-	-	1	-	-	1	1	O'Mahony et al., 2010
Duration of vasopressor use	-	-	1	-	1	-	1	Cox et al., 2020
Nonbeneficial interventions after end-of-life conference vasopressors	-	-	1	-	1	-	1	Lautrette et al., 2007
Life-sustaining treatments withdrawn Vasopressors	-	-	1	-	1	-	1	Lautrette et al., 2007
Use of specific non-beneficial life-prolonging treatments in persons at the end-of-life – inotropic support	-	-	1	-	-	1	1	O'Mahony et al., 2010
Nonbeneficial interventions after end-of-life conference - dialysis	-	-	1	-	1	-	1	Lautrette et al., 2007

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Use of specific non-beneficial life-prolonging treatments in persons at the end-of-life - dialysis	-	-	1	-	-	1	1	O'Mahony et al., 2010
Life-sustaining treatments withdrawn Dialysis	-	-	1	-	1	-	1	Lautrette et al., 2007
No. of nonbeneficial interventions provided after decision to forgo life-sustaining treatments	-	-	1	-	1	-	1	Lautrette et al., 2007
Use of specific non-beneficial life-prolonging treatments in persons at the end-of-life – artificial hydration	-	-	1	-	-	1	1	O'Mahony et al., 2010
Use of specific non-beneficial life-prolonging treatments in persons at the end-of-life - nutrition	-	-	1	-	-	1	1	O'Mahony et al., 2010
Use, timing, and duration of aggressive medical care	-	-	1	-	1	-	1	Cox et al., 2020

Core outcome domain: 36: Further intervention – MDT

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Palliative care and ethics consultations	-	1	-	-	1	-	1	Lincoln et al., 2020
Time from ICU admission to palliative consultation	-	-	1	-	-	1	1	O'Mahony et al., 2010
Number of PC visits/consults before transfer or death	-	-	1	-	-	1	1	Tabibian et al., 2019
Pastoral care involvement	-	1	-	-	1	-	1	Lincoln et al., 2020
Pastoral care consultation	-	-	1	-	-	1	1	Tabibian et al., 2019
Saw a psychologist after death of patient	-	-	1	-	1	-	1	Lautrette et al., 2007
Social work involvement	-	1	-	-	1	-	1	Lincoln et al., 2020
Frequency of multidisciplinary communication	-	1	-	-	1	-	1	Lincoln et al., 2020

Core outcome domain: 36: Further intervention

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Respiratory secretion meds ordered within 24 hours of death	-	-	1	-	-	1	1	Tabibian et al., 2019
Anxiolytics/agitation meds ordered within 24 hours of death	-	-	1	-	-	1	1	Tabibian et al., 2019
Nausea medication ordered within 24 hours of death	-	-	1	-	-	1	1	Tabibian et al., 2019
Pain/dyspnea medication ordered within 24 hours of death	-	-	1	-	-	1	1	Tabibian et al., 2019
Tracheotomy	-	-		1	-	1	1	Cox et al., 2018
Surgeries	-	-	1	-	1	-	1	Cox et al., 2020
Incidence and timing of life support decisions	-	1	-	-	1	-	1	Lincoln et al., 2020
Time to end-of-life decision to withhold and withdraw therapies	-	1	-	-	1	-	1	Robin et al., 2021
Modalities of end-of-life processes	-	1	-	-	1	-	1	Robin et al., 2021
Rate of decision to withhold and withdraw life-sustaining therapies in different intensive care units from the hospital	-	1	-	-	1	-	1	Robin et al., 2021
Advance directives present	-	-	1	-	-	1	1	Robley & Denton, 2006
Restraints ordered within 48 hours before death	-	-	1	-	-	1	1	Tabibian et al., 2019
Number of procedures performed in the 48 hours before death	-	-	1	-	-	1	1	Tabibian et al., 2019
Post-discharge healthcare utilisation	-	1	-	-	1	-	1	Lincoln et al., 2020

Core outcome domain: 37: Societal burden – anxiety and depression

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Symptoms of anxiety	-	2	1[E]	-	3	-	3	Cox et al., 2020; Curtis et al., 2012; Prigerson et al., 2019
Family members' symptoms of anxiety	-	1	-	-	1	-	1	Curtis et al., 2016
Anxiety	-	1	-	-	1	-	1	Lichtenthal et al., 2022
Symptoms of anxiety and depression	-	2	-	-	2	-	2	Kentish-Barnes et al., 2022; Lautrette et al., 2007
Anxiety and depression	-	2	-	-	1	1	2	Lichtenthal et al., 2022; Lincoln et al., 2020
Anxiety and depression symptoms	-	1	-	-	1	-	1	Robin et al., 2021
Anxiety and depression symptoms in relatives	-	1	-	-	-	1	1	Robert et al., 2017
Received newly prescribed psychotropic drugs after death of patient	-	-	1	-	1	-	1	Lautrette et al., 2007
Individuals who asked/seen by a psychiatrist/psychologist	-	1	-	-	1	-	1	Robin et al., 2021
Symptoms of depression	-	1	1[E]	-	2	-	2	Cox et al., 2020; Prigerson et al., 2019
Families' symptoms of depression	1	-	-	-	1	-	1	Curtis et al., 2012
Family members' symptoms of depression	1	-	-	-	1	-	1	Curtis et al., 2016
Depression	-	1	-	-	-	1	1	Lichtenthal et al., 2022
Burden of psychological symptoms experienced by family members of those admitted to the ICU	-	1[C]	-	-	-	1	1	Braus et al., 2016
Family outcome: Depression, anxiety, and stress	-	-	1	-	1	-	1	Scharf et al., 2021

Core outcome domain: 37: Societal burden – stress

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Families' distress	-	1	-	-	1	-	1	Liu et al., 2022
Ability to tolerate stress	-	-	1	-	1	-	1	Prigerson et al., 2019
Distress tolerance	-	1	-	-	-	1	1	Lichtenthal et al., 2022
Peritraumatic distress	1	-	-	-	-	1	1	Lichtenthal et al., 2022
Symptoms of peritraumatic distress	1	-	-	-	1	-	1	Prigerson et al., 2019
Symptoms of dissociation	-	-	1	-	1	-	1	Prigerson et al., 2019
Symptoms of PTSD	-	1	-	-	1	-	1	Curtis et al., 2012
Symptoms of post-traumatic stress disorder	-	2	-	-	2	-	2	Cox et al., 2020; Prigerson et al., 2019
PTSD symptoms	-	1	-	-	1	-	1	Kentish-Barnes et al., 2022
Post Traumatic Stress Disorder Symptoms	-	1	-	-	-	1	1	Lichtenthal et al., 2022
Posttraumatic stress symptoms	1	-	-	-	-	1	1	Robert et al., 2017
Post-traumatic stress	-	1	-	-	1	-	1	Lincoln et al., 2020
Family members' symptoms of PTSD	-	1	-	-	1	-	1	Curtis et al., 2016
Family Symptoms of Post-Traumatic Stress Disorder	-	-	1	-	1	-	1	Scharf et al., 2021
Post traumatic Stress Disorder of relatives	-	1	-	-	-	1	1	Robert et al., 2017
Proportion of relatives with PTSD symptoms	1	-	-	-	1	-	1	Robin et al., 2021
Burden of psychological symptoms experienced by family members of those admitted to the ICU	-	1[C]	-	-	-	1	1	Braus et al., 2016
Score on the Impact of Event Scale (IES)	1	-	-	-	1	-	1	Lautrette et al., 2007
Mean level of Impact of Event Scale (IES)	-	1	-	-	1	-	1	Robin et al., 2021

C=Composite

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Experiential avoidance	-	1	-	-	-	1	1	Lichtenthal et al., 2022
Symptoms of experiential avoidance	-	1	-	-	1	-	1	Prigerson et al., 2019
Family general health scores	-	-	1	-	1	-	1	Scharf et al., 2021
Family member well-being	-	-	1	-	1	-	1	Scharf et al., 2021

Core outcome domain: 37: Societal burden – grief

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Anticipatory grief	-	1	-	-	-	1	1	Lichtenthal et al., 2022
Attachment-related distress associated with anticipatory grief	-	-	1	-	1	-	1	Prigerson et al., 2019
Pre- or post-loss grief intensity	-	1[C]	-	-	-	1	1	Lichtenthal et al., 2022
Differences in symptoms of prolonged grief disorder	-	1[C]	-	-	1	-	1	Prigerson et al., 2019
Proportion of relatives with prolonged grief	1	-	-	-	1	-	1	Kentish-Barnes et al., 2022
Complicated grief symptoms in relatives	-	1	-	-	-	1	1	Robert et al., 2017
Lifestyle disruption	-	-	1	-	1	-	1	Kentish-Barnes et al., 2022
Living situation at 6 months	-	1	-	-	1	-	1	Lincoln et al., 2020

C=Composite

Core outcome domain: 37: Societal burden

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Intensivist Composite scores for satisfaction with quality of care	1	-	-	-	1	-	1	Cheung et al., 2010
Nursing Composite scores for satisfaction with quality of care	1	-	-	-	1	-	1	Cheung et al., 2010
Intensivist changes in domain scores: Satisfaction with goals of care	-	1	-	-	1	-	1	Cheung et al., 2010
Nursing Staff changes in domain scores: Satisfaction with goals of care	-	1	-	-	1	-	1	Cheung et al., 2010
Intensivist changes in domain scores: Satisfaction with symptom management	-	1	-	-	1	-	1	Cheung et al., 2010
Nursing staff Satisfaction scores: Satisfaction with symptom management	-	1	-	-	1	-	1	Cheung et al., 2010
Intensivist changes in domain scores: Satisfaction with communication and support	-	1	-	-	1	-	1	Cheung et al., 2010
Nursing Staff changes in domain scores: Satisfaction with communication and support	-	1	-	-	1	-	1	Cheung et al., 2010
Intensivist changes in domain scores: Overall satisfaction with patient management	-	1	-	-	1	-	1	Cheung et al., 2010
Nursing staff changes in domain scores: Overall satisfaction with patient management	-	1	-	-	1	-	1	Cheung et al., 2010
Intensivist changes in domain scores: changes in grading of difficulty in managing family in day-to-day issues	-	1	-	-	1	-	1	Cheung et al., 2010
Nursing staff changes in domain scores: Grading of difficulty in managing family day-to-day issues	-	1	-	-	1	-	1	Cheung et al., 2010

Verbatim Outcome	Primary outcome	Secondary outcome	Unclear	Theme	Randomised Studies	Non-randomised	Total number of studies	Study
Intensivist changes in domain scores: Grading of difficulty in managing family in end-of-life issues	-	1	-	-	1	-	1	Cheung et al., 2010
Nursing staff changes in domain score: Grading of difficulty in managing family in end-of-life issues	-	1	-	-	1	-	1	Cheung et al., 2010
Medical Doctor satisfaction with the processus	-	1	-	-	1	-	1	Robin et al., 2021
Nurse's satisfaction with the patients' end-of-life care	-	1	-	-	-	1	1	Robert et al., 2017
Decision-making self-efficacy	-	1	-	-	-	1	1	Lichtenthal et al., 2022
Decisional regret	-	1	1[E]	-	2	-	2	Lincoln et al., 2020; Prigerson et al., 2019
Lifestyle disruption	-	-	1	-	1	-	1	Kentish-Barnes et al., 2022
Living situation at 6 months	-	1	-	-	1	-	1	Lincoln et al., 2020
Clinician burn-out	-	1	-	-	1	-	1	Lincoln et al., 2020
Job strain in staff	-	1	-	-	-	1	1	Robert et al., 2017

Appendix 14 Unique outcomes

Core area: Death

Core outcome domain: 1: Mortality/survival

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instrument	Instrument	Data source	Study
Hospital mortality	4 (16%)	4	4	0	0	Not reported	• Medical record	Braus et al., 2016; Cheung et al., 2010; Curtis et al., 2016; Lincoln et al., 2020
ICU mortality	3 (12%)	3	3	0	0	Not reported	• Medical record	Braus et al., 2016; Cheung et al., 2010; Curtis et al., 2016
Mortality rates estimate	1 (4%)	1	1	0	1	APACHE III	• Medical record	Lustbader et al., 2011
90 day mortality	1 (4%)	1	1	0	0	Not reported	• Medical record • Obituary searches • Social Security Death Master File	Braus et al., 2016
All cause 6 month mortality	1 (4%)	1	1	0	0	Telephone interview	• Hospital records • Family/surrogate • National Death Index	Lincoln et al., 2020
Median survival time	1 (4%)	1	1	0	1	Study-specific standardised form	• Medical record	O'Mahony et al., 2010
Time from change to comfort care–do-not-resuscitate (CC-DNR) to death	1 (4%)	1	1	0	0	Not reported	• Medical record	Tabibian et al., 2019
Location of death	1 (4%)	1	1	0	0	Not reported	• Medical record	Lustbader et al., 2011

[APACHE III] = Acute Physiology and Chronic Health Evaluation III score

Core area: Physiological/clinical

Core outcome domain: 9: General outcomes

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Illness severity	1 (4%)	1	1	0	1	APACHE II Score	• Medical record	(Cox et al., 2020)

[APACHE II] = Acute Physiology and Chronic Health Evaluation II score

Core outcome domain: 22: Respiratory, thoracic and mediastinal outcomes

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Patient respiratory comfort	2 (8%)	2	2	0	3	AOS, BPS, RDOS	• Clinical team	(Campbell, 2017; Robert et al., 2017)

[AOS] = Airway Obstruction Scale [BPS] = Behavioural Pain Scale score [RDOS] = Respiratory Distress Observation Scale

Core area: Functional

Core outcome domain: 25: Physical functioning

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Functional status	1 (4)%	1	1	1	1	Katz ADL	• Family/surrogate	(Lincoln et al., 2020)

[Katz ADL] = Katz Activities of Daily Living

Core outcome domain: 30: Global quality of life

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Patients' life quality	2 (8%)	2	2	0	2	QoL2, CEQUEL-Revised	• Family/surrogate	(X. Liu et al., 2022; Prigerson et al., 2019)

[QoL2] = Quality of Life scale for terminal cancer patients [CEQUEL-Revised] = Caregiver Evaluation of the Quality of End-of-Life Scales - Revised

Core outcome domain: 32: Delivery of care – End-of-Life

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Family satisfaction with end-of-life care	6 (24%)	7	5	3	3	FS-ICU-24 FS-ICU-35 Study-specific questionnaire	• Family/surrogate	Braus et al., 2016; Cheung et al., 2010; Kaufer et al., 2008; McDonagh et al., 2004; Robert et al., 2017; Scharf et al., 2021
Quality of death and dying	6 (24%)	6	6	0	6	QODD, QODD-1 CAESAR, CEQUEL QEOLC-10, ICUQODD	• Family/surrogate • Clinical team	Braus et al., 2016; Cook et al., 2015; Curtis et al., 2012; Kentish-Barnes et al., 2022; O'Mahony et al., 2010; Prigerson et al., 2019
Palliative care needs	2 (8%)	3	3	0	3	NEST – Adapted, NEST, PCCS	• Family/surrogate • Patient	Cox et al., 2018, 2020
Family preparation for patient dying	2 (8%)	2	1	1	2	Semi-structured interview Study-specific questionnaire	• Family/surrogate	Robley & Denton, 2006; Scharf et al., 2021
Patient-centeredness of Care	2 (8%)	2	2	0	2	PCC, PPC modified	• Family/surrogate	Cox et al., 2020; Lincoln et al., 2020
Personalising dying	1 (4%)	1T	0	1	1	Semi-structured interview	• Family/surrogate; • Clinical team	Cook et al., 2015
Dignifying the Patient	1 (4%)	1T	0	1	1	Semi-structured interview	• Family/surrogate	Cook et al., 2015
Clinical compassion	1 (4%)	1T	0	1	1	Semi-structured interview	• Family/surrogate	Cook et al., 2015
Respect for cultural and spiritual beliefs	1 (4%)	1	1	0	1	Study-specific Likert scale	• Family/surrogate	Robley & Denton, 2006

[QODD] = Quality of Death and Dying Scale [QODD-1] = Quality of Death and Dying Scale 1 [CAESAR] = Care Assessment of the Experience of Relatives scale [CEQUEL] = Caregiver Evaluation of the Quality of End-of-Life Scales [QEOLC-10] = Quality of End-of-Life Care–10 instrument [ICUQODD] = Quality of Dying and Death in the ICU instrument [FS-ICU-24] = Family Satisfaction in the Intensive Care Unit Questionnaire [NEST-Adapted] = Adapted needs of social nature, existential concerns, symptoms, and therapeutic interaction scale [NEST] = Needs of social nature, existential concerns, symptoms, and therapeutic interaction scale [PCCS] = Patient-Centeredness of Care Scale [PPC modified] = Patient perception of patient-centredness scale, modified for use by surrogate

Core outcome domain: 32: Delivery of care - Communication

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Quality of communication	4 (16%)	6	3	3	1	QOC, Not reported	• Family/surrogate • Clinical team	Chen et al., 2022; Cox et al., 2018; Curtis et al., 2016; Lincoln et al., 2020
Satisfaction with communication	3 (12%)	4	2	2	4	Study-specific questionnaire MISS-21 Rapport subscale Semi-structured interview Study-specific Likert scale	• Family/surrogate	Cheung et al., 2010; Kentish-Barnes et al., 2022; Robley & Denton, 2006
Effectiveness of overall information provided	1 (4%)	1	1	0	1	Interview	• Family/surrogate	Lautrette et al., 2007
Giving the Family a Voice	1 (4%)	1[T]	0	1	1	Semi-structured interview	• Family/surrogate	Cook et al., 2015

[MISS-21] = Rapport subscale of the medical interview satisfaction scale [QOC] = Quality of Communication questionnaire

Core outcome domain: 32: Delivery of care – care satisfaction

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Satisfaction with quality of care	3 (12%)	3	3	0	3	CEQUEL QEOLC-10 Study specific questionnaire	• Family/surrogate	Cheung et al., 2010; Cook et al., 2015; Prigerson et al., 2019
Caregiver Self-Efficacy in the ICU	1 (4%)	1	0	1	1	COSMIC	• Family/surrogate	Prigerson et al., 2019
Family satisfaction with continuity of care	1 (4%)	1	1	0	1	Study-specific questionnaire	• Family/surrogate	Cheung et al., 2010
Family satisfaction with emotional and practical support	1 (4%)	1	1	0	1	Study-specific questionnaire	• Family/surrogate	Cheung et al., 2010
Family satisfaction with spiritual support	1 (4%)	1	1	0	1	Study-specific questionnaire	• Family/surrogate	Cheung et al., 2010
Family satisfaction with symptom management and comfort care	1 (4%)	1	0	1	1	Study-specific questionnaire	• Family/surrogate	Cheung et al., 2010
Clinicians' ratings of nurse-physician collaboration	1 (4%)	1	0	1	0	Not reported	• Clinical team	Curtis et al., 2016
Attentive to the distress of the family members	1 (4%)	1	0	1	1	Study-specific Likert scale	• Family/surrogate	Robley & Denton, 2006

[CEQUEL] = Caregiver Evaluation of the Quality of End-of-Life Scales [COSMIC] = Caregiver Self-Efficacy in the ICU Scale [QEOLC-10] = Quality of End-of-Life Care–10 instrument

Core outcome domain: 32: Delivery of care – Decision-making

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Family satisfaction with decision-making	5 (20%)	5	2	3	5	Study-specific analogue scale, SSDM, FS-ICU-24 CCFSS, Interview	• Family/surrogate	Cheung et al., 2010; Liu et al., 2022; O'Mahony et al., 2010; Prigerson et al., 2019; Scharf et al., 2021)
Concordant care	3 (12%)	4	4	0	3	Study-specific questionnaire, PCCS	• Family/surrogate • Medical record	Cox et al., 2018, 2020; Prigerson et al., 2019)
Change in resuscitation status	2 (8%)	2	1	1	0	Not reported	• Medical record	Cox et al., 2018; Tabibian et al., 2019)
Do Not Resuscitate (DNR) orders	2 (8%)	2	1	1	0	Not reported	• Medical record	Robley & Denton, 2006; Tabibian et al., 2019
Non-concordant care	1 (4%)	1	1T	0	1	Study-specific questionnaire	• Family/surrogate	Robley & Denonton, 2006
ICU clinicians' collaboration and satisfaction about care decisions	1 (4%)	1	1	0	1	CSACD	• Clinical team	Liu et al., 2022)
Decision to forgo life-sustaining treatments	1 (4%)	1	0	1	1	Study-specific standardised form	• Clinical team	Lautrette et al., 2007
ICU staff conflicts with family members	1 (4%)	1	0	1	0	Not reported	• Clinical team	Lautrette et al., 2007
Cardiopulmonary resuscitation (CPR) for full care	1 (4%)	1	1	0	0	Not reported	• Medical record	Cox et al., 2018
Allow natural death orders	1 (4%)	1	0	1	0	Not reported	• Medical record	Robley & Denton 2006

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Respectfulness of the law regarding withholding and withdrawing life-sustaining therapies	1 (4%)	1	0	1	0	Not reported	• Unclear	Robin et al., 2021

[SSDM] = Satisfaction on Shared Decision-Making scale [FS-ICU-24] = Family Satisfaction with Care in the Intensive Care Unit-24 [CCFSS] = Critical Care Family Satisfaction Survey [PCCS] = Patient-centeredness of Care Scale [CSACD] = Collaboration and Satisfaction about Care Decisions Scale

Core outcome domain: 32: Delivery of care – Withdrawal

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Evaluation of the Experience of Withdrawal	1 (4%)	2	2	0	2	POMS-SF, EEW	• Family/surrogate	(Kirchhoff et al., 2008)
Withdrawal of mechanical ventilation (terminal wean)	1 (4%)	1	1	0	0	Not reported	• Medical record	(Lustbader et al., 2011)

[POMS-SF] = Profile of Mood Short Form [EEW] = Evaluation of the Experience of Withdrawal questionnaire

Core area: Resource use

Core outcome domain: 34: Economic

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
ICU costs	3 (12%)	7	6	1	0	Not reported	• Medical record • Administrative financial databases • Hospital information database	Curtis et al., 2016; Liu et al., 2022; O'Mahony et al., 2010
Hospital costs	2 (8%)	5	4	1	0	Not reported	• Medical record • Administrative financial databases • Hospital billing records • Insurance system	Curtis et al., 2016; Lincoln et al., 2020
Number of medical teams caring or consulting for the patient	1 (4%)	1	1	0	0	Not reported	• Medical team	Cheung et al., 2010

Core outcome domain: 35: Hospital

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
ICU length of stay	10 (40%)	13	6	7	1	Study-specific standardised form	• Medical record • Hospital information database	Braus et al., 2016; Cheung et al., 2010; Cox et al., 2018; J. Curtis et al., 2012; R. Curtis et al., 2016; Lautrette et al., 2007; Lincoln et al., 2020; Liu et al., 2022; Lustbader et al., 2011; Robin et al., 2021
Hospital length of stay	8 (32%)	12	4	8	1	Study-specific standardised form	• Medical record	Braus et al., 2016; Cheung et al., 2010; Cox et al., 2018; Curtis et al., 2012; Curtis et al., 2016; Lincoln et al., 2020; Lustbader et al., 2011; O'Mahony et al., 2010
Hospital discharge disposition	4 (16%)	4	1	3	0	Not reported	• Medical record • Registration data	Braus et al., 2016; Cox et al., 2018, 2020; Lincoln et al., 2020
Duration of the end-of-life processes	2 (8%)	2	1	1	1	Study-specific standardised form	• Medical record	Lautrette et al., 2007; Robin et al., 2021

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Interdisciplinary family meeting	1 (4%)	1	1	0	0	Not reported	• Medical record	Braus et al., 2016
Time between ICU admission and the occurrence of an interdisciplinary family meeting	1 (4%)	1	1	0	0	Not reported	• Medical record	Braus et al., 2016
Number of days from ICU admission to decision to forgo life-sustaining treatments	1 (4%)	1	0	1	1	Study-specific standardised form	• Medical record	Lautrette et al., 2007
Time from code status change to palliative care consultation	1 (4%)	1	1	0	0	Not reported	• Medical record	Tabibian et al., 2019
DNR designation at death	1 (4%)	1	0	1	0	Not reported	• Medical record	Lustbader et al., 2011
ICU discharge disposition	1 (4%)	1	1	0	0	Not reported	• Medical record	Liu et al., 2022
Hospital readmission rates	1 (4%)	1	1	1	1	Telephone interview	• Family/surrogate	Lincoln et al., 2020

Core outcome domain: 36: Organ support

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Use of nonbeneficial interventions	3 (12%)	10	10	0	1	Study-specific standardised form	• Hospital accounting Excel databases • Medical record	Cox et al., 2020; Lautrette et al., 2007; O'Mahony et al., 2010
Mechanical ventilation duration	3 (12%)	5	5	0	0	Not reported	• Medical record	Cox et al., 2018, 2020; Lustbader et al., 2011
Life-sustaining treatments withdrawn	1 (4%)	3	3	0	1	Study-specific standardised form	• Medical record	Lautrette et al., 2007
Tracheotomy	1 (4%)	1	1	0	0	Not reported	• Medical record	Cox et al., 2018
Vasopressor duration	1 (4%)	1	1	0	0	Not reported	• Medical record	Cox et al., 2020

Core outcome domain: 36: Further investigation - MDT

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Pastoral care involvement	2 (8%)	2	0	2	0	Not reported	• Medical record	Lincoln et al., 2020; Tabibian et al., 2019
Ethics consultations	1 (4%)	1	0	1	0	Not reported	• Medical record	Lincoln et al., 2020
Time from ICU admission to palliative consultation	1 (4%)	1	1	0	1	Study-specific standardised form	• Medical record	O'Mahony et al., 2010
Number of PC visits/consults before transfer or death	1 (4%)	1	1	0	0	Not reported	• Medical record	Tabibian et al., 2019
Psychologist involvement after patient death	1 (4%)	1	0	1	0	Not reported	• Medical record	Lautrette et al., 2007
Social work involvement	1 (4%)	1	0	1	0	Not reported	• Medical record	Lincoln et al., 2020
Frequency of multidisciplinary communication	1 (4%)	1	0	1	0	Not reported	• Medical record	Lincoln et al., 2020

Core outcome domain: 36: Further investigation

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Anticipatory medication prescribed	1 (4%)	4	4	0	0	Not reported	• Medical record	Tabibian et al., 2019
Time to end-of-life decision to withold and withdraw therapies	2 (8%)	2	1	1	1	Study-specific standardised form	• Medical record	Lincoln et al., 2020, Robin et al., 2021
Surgeries	1 (4%)	1	0	1	0	Not reported	• Medial record	Cox et al., 2020
Modalities of end-of-life processes	1 (4%)	1	0	1	1	Study-specific standardised form	• Medical record	Robin et al., 2021
Rate of decision to withhold and withdraw life-sustaining therapies	1 (4%)	1	0	1	1	Study-specific standardised form	• Medical record	Robin et al., 2021
Advance directives present	1 (4%)	1	1	0	1	Semi-structured interview	• Family/surrogate	Robley & Denton, 2006
Restraints ordered	1 (4%)	1	0	1	0	Not reported	• Medical record	Tabibian et al., 2019
Number of procedures performed	1 (4%)	1	0	1	0	Not reported	• Medical record	Tabibian et al., 2019
Postdischarge healthcare utilisation	1 (4%)	1	1	0	1	Semi-structured interview	• Family/surrogate • Medical records • Hospital billing records	Lincoln et al., 2020

Core outcome domain: 37: Social burden – anxiety and depression

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Family members symptoms of anxiety and depression	8 (32%)	8	8	0	1	HADS	• Family/surrogate	Chen et al., 2022; Kentish-Barnes et al., 2022; Lautrette et al., 2007; Lincoln et al., 2020; Liu et al., 2022; Prigerson et al., 2019; Robert et al., 2017; Robin et al., 2021
Family members symptoms of depression	6 (24%)	6	4	2	2	PHQ-9, PHQ-8	• Family/surrogate	Braus et al., 2016; Cox et al., 2018; Curtis et al., 2016; Lichtenthal et al., 2022; Prigerson et al., 2019
Family members symptoms of anxiety	5 (20%)	5	3	2	2	GAD-7, STAI-Y	• Family/surrogate	Cox et al., 2020; Curtis et al., 2012; Curtis et al., 2016; Lichtenthal et al., 2022; Prigerson et al., 2019
Received newly prescribed psychotropic drugs after death of patient	1 (4%)	1	0	1	1	Interview	• Family/surrogate	Lautrette et al., 2007
Individuals who asked/seen by a psychiatrist/psychologist	1 (4%)	1	0	1	1	Interview	• Family/surrogate	Robin et al., 2021
Family members depression, anxiety, and stress	1 (4%)	1	0	1	1	DASS	• Family/surrogate	Scharf et al., 2021

[GAD-7] = The Generalised Anxiety Disorder 7-item scale [STAI-Y] = State Trait Anxiety Questionnaire—Trait Scale [HADS] = Hospital Anxiety and Depression Scale [PHQ-9] = Patient Health Questionnaire 9-item scale [PHQ-8] = The Patient Health Questionnaire depression scale [DASS] = Depression Anxiety Stress Scales

Core outcome domain: 37: Social burden – stress

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Family member symptoms of post-traumatic stress disorder (PTSD)	11 (44%)	14	10	4	4	IES, IES-R, PTSD PCL-C, PTSS	• Family/surrogate	Braus et al., 2016; Cox et al., 2020; Curtis et al., 2016; Kentish-Barnes et al., 2022; Lautrette et al., 2007; Lichtenthal et al., 2022; Lincoln et al., 2020; Prigerson et al., 2019; Robert et al., 2017; Robin et al., 2021; Scharf et al., 2021
Families distress tolerance	2 (8%)	2	2	0	2	DTS, DTS revised	• Family/surrogate	Lichtenthal et al., 2022; Prigerson et al., 2019
Symptoms of peritraumatic distress	2 (8%)	2	2	0	2	PDI, PDI modified	• Family/surrogate	Lichtenthal et al., 2022; Prigerson et al., 2019
Symptoms of experiential avoidance	2 (8%)	2	1	1	1	BEAQ	• Family/surrogate	Lichtenthal et al., 2022; Prigerson et al., 2019
Symptoms of dissociation	1 (4%)	1	1	0	1	PDEQ	• Family/surrogate	Prigerson et al., 2019
Family general health scores	1 (4%)	1	0	1	1	SF-36	• Family/surrogate	Scharf et al., 2021
Family member well-being	1 (4%)	1	0	1	1	RMWBQ	• Family/surrogate	Scharf et al., 2021
Lifestyle disruption	1 (4%)	1	0	1	1	Study-specific questionnaire	• Family/surrogate	Kentish-Barnes et al., 2022

[PDI] = Peritraumatic Distress Inventory [PDI modified] = Peritraumatic Distress Inventory modified [PDEQ] = Peritraumatic Dissociative Experiences Questionnaire [IES] = Impact of Events Scale [IES-R] = Impact of Event Scale Revised [PTSD PCL-C] = Post-Traumatic Stress Disorder Checklist Civilian Version [PTSS] = The Post-Traumatic Stress Syndrome inventory [BEAQ] = Brief Experiential

Core outcome domain: 37: Social burden – grief

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Prolonged grief	3 (12%)	4	4	0	3	PG12 PG12 – carer version PG13	• Family/surrogate	Lichtenthal et al., 2022; Prigerson et al., 2019 ; Kentish-Barnes et al., 2022
Anticipatory grief	1 (4%)	2	2	0	1	PG12	• Family/surrogate	Lichtenthal et al., 2022
Attachment related distress	1 (4%)	1	0	1	1	FOLLOS	• Family/surrogate	Prigerson et al., 2019
Family members' symptoms of complicated grief	1 (4%)	1	1	0	1	ICG	• Family/surrogate	Robert et al., 2017

[PG-12] = Prolonged Grief 12 [PG-12 carer version] = Prolonged Grief Disorder Carer Version [FOLLOS] = Fear of Losing Loved Ones Scale [PG-13] = Prolonged Grief 13 [ICG] = Inventory of Complicated Grief

Core outcome domain: 37: Social burden

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Satisfaction with quality of care	2 (8%)	3	3	0	2	Study-specific questionnaire	• Clinical team (Intensivist) • Clinical team (Nurse)	Cheung et al., 2010; Robert et al., 2017
Decision regret	2 (8%)	3	1	2	2	Regret assessment DRS	• Family/surrogate	Lincoln et al., 2020; Prigerson et al., 2019
Satisfaction with goals of care	1 (4%)	2	2	0	2	Study-specific questionnaire	• Clinical team (Intensivist) • Clinical team (Nurse)	Cheung et al., 2010
Satisfaction with symptom management	1 (4%)	2	2	0	2	Study-specific questionnaire	• Clinical team (Intensivist) • Clinical team (Nurse)	Cheung et al., 2010
Satisfaction with communication and support	1 (4%)	2	2	0	2	Study-specific questionnaire	• Clinical team (Intensivist) • Clinical team (Nurse)	Cheung et al., 2010
Satisfaction with patient management	1 (4%)	2	2	0	2	Study-specific questionnaire	• Clinical team (Intensivist) • Clinical team (Nurse)	Cheung et al., 2010
Difficulty in managing family in day-to-day issues	1 (4%)	2	2	0	2	Study-specific questionnaire	• Clinical team (Intensivist) • Clinical team (Nurse)	Cheung et al., 2010
Difficulty in managing family in end-of-life issues	1 (4%)	2	2	0	2	Study-specific questionnaire	• Clinical team (Intensivist) • Clinical team (Nurse)	Cheung et al., 2010
Decision-making self-efficacy	1 (4%)	2	2	0	2	FDMSE, FDMSS	• Family/surrogate	Lichtenthal et al., 2022

Redefined outcome	Number of studies	Number of outcomes	Number of definitions	Number not defined	Number of Instruments	Instrument	Data source	Study
Medical Doctor satisfaction with the process	1 (4%)	1	0	1	0	Not reported	• Clinical team	Robin et al., 2021
Decision conflict	1 (4%)	1	1	0	1	DCS	• Family/surrogate	Chen et al., 2021
Clinician burn-out	1 (4%)	1	1	0	1	Maslach Burnout Inventory	• Clinical team	Lincoln et al., 2020
Job strain in staff	1 (4%)	1	1	0	1	JSS	• Clinical team	Robert et al., 2017
Living situation at 6 months	1 (4%)	1	0	1	1	Telephone interview	• Family/surrogate	Lincoln et al., 2020

[FDMSE] Family Decision-Making Self-efficacy Scale: Unconscious Patient Scenario [DRS] Decision Regret Scale [DCS] Decision Conflict Scale [JSS] Job Strain Score

Appendix 15 Outcome assessment timing

The following key applies to the outcomes presented in this specific appendix. The number preceding the icon indicates the number of studies that measured the outcome at that time point.

Icon	Explanation
W7BA	Within 7 days of completion of baseline assessment
W7I	Within 7 days of intervention
CI	From completion of intervention
FC	After family conference
PC	After palliative care consultation
PS	Dependent on patient status
DID	From patient death in ICU or ICU Discharge
D	From patient death
ID	From ICU discharge
IHD	From patient's discharge from the index hospitalisation
*	Outcome time point not reported, author was contacted but no response

Outcome	OIM Abbreviation	Pre-intervention	FM or PC consult	MV withdraw	MV change, turn off	24 hours	48 hours	4 Days	5 Days	7 Days	8 Days	14 Days	15 Days	Between 7-14 days	Between 14-16 days	30 Days	Between 31-182	42 Days	45 Days	60 Days	Between 60 -182	90 Days	180 Days	ICU Death or	Hospital discharge	365 Days
COMET Core outcome domain: 01 Mortality																										
Mortality rate estimate	APACHE III									1●			1●			1●			1●	1●						
ICU Mortality	Not reported																							3●		
Hospital mortality	Not reported																					1●	1●		4●	
90 day mortality	Not reported																					1●DID				
All-cause 6 month mortality	Interview																						1●			
Median survival time	Study-specific																								1●D	
Time from change to comfort care–do-not-resuscitate to death	Not reported																							1●D		
Location of death	Not reported																								1●	
COMET Core outcome domain: 09 General																										
Illness severity	APACHE II	1●																								
COMET Core outcome domain: 22 Respiratory, thoracic and mediastinal																										
Patient respiratory comfort	AOS			1●																				1●D		
	BPS			1●																				1●D		
	RDOS	1●			1●																					
COMET core outcome domain: 25 Physical functioning																										
Functional status at 6 months	KADL																						1●IHD			

FC or PC = Family conference or Palliative care consult

Outcome	OIM Abbreviation	Pre-intervention	FM or PC consult	MV withdraw	MV change, turn off	24 hours	48 hours	4 Days	5 Days	7 Days	8 Days	14 Days	15 Days	Between 7-14 days	Between 14-16 days	30 Days	Between 31-182	42 Days	45 Days	60 Days	Between 60 -182	90 Days	180 Days	ICU Death or	Hospital discharge	365 Days
Core outcome domain: 29 Cognitive functioning																										
Dying as a spiritual event	Interview													1 D			1 D									
Core outcome domain: 30 Global quality of life																										
Patients quality of life	CEQUEL-Revised															1 PS						1 PS				
	QoL2	1								1 DID																
Core outcome domain: 32 Delivery of care – end of life																										
Family satisfaction with end-of-life care	FS-ICU-24															1 D		1 DID			1 D					
	FS-ICU-35																				1					
	Study-specific	1	1 FC																			1 D		1		
Quality of death and dying	QEOLC-10																1 D									
	QODD																					1 D	1 D			
	QODD-1															1 D		1 DID								
	CAESAR															1 D										
	CEQUEL															1 PS						1 PS				
	ICUQODD*																									
Palliative care needs	NEST - Adapted	1						1																		
	PCC	1						1																		
	NEST	1						1			1															
Family preparation for patient dying	Interview															1 D						D				
	Study-specific																					1				

Outcome	OIM Abbreviation	Pre-intervention	FM or PC consult	MV withdraw	MV change, turn off	24 hours	48 hours	4 Days	5 Days	7 Days	8 Days	14 Days	15 Days	Between 7-14 days	Between 14-16 days	30 Days	Between 31-182	42 Days	45 Days	60 Days	Between 60 -182	90 Days	180 Days	ICU Death or	Hospital discharge	365 Days
Patient-centeredness of care	PCCS										1●															
	PCC-modified																						1●			
Personalising dying	Interview													1●D			1●D									
Dignifying the patient	Interview													1●D			1●D									
Clinical compassion	Interview													1●D			1●D									
Respect for cultural and spiritual beliefs	Study-specific																					1●D				
Core outcome domain: 32: Delivery of care – Communication																										
Quality of communication	QOC	3●			1●			1●			1●	1●ID											1●IHD			
	Not reported																							2●		
Satisfaction with end-of-life communication	Study-specific	1●																						1●		
	MISS-21															1●D										
	Interview																					1●D				
	Likert scale																					1●D				
Effectiveness of overall information provided	Interview																					1●D				
Giving the Family a Voice	Interview													1●D			1●D									
Core outcome domain: 32: Delivery of care – care satisfaction																										
Satisfaction with quality of care	CEQUEL																●D									
	QEOLC-10																●D									
	Study-specific	1●																						1●		

Outcome	OIM Abbreviation	Pre-intervention	FM or PC consult	MV withdraw	MV change, turn off	24 hours	48 hours	4 Days	5 Days	7 Days	8 Days	14 Days	15 Days	Between 7-14 days	Between 14-16 days	30 Days	Between 31-182	42 Days	45 Days	60 Days	Between 60 -182	90 Days	180 Days	ICU Death or	Hospital discharge	365 Days
Caregiver Self-Efficacy in ICU	COSMIC	1●								1●W7I																
Family satisfaction with quality of care	Study-specific	1●																						1●		
Family satisfaction with continuity of care	Study-specific	1●																						1●		
Family satisfaction with emotional and practical support	Study-specific	1●																						1●		
Family satisfaction with spiritual support	Study-specific	1●																						1●		
Family satisfaction with symptom management and comfort care	Study-specific	1●																						1●		
Clinicians' ratings of nurse-physician collaboration	Not reported																							1●		
Attentive to the distress of the family members	Study-specific																					1●D				
Core outcome domain: 32: Delivery of care – decision making																										
Family satisfaction with decision-making	Study-specific	1●																						1●		
	SSDM	1●								1●DID																
	FS-ICU-24															1●D										
	CCFSS															1●CI										
	Interview																						1●D			

Outcome	OIM Abbreviation	Pre-intervention	FM or PC consult	MV withdraw	MV change, turn off	24 hours	48 hours	4 Days	5 Days	7 Days	8 Days	14 Days	15 Days	Between 7-14 days	Between 14-16 days	30 Days	Between 31-182	42 Days	45 Days	60 Days	Between 60 -182	90 Days	180 Days	ICU Death or	Hospital discharge	365 Days
Concordant care	PCCS										1●															
	Study specific	3●						2●			1●															
Change in resuscitation status	Not reported		1● PC																					1●		
Do Not Resuscitate (DNR) orders	Not reported																							1●	1●	
Non-concordant care	Interview																					1● D				
ICU clinicians' collaboration and satisfaction about care decisions	CSACD	1●								1● DID																
Decision to forgo life-sustaining treatments	Study-specific*																									
ICU staff conflicts with family members	Not reported		1● FC																							
CPR for full care	Not reported	1●																						1●		
Allow Natural Death (AND) orders	Not reported																								1●	
Respectfulness of the law regarding withholding and withdrawing life-sustaining therapies	Not reported*																									

Outcome	OIM Abbreviation	Pre-intervention	FM or PC consult	MV withdraw	MV change, turn off	24 hours	48 hours	4 Days	5 Days	7 Days	8 Days	14 Days	15 Days	Between 7-14 days	Between 14-16 days	30 Days	Between 31-182	42 Days	45 Days	60 Days	Between 60 -182	90 Days	180 Days	ICU Death or	Hospital discharge	365 Days
Evaluation of the experience of withdrawal	EEW														1● D										1● D	
	POMS-SF														1● D										1● D	
Withdrawal of mechanical ventilation (terminal wean)	Not reported																							1●		
COMET Core outcome domain: 34 Economic																										
ICU costs	Not reported																							3●		
Hospital costs	Not reported																								2●	
Number of medical teams caring or consulting for patient	Not reported																							1●		
COMET Core outcome domain: 35 Hospital																										
ICU length of stay	Not reported																							9●		
	Study-specific																					1● D				
Hospital length of stay	Not reported																							1●	7●	
	Study-specific																								1●	
Hospital discharge disposition	Not reported																								4●	
Duration of end-of-life processes	Study-specific																							2●		
Interdisciplinary family meeting	Not reported																								1●	
Time between ICU admission and the occurrence of an interdisciplinary family meeting	Not reported																								1●	

Outcome	OIM Abbreviation	Pre-intervention	FM or PC consult	MV withdraw decision	MV change, turn off	24 hours	48 hours	4 Days	5 Days	7 Days	8 Days	14 Days	15 Days	Between 7-14 days	Between 14-16 days	30 Days	Between 31-182 Days	42 Days	45 Days	60 Days	Between 60 -182 Days	90 Days	180 Days	ICU Death or discharge	Hospital discharge	365 Days
Number of days from ICU admission to decision to forgo life-sustaining treatments	Study-specific																							1●		
Time from code status change to PC consultation	Not reported																							1●		
DNR designation at death	Not reported																								1●	
ICU discharge disposition	Not reported																							1●		
Hospital readmission rates	Interview																								1●	
COMET Core outcome domain: 36 Further investigation – organ support																										
Use of nonbeneficial interventions	Study-specific																							5●		
	Not reported																							4●	1●	
Mechanical ventilation duration	Not reported																							4●	1●	
Life-sustaining treatments withdrawn	Study-specific																							3●		
Tracheotomy	Not reported																							1●		
Vasopressor duration	Not reported																								1●	
COMET Core outcome domain: 36 Further investigation – MDT																										
Pastoral care involvement	Not reported																							1●	1●	
Ethics consultations	Not reported																							1●		
Time from ICU admission to palliative consultation	Study-specific		1●PC																							

Outcome	OIM Abbreviation	Pre-intervention	FM or PC consult	MV withdraw decision	MV change, turn off	24 hours	48 hours	4 Days	5 Days	7 Days	8 Days	14 Days	15 Days	Between 7-14 days	Between 14-16 days	30 Days	Between 31-182 Days	42 Days	45 Days	60 Days	Between 60 -182 Days	90 Days	180 Days	ICU Death or discharge	Hospital discharge	365 Days
Number of PC visits/consults before transfer or death	Not reported																							1●		
Psychologist involvement	Not reported																					1● D				
Social work involvement	Not reported																								1●	
Frequency of multidisciplinary communication	Not reported																								1●	
Anticipatory medication prescribed	Not reported					4● D																				
Time to end-of-life decision to withold and withdraw therapies	Study-specific																					1● D				
Surgeries	Not reported																								1●	
Modalities of end-of-life processes	Study-specific																					1● D				
Rate of decision to withhold and withdraw life-sustaining therapies	Not reported																							1●		
Advance directives present	Interview																					1● D				
Restraints ordered	Not reported						1● D																			
Number of procedures performed	Not reported						1● D																			
Postdischarge healthcare utilisation	Interview																						1●			

Outcome	OIM Abbreviation	Pre-intervention	FM or PC consult	MV withdraw decision	MV change, turn off	24 hours	48 hours	4 Days	5 Days	7 Days	8 Days	14 Days	15 Days	Between 7-14 days	Between 14-16 days	30 Days	Between 31-182 Days	42 Days	45 Days	60 Days	Between 60 -182 Days	90 Days	180 Days	ICU Death or discharge	Hospital discharge	365 Days
COMET Core outcome domain: 36 Further investigation – anxiety and depression																										
Family members' symptoms of anxiety and depression	HADS	3●								1● W7BA 1● DID						1● D						4● D	2● D 2● IHD			1● D
Family members' symptoms of depression	PHQ-9	4●								1● W7BA	1●											1● 2● CI 1● DID	1● DID			
	PHQ-8																	1● DID								
Family members' symptoms of anxiety	GAD-7	3●								1● W7BA	1●					1● CI						1● 1● CI 1● DID	1● DID			
	STAI-Y	1●								1● W7						1● CI						1● CI				
Received newly prescribed psychotropic drugs	Interview																					1● D				
Individuals who asked/seen by a psychiatrist/psychologist	Interview																					1● D				
Family members' depression, anxiety, and stress	DASS															1● D										
COMET Core outcome domain: 36 Social burden - stress																										
Family member symptoms of post-traumatic stress disorder (PTSD)	PTSS	1●									1●											1●				
	IES-R	1●								1● W7I						1● CI 1● D						2● C 3● D	1● D			1● D
	IES																					3● D	1● IHD			
	PTSD PCL-C	1●																1● DID				1● DID	1● DID			
Families' distress tolerance	DTS	1●								1● W7BA						1● CI						1● CI				
	DTS-revised	1●								1● W7I						1● CI						1● CI				

Outcome	OIM Abbreviation	Pre-intervention	FM or PC consult	MV withdraw	MV change, turn off	24 hours	48 hours	4 Days	5 Days	7 Days	8 Days	14 Days	15 Days	Between 7-14 days	Between 14-16 days	30 Days	Between 31-182	42 Days	45 Days	60 Days	Between 60 -182	90 Days	180 Days	ICU Death or	Hospital discharge	365 Days
Symptoms of peritraumatic distress	PDI	1●								1● W7I						1● CI						1● CI				
	PDI modified	1●								1● W7B																
Symptoms of experiential avoidance	BEAQ	2●								1● W7BA 1● W7I																
Symptoms of dissociation	PDEQ	1●								1● W7I																
Family general health scores	SF-36															1● D										
Family member well-being	FMWBQ															1● D										
Lifestyle disruption	Study-specific																						1● D			
Living situation at 6 months	Interview																						1●			
COMET Core outcome domain: 36 Social burden - grief																										
Prolonged grief	PG-12	1●								1● W7BA						1● CI						1● CI				
	PG-12 carer version	1●								1● W7I						1● CI						1● CI				
	PG-13	2●								1● W7BA 1● W7I						2● CI						2● CI				
Anticipatory grief	PG-12	1●								1● W7BA						1● CI						1● CI				
Attachment-related distress	FOLLOS	1●								1● W7I						1● CI						1● CI				
Family members' symptoms of complicated grief	ICG																						1● D			1● D
COMET Core outcome domain: 36 Social burden																										
Satisfaction with quality of care	Study-specific	2●																						2● 1● D		
Decision regret	DRS	2●								2● W7I						1● CI						1● CI	1● IHD			
Satisfaction with goals of care	Study-specific	2●																						2●		

Outcome	OIM Abbreviation	Pre-intervention	FM or PC consult	MV withdraw decision	MV change, turn off	24 hours	48 hours	4 Days	5 Days	7 Days	8 Days	14 Days	15 Days	Between 7-14 days	Between 14-16 days	30 Days	Between 31-182 Days	42 Days	45 Days	60 Days	Between 60 -182 Days	90 Days	180 Days	ICU Death or discharge	Hospital discharge	365 Days
Satisfaction with symptom management	Study-specific	2●																						2●		
Satisfaction with communication and support	Study-specific	2●																						2●		
Satisfaction with patient management	Study-specific	2●																						2●		
Difficulty in managing family in day-to-day issues	Study-specific	2●																						2●		
Difficulty in managing family in end-of-life issues	Study-specific	2●																						2●		
Decision-making self-efficacy	FDMSS	1●								1● W7BA																
Medical Doctor satisfaction with the process	Not reported																							1●		
Decision conflict	DCS	1●										1● ID														
Clinician burn-out	MBI	1●																					1● IHD			
Job strain in staff	JSS																							1●		
Living situation at 6 months	Interview																						1●			

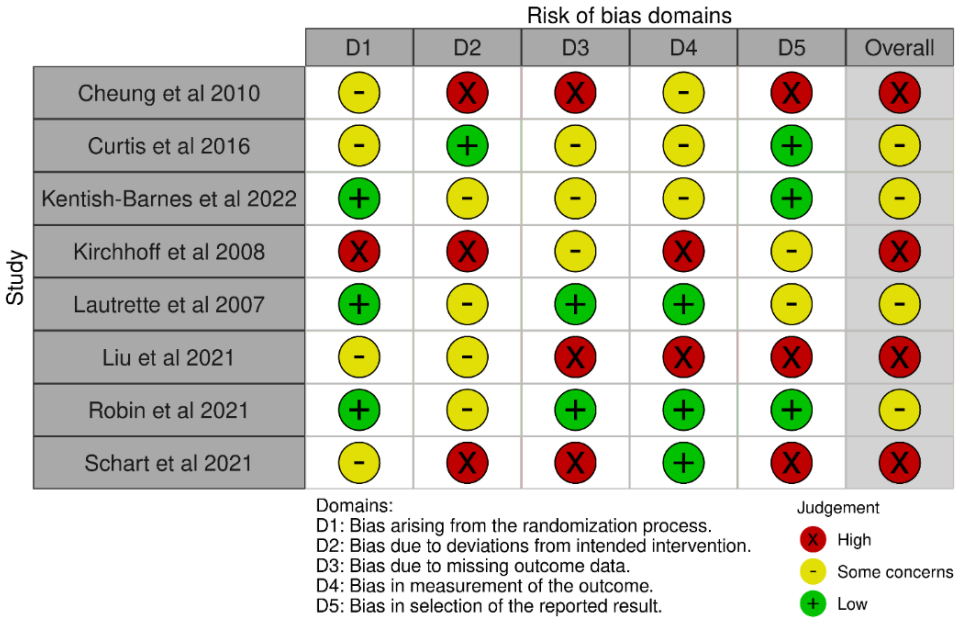
Appendix 16 Quality assessment MOMENT score

Author and Year	Primary outcome		Secondary outcomes		Do the authors explain the use of the outcomes they have selected?	Are methods used to enhance the quality of outcome measurement if appropriate?	Overall score
	Clearly stated?	Clearly defined so that another researcher would be able to reproduce?	Clearly stated?	Clearly defined?			
Braus et al 2016	Yes	Yes	Yes	No	No	No	3
Chen et al 2021	Yes	No	No	No	No	Yes	2
Cheung et al 2010	Yes	Yes	Yes	Yes	Yes	Yes	6
Cox et al 2018	No	No	No	No	Yes	Yes	2
Curtis et al 2016	Yes	Yes	Yes	Yes	Yes	Yes	6
Kaufer et al 2008	Yes	Yes	Yes	Yes	Yes	Yes	6
Kentish-Barnes et al 2022	Yes	Yes	No	No	Yes	No	3
Kirchhoff et al 2008	Yes	Yes	Yes	Yes	Yes	Yes	6
Lautrette et al 2007	No	Yes	No	No	Yes	No	2
Lichtenthal et al 2022	Yes	Yes	Yes	Yes	Yes	Yes	6
Liu et al 2022	Yes	Yes	Yes	Yes	No	Yes	5
Lustbader et al 2011	Yes	Yes	No	No	Yes	Yes	4
McDonagh et al 2004	No	No	No	No	No	No	0
O'Mahony et al 2010	Yes	Yes	No	No	No	No	2
Robert et al 2017	No	No	No	No	Yes	No	1
Robin et al 2021	Yes	Yes	Yes	Yes	Yes	Yes	6
Robley & Denton 2006	Yes	Yes	Yes	Yes	Yes	Yes	6
Schart et al 2021	No	No	No	No	No	No	0
Tabibian et al 2019	No	No	No	No	Yes	No	1

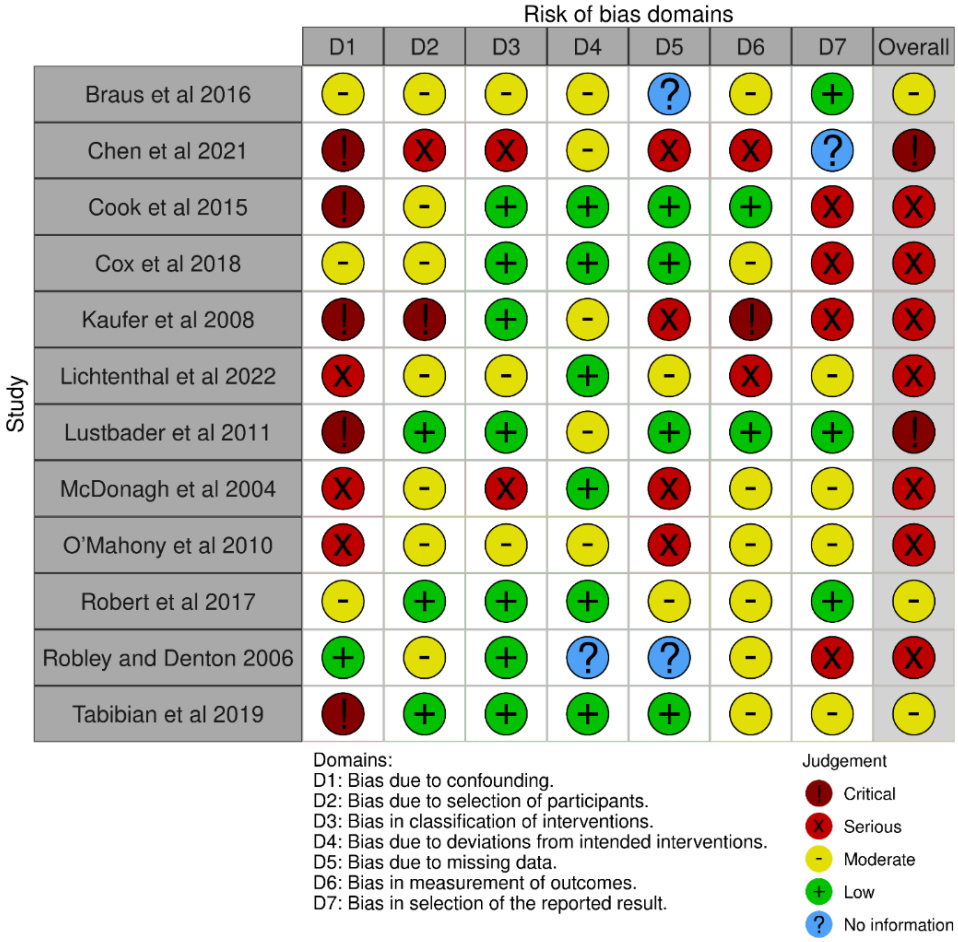
Appendix 17 CASP quality assessment

	Swinton et al 2017
Was there a clear statement of the aims of the research?	Yes
Is a qualitative methodology appropriate?	Yes
Was the research design appropriate to address the aims of the research?	Yes
Was the recruitment strategy appropriate to the aims of the research?	Yes
Was the data collected in a way that addressed the research issue?	Yes
Has the relationship between researcher and participants been adequately considered	Yes
Have ethical issues been taken into consideration?	Unclear
Was the data analysis sufficiently rigorous?	Yes
Is there a clear statement of findings?	Yes
How valuable is the research?	Page 198 - Family members and clinicians consider spirituality an important dimension of end-of-life care. Many people, whether self-reportedly spiritual, religious, both, or neither, regardless of remote or recent affinity, call forth a spiritual response when bearing witness to death. Soliciting and realising personal wishes at the end of life fosters spiritual care by inviting the expression of myriad forms of spirituality during the dying process in the ICU. Research provides a framework to explore spiritual aspects of the dying process, which families and clinicians, whether religious or not, appreciate in the context of the dying patient.

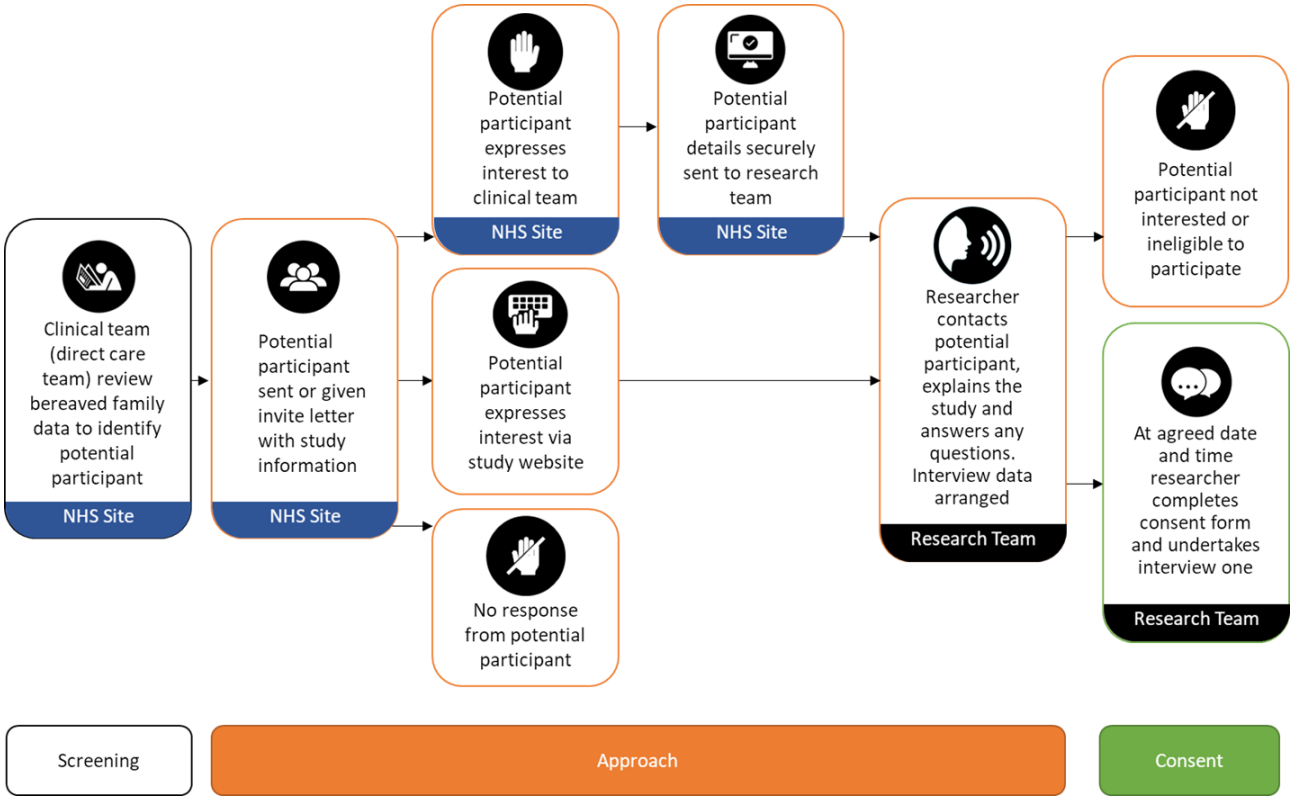
Appendix 18 Cochrane risk of bias tool



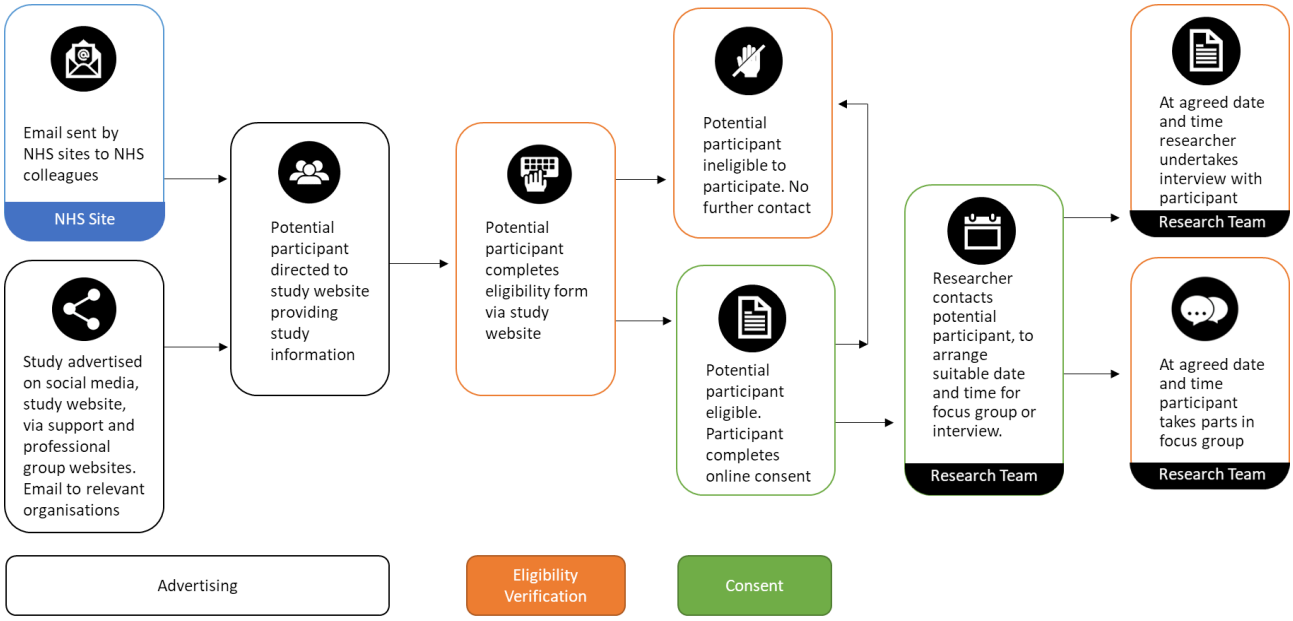
Appendix 19 ROBINS-I tool



Appendix 20 Stage Two NHS family members recruitment flow chart



Appendix 21 Stage Two Health professionals recruitment flow chart



Appendix 22 Stage Two participant booklet and consent form example

PEACE-COS

Person-centred outcome measures in End-of-life cAre in Critical carE (PEACE-COS)

Invitation

We are inviting healthcare professionals who have experience of end-of-life care within critical care (also known as intensive care or ICU) in the past two years to take part in a research study led by the University of Hertfordshire. The study aims to find out what matters to patients and their families in end-of-life care to help develop a core outcome set.

Before you decide whether or not to participate it is important that you understand why the research is being done, what it will involve for you and how we will use the information we collect from you.

Please take time to read the following information carefully. You may discuss it with others if you wish. A blank page at the end of this information leaflet is provided for you to make any notes or list any questions that you might have.

Please ask us if there is anything that is not clear, you would like more information or the information in an alternative format. A member of our research team will go through the information sheet with you and answer any questions you have.

Thank you for taking the time to read this information and considering taking part in the PEACE-COS study.

Why is this study needed?

We are interested in defining person-centred outcomes in end-of-life care in critical care. This study is using a four stage process. This interview study is the second stage of the PEACE-COS study where we want to know what matters most to healthcare professionals.

At the moment, researchers use a range of different measures ('outcomes') to evaluate end-of-life care. For example, research may look at how long patients stayed in critical care or what treatment a patient received. We don't understand which outcomes matter most to the person at the centre of the care (the patient), their family or healthcare professionals involved in their care.

By finding out which outcomes matter most we can make recommendations to develop person-centred outcome measures for future research studies that accurately reflect what matters most to all involved, as well as improving quality of care.

The outcomes identified in this stage of the study will inform stage three where people will be invited to rate the importance of each outcome.



Why have I been invited?

You have been invited to participate in this study because within the past two years you have professional experience of end-of-life care in critical care. We want to understand what is important in end-of-life care from your experience. To be eligible for the study, there are some conditions that you must meet. These include being:

- aged 18 years or over
- a healthcare professional with direct experience of an adult (>18 years) receiving end-of-life care in critical care within less than two years and be able to remember the end-of-life care process
- able to participate in one in person, telephone or online interview.

Do I have to take part?

No. It is up to you to decide whether or not to take part. This information sheet will describe the research study and help you decide. You can also discuss taking part with your friends and family.

If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to not take part in this study or to withdraw at any time.

Organisation and Funding

The research is being organised and run by the University of Hertfordshire. The study is led by Sally Humphreys, a PhD research student at the University of Hertfordshire and NHS critical care research nurse. She is supervised by Professor Natalie Pattison and Dr Rosemary Godbold at the University of Hertfordshire and Dr Nazir Lone at the University of Edinburgh, all of whom have extensive experience in conducting research.

The day-to-day conduct of the study will be managed by Sally Humphreys and the study will contribute towards Sally's PhD thesis.

Expenses & Payments

None of the study team are paid for you participating in this study.

You will not be paid for participating in this study. Participation is entirely voluntary.



What will happen if I

1. We ask you to complete the online form confirming you have read the participant information sheet and meet the study criteria.



2. On the same form we will ask you to consent to participating in the study. You will be invited to answer five mandatory demographic, accessibility and contact questions. You can save this data.



3. We will contact you to arrange a suitable interview time. Your interview will be conducted in person by telephone, or online via TEAMS or Zoom.



4. We will ask you to tell us in your own words about your experience of end-of-life care. We will explore which outcomes you think are important. The interview will last up to an hour.



5. We will take notes and make an audio recording of your interview. Your interview will be written up (transcribed) and anonymised. The recording will be deleted.



take part in the study?

6. The results will be written up and published in professional journals and Sally's PhD thesis. If requested we can send you a copy of the overall study results.



7. If you agree at the end of the interview, we will phone you the following week to ensure that you are OK.



8. Your interview will last up to an hour maximum and you can stop or take a break during either interview at any time without giving a reason.



9. Your involvement in the study will finish following your interview. We will write up the results and may use direct quotes in publications.



If we discover a serious concern, the interviewer will stop the interview immediately. Information may be shared in line with the law and local safeguarding procedures.



Possible benefits

Participating in this study may not help you directly but will allow us to develop a clearer understanding about what end-of-life outcomes truly matter to healthcare professionals, which will improve future research together with patient and family care.

Possible disadvantages

We understand that thinking about and talking about end-of-life care and the death of your loved one is likely to be emotional or stressful experience for you. It can make you feel upset, angry, sad and cry. These powerful feeling can occur before, during or after the interview.



Each interview will be conducted in a sensitive manner by a researcher who has appropriate training to minimise the risk of painful memories, or you becoming distressed by talking about your experience. If you do feel upset or distressed at any point, we can pause the interview, take a break or stop altogether depending on your wishes. There are no right or wrong answers to the questions and you do not have to answer any question that you do not want to.

Support Services

If you wish, we can provide you with a list of bereavement support services. This is also freely available on the study website.

Www.peacecos.com

What if there is a problem?



If you have any concerns about any aspect of the study then you can speak with the researchers in the first instance who will do their best to answer your questions or concerns.



If you have any complaints or concerns about any aspect of the way you have been approached or treated during this study, you can also write to the University's Secretary and Registrar at the following address:

Sharon Harrison-Barker
Secretary and Registrar, University of Hertfordshire,
College Lane, Hatfield, Hertfordshire, AL10 9AB.

Email: s.harrison-barker@herts.ac.uk

How we use your data



In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write.

We will need to use information from you for this research project. This information will include your name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all your information about you safe and secure.

Once we have finished the study, we will keep some of the data so that we can check the results. We will write our report in a way that no-one can work out that you took part in the study.

What are my choices in how my information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study in the secure University data systems. Your data will be anonymous, meaning you will not be identified.



More information

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking a member of the research team
- by sending an email to dataprotection@herts.ac.uk

Who has reviewed the study?

To protect your interests this study has been looked at by an independent group of people, called a Research Ethics Committee (REC). All the study information has been reviewed and given a favourable opinion by North East – Tyne & Wear South REC and the Health Research Authority (HRA). It has also been reviewed by the University of Hertfordshire Health, Science, Engineering and Technology Ethics Committee with Delegated Authority.



Study Results

The results of the study will be written up and published in a professional journal and will form part of Sally Humphreys' PhD thesis. The results will also be presented at conferences. The data will be anonymous, meaning none of the people involved in the study will be identified in any report or publication.

If you would like a copy of the overall study results, or publication, please let a member of the research team know.

Our Contacts

You are encouraged to ask any questions you wish, before during or after the study. If you have any questions or require further information about the study please contact one of the following people:

Lead Researcher

Sally Humphreys Email: peace-cos@herts.ac.uk

Primary Supervisor

Natalie Pattison Email: n.pattison@herts.ac.uk

The information provided here is the same as that found on the study web pages which you can refer to www.peacecos.com

Independent Contact:

If you would like to discuss this study with someone independent of the study, please contact **Melanie Handley**

E-mail: m.j.handley@herts.ac.uk

Phone: 01707 289375

Consent Form

This is an example of the consent form for your reference.

Protocol Reference: Participant ID:

Name of Researcher: Date:

Consent will be captured using an online form or digitally recorded. The researcher will ask you all the questions below. You will be asked to say "Yes I agree" or "No I disagree" to indicate your response. The researcher will initial the boxes. Once all the questions have been asked, the researcher will ask you to state your full name and the date.

1. I confirm that I have read and understand the information sheet dated (version) for the PEACE-COS study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without affecting my legal rights.
3. I understand that relevant sections of my data collected during the study may be looked at by individuals from the Sponsor of the study (University of Hertfordshire) or from regulatory authorities. I give permission for these individuals to have access to my data (which may include them being sent a copy of this Consent Form).

Consent Form

4. I understand that my interview will be audio-recorded and have been informed of how my recording will be transmitted and transcribed.
5. I understand that data collected about me during the study will be converted to anonymised data.
6. I agree to anonymised extracts from my interview being used in reports and publications of the study findings. No Yes
7. I agree to my anonymized data being used in future studies. No Yes
8. I understand that if I disclose anything which in view of the researcher concerns a serious breach of professional conduct, criminal activity, whistleblowing or safeguarding, then it will be disclosed in accordance with the law and local safeguarding procedures.
9. I agree to take part in the above study.
10. I agree for my personal details to be retained to receive a results summary. No Yes

Name of Participant: Date:

Notes & Questions

This page has been left blank for your use as you wish

PEACE-COS

Thank you for taking the time to read this information and to consider participating in this study.

Appendix 23 Stage Two poster example



Appendix 24 Stage Two social media assets

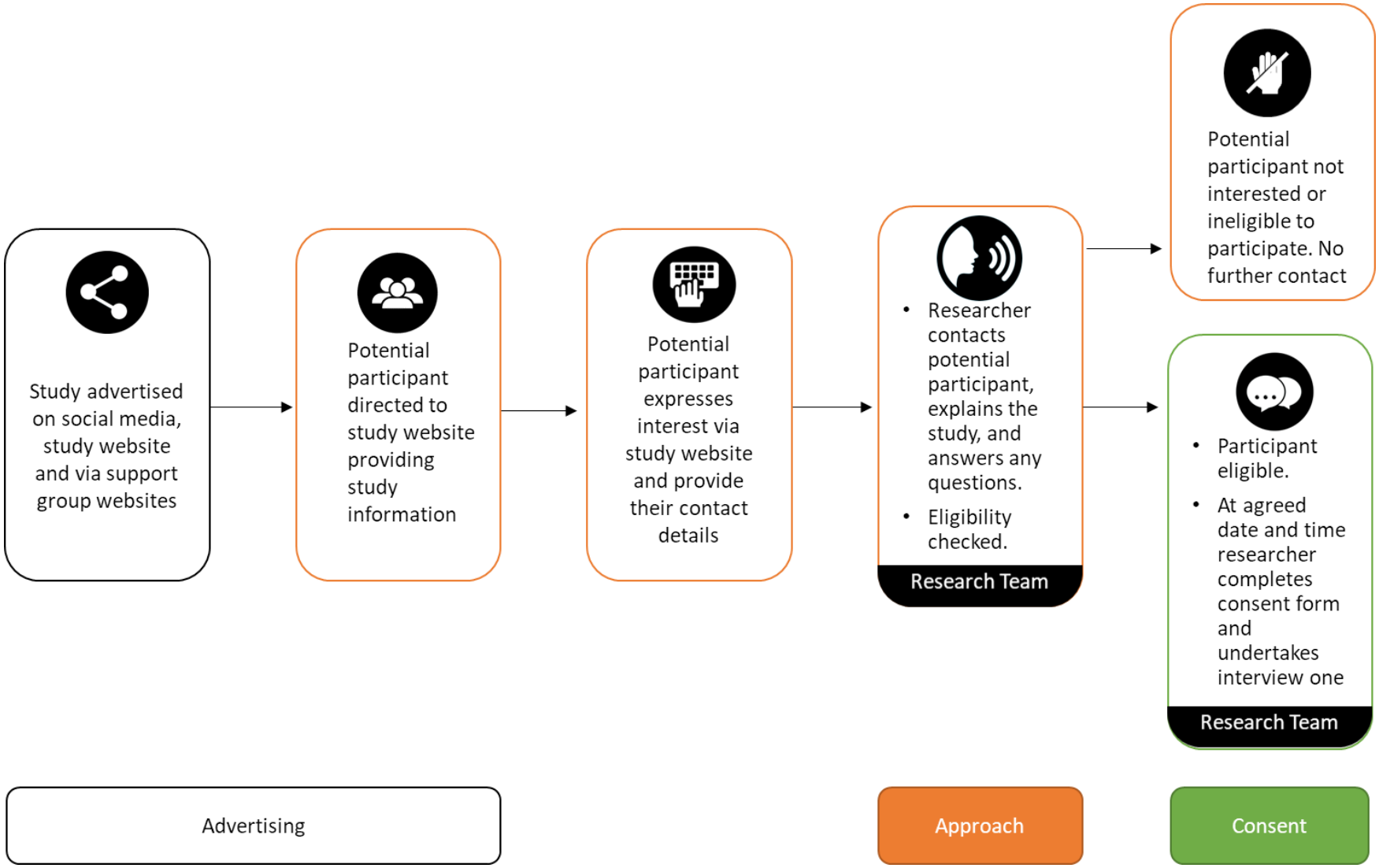




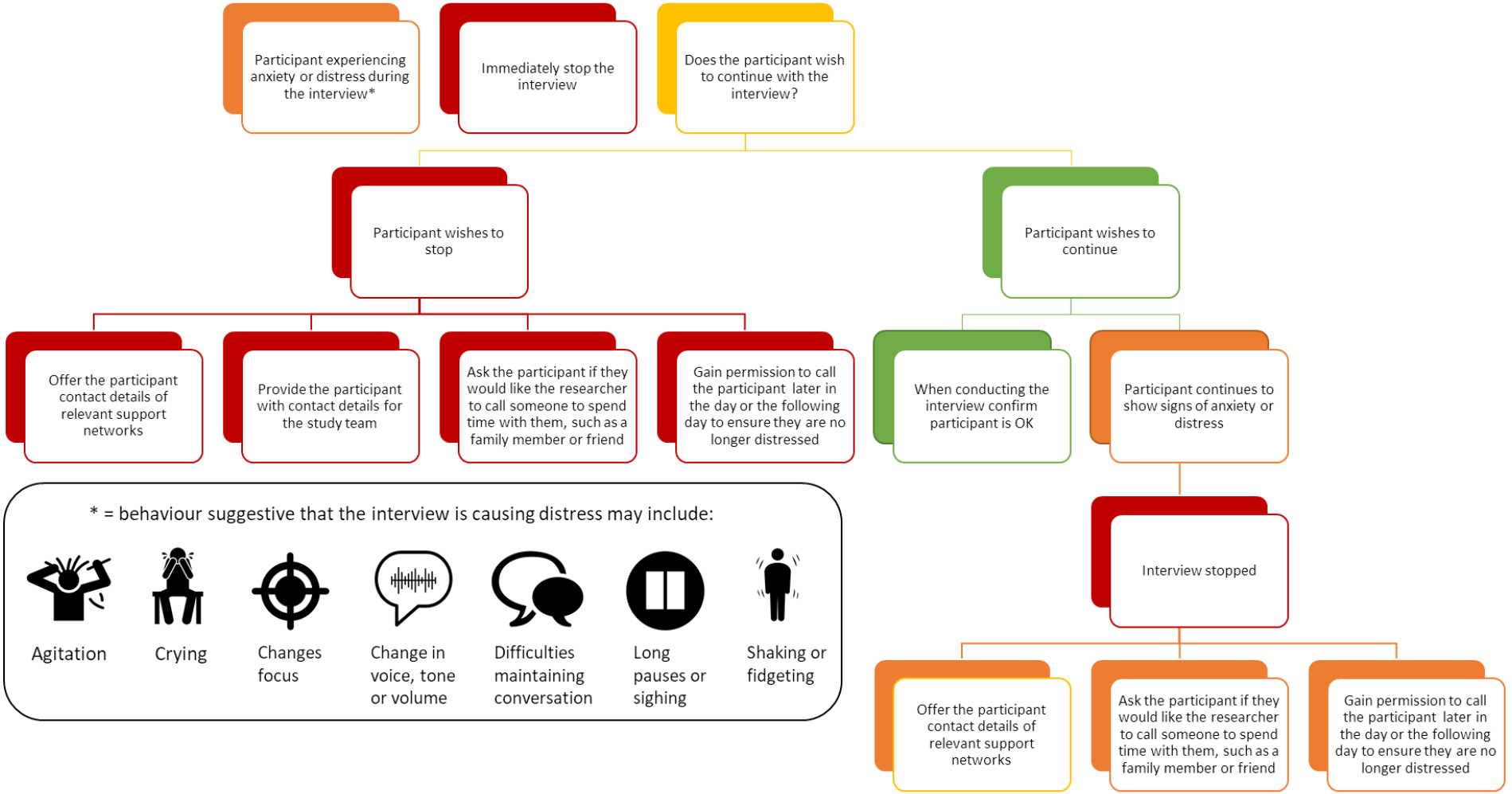




Appendix 25 Stage Two Non-NHS family member recruitment flow chart

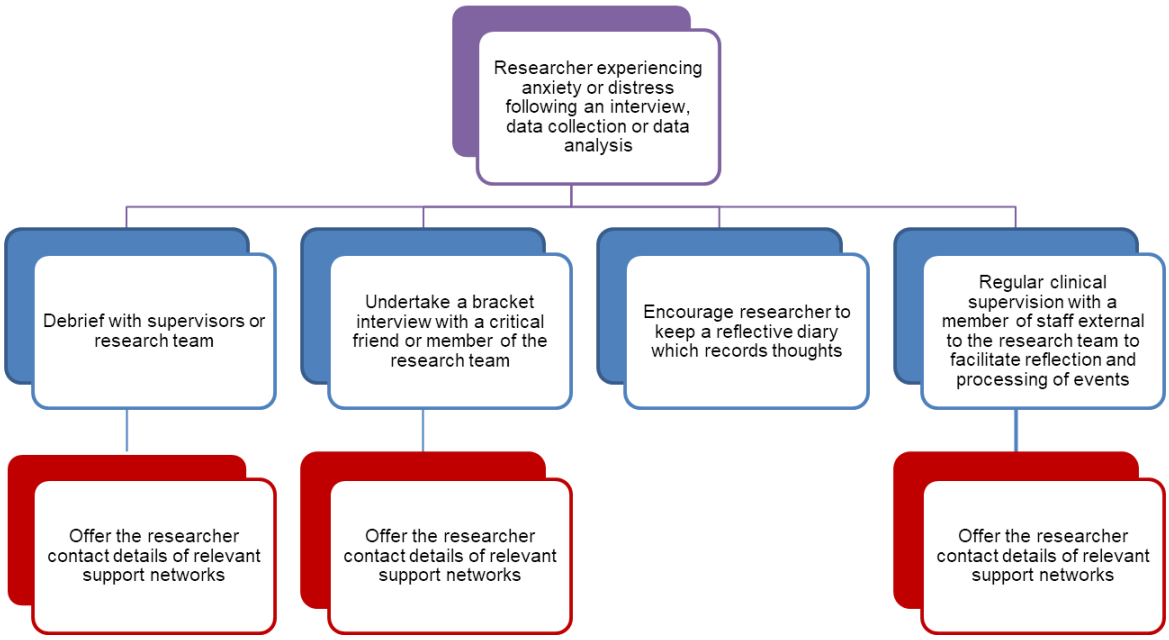


Appendix 26 Management of distressed participants protocol



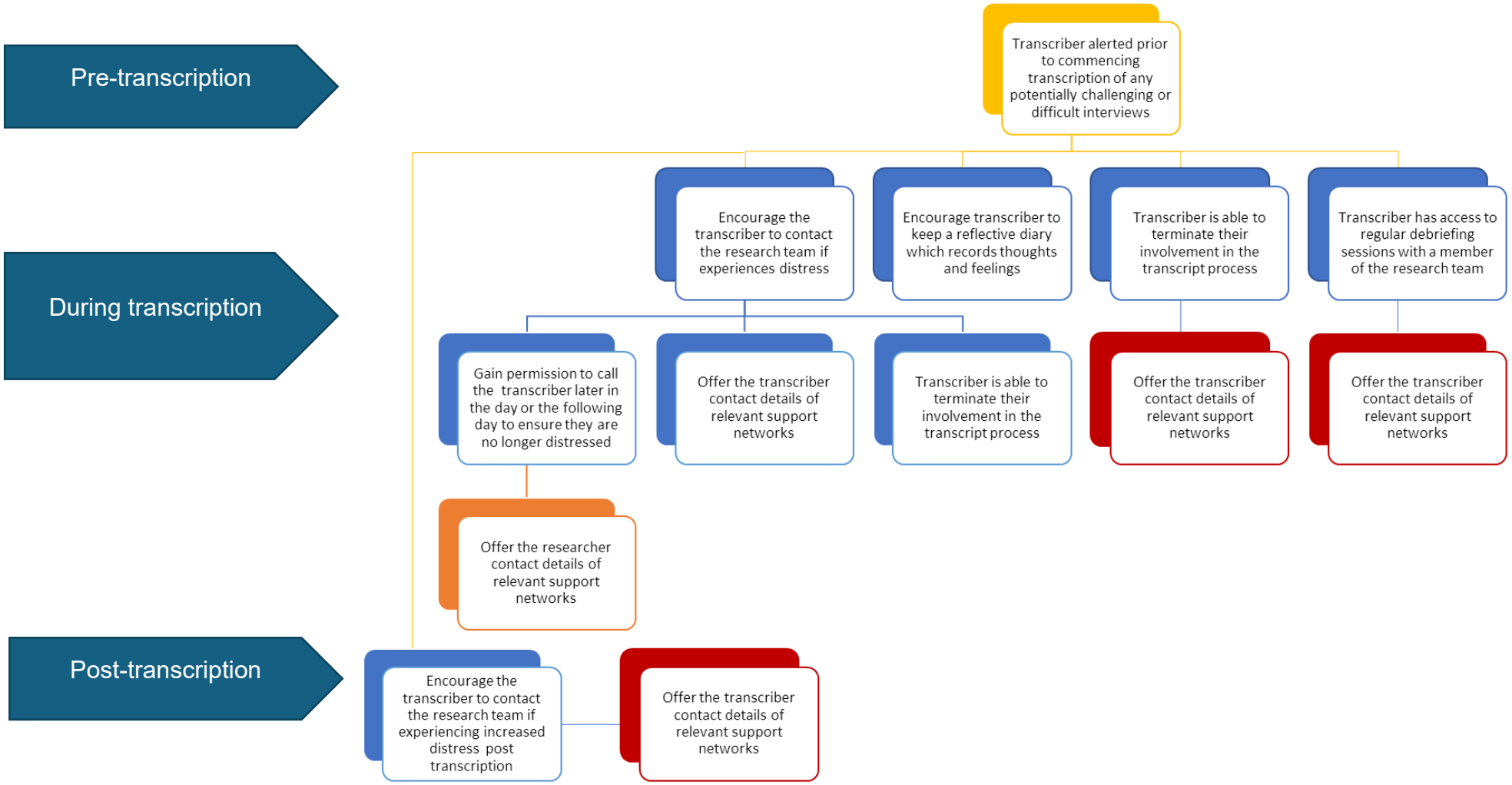
Adapted from: Dempsey, L., Dowling, M., Larkin, P., & Murphy, K. (2016). Sensitive Interviewing in Qualitative Research. *Research in Nursing and Health*, *39*(6), 480–490. https://doi.org/10.1002/nur.21743

Appendix 27 Stage Two researcher safety protocol



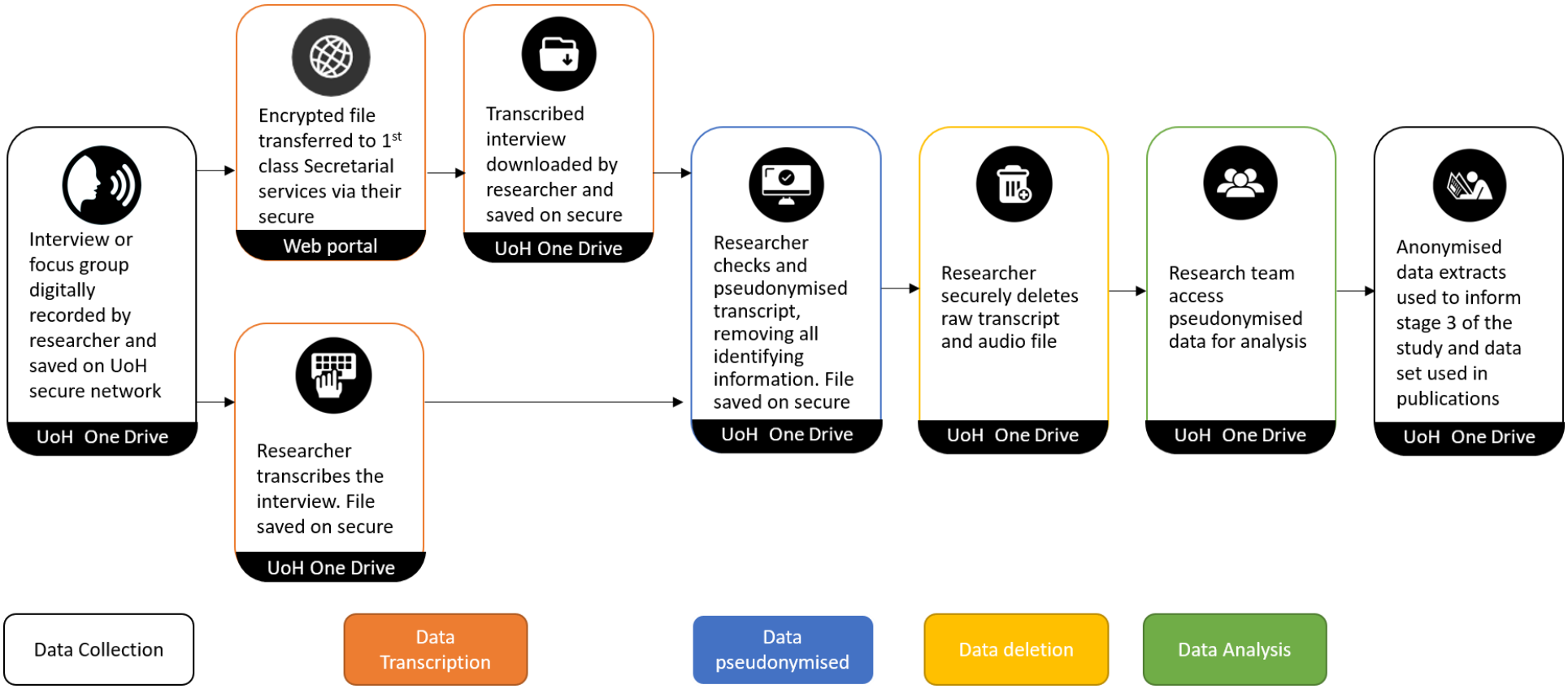
Adapted from: Dempsey, L., Dowling, M., Larkin, P., & Murphy, K. (2016). Sensitive Interviewing in Qualitative Research. *Research in Nursing and Health*, *39*(6), 480–490. https://doi.org/10.1002/nur.21743

Appendix 28 Transcriber distress protocol



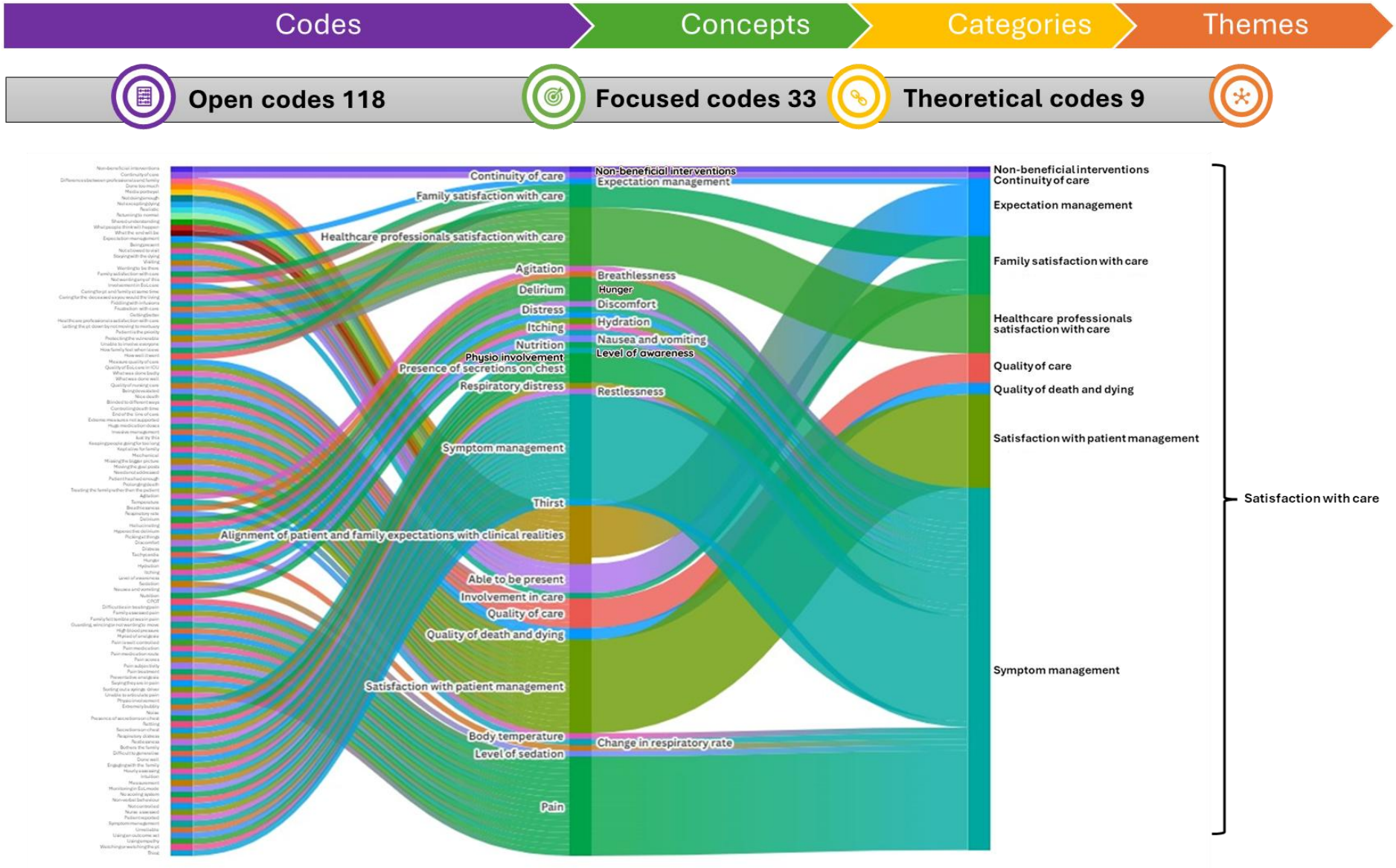
Adapted from: Mccosker, H., Barnard, A., & Gerber, R. (2001). Undertaking Sensitive Research: Issues and Strategies for Meeting the Safety Needs of All Participants. *Forum: Qualitative Social Research*, *2*(1). https://doi.org/10.17169/fqs-2.1.983

Appendix 29 Data information flow protocol

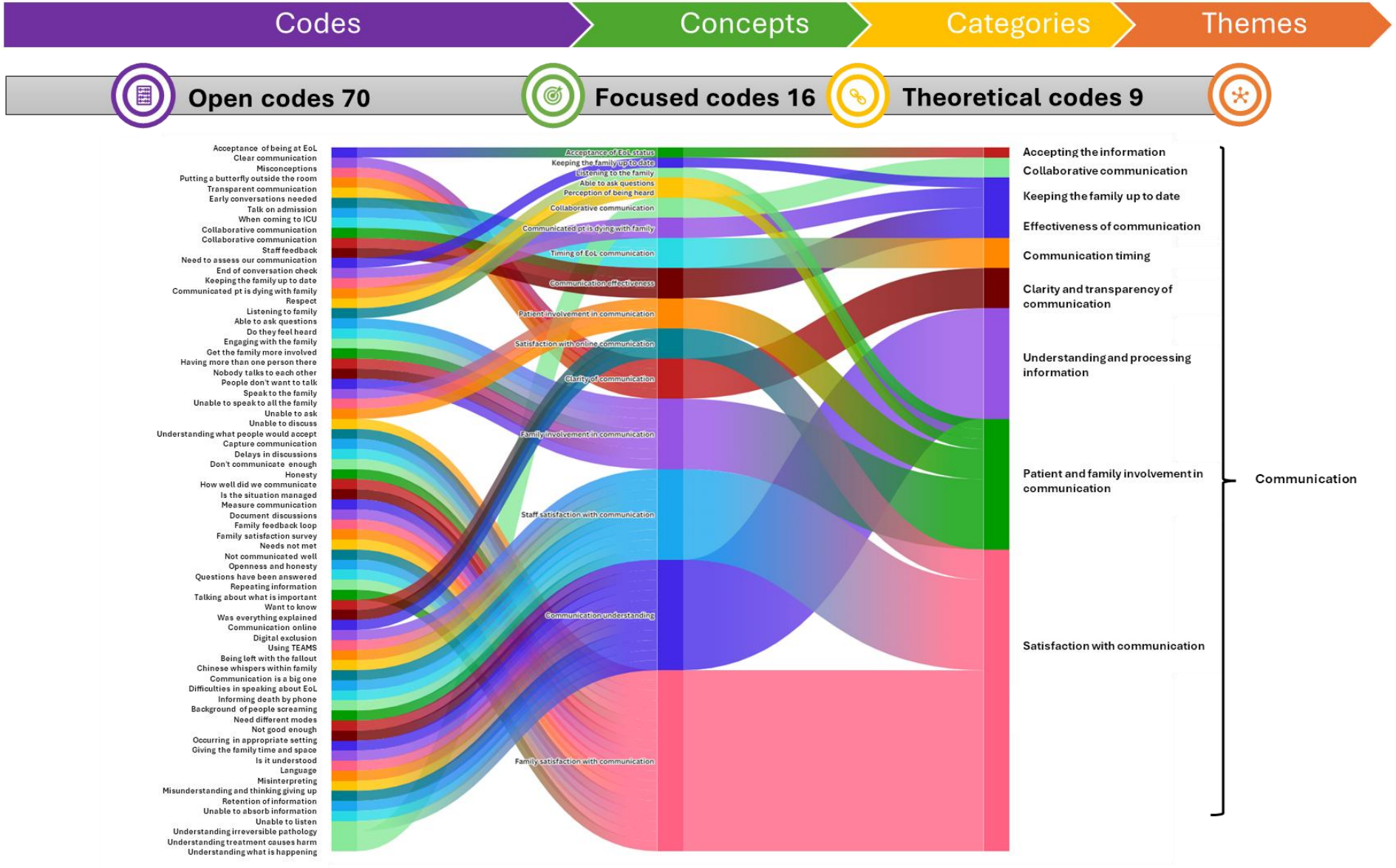


1st Class Secretarial provides professional digital audio transcription services for academic research to universities. When uploading the files, they are transferred over a 256-bit SSL-encrypted channel which ensure that the transfer is secure. The extranet itself resides on a dedicated server to which only 1st Class Secretarial have access. The server is also security patched to the latest standards and holds Cyber Essentials accreditation (IASME-CE-021159) adhering to the principles of GDPR. Copies of all data held by 1st Class Secretarial will be deleted in accordance with their privacy policy. No information is transferred outside the European Economic Area (EEA).

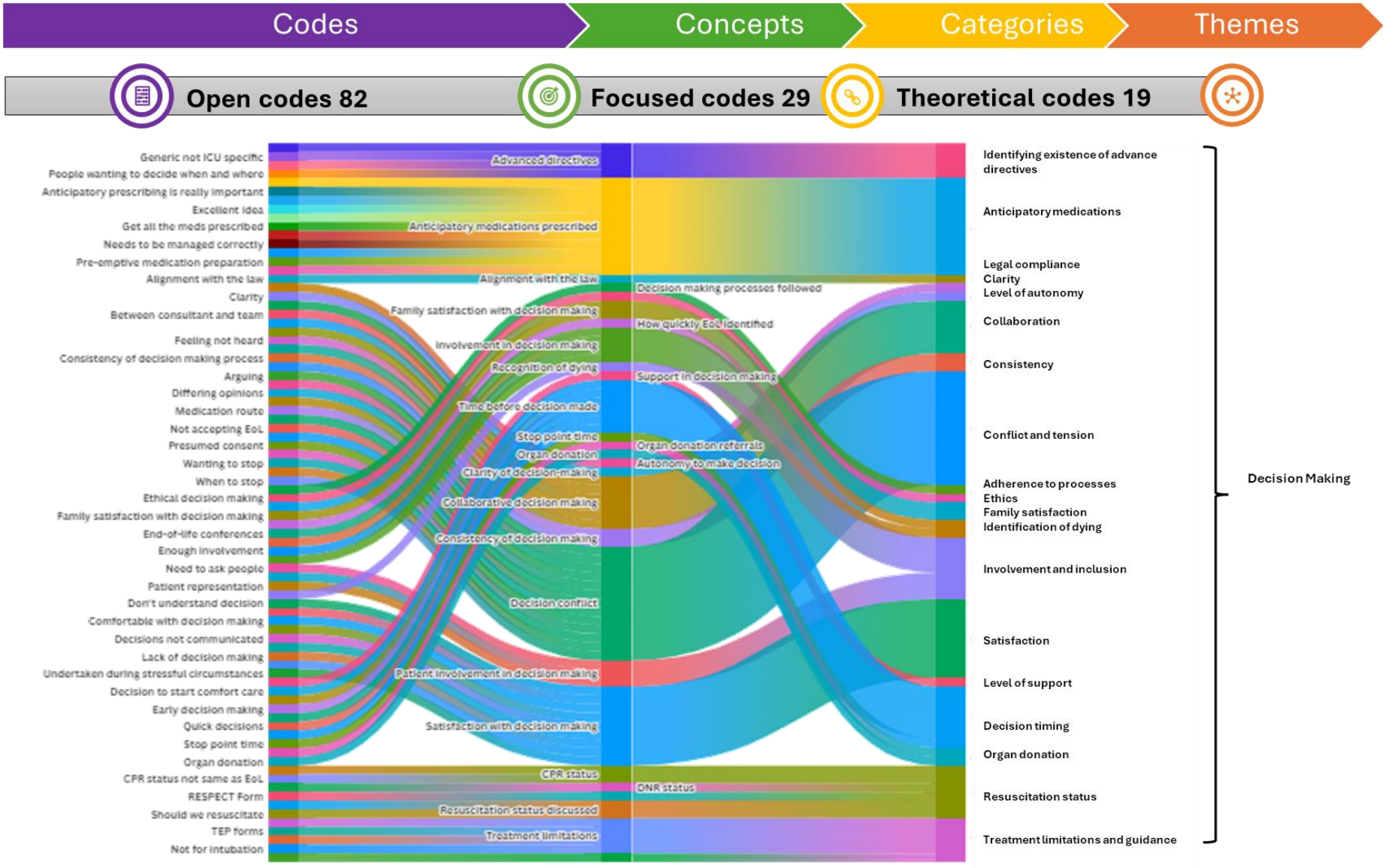
Appendix 30 Theme care satisfaction coding



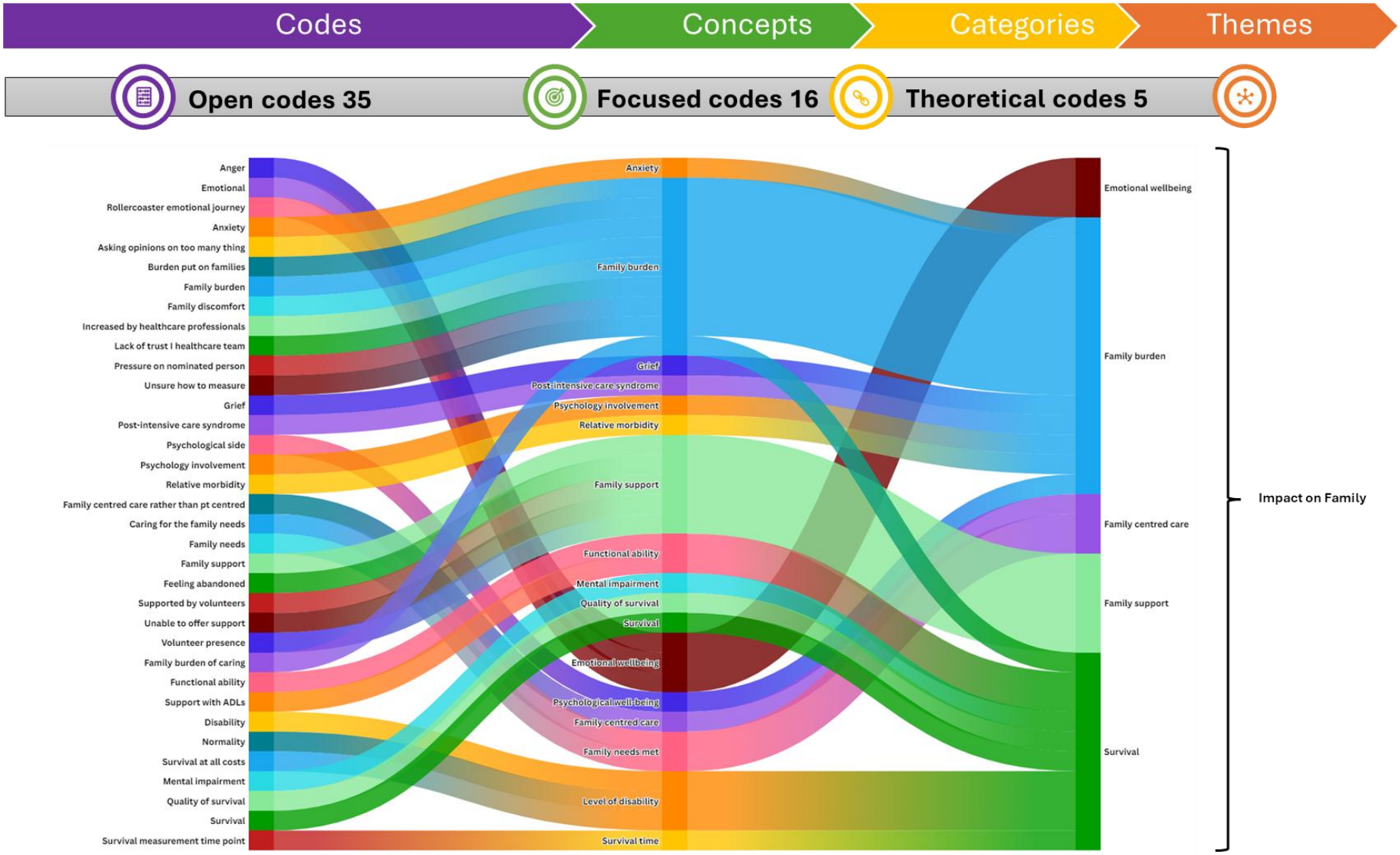
Appendix 31 Theme communication coding



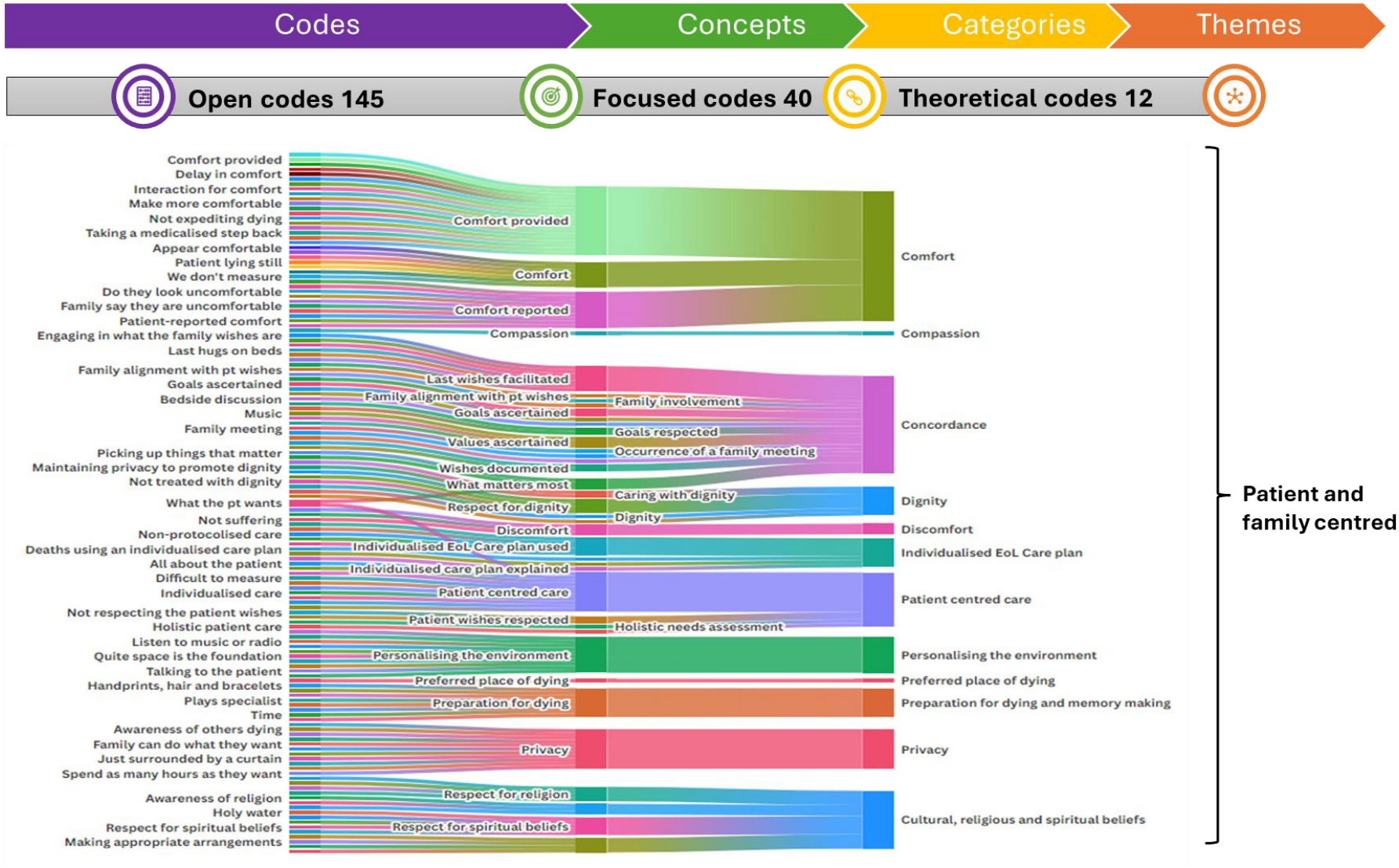
Appendix 32 Theme decision-making coding



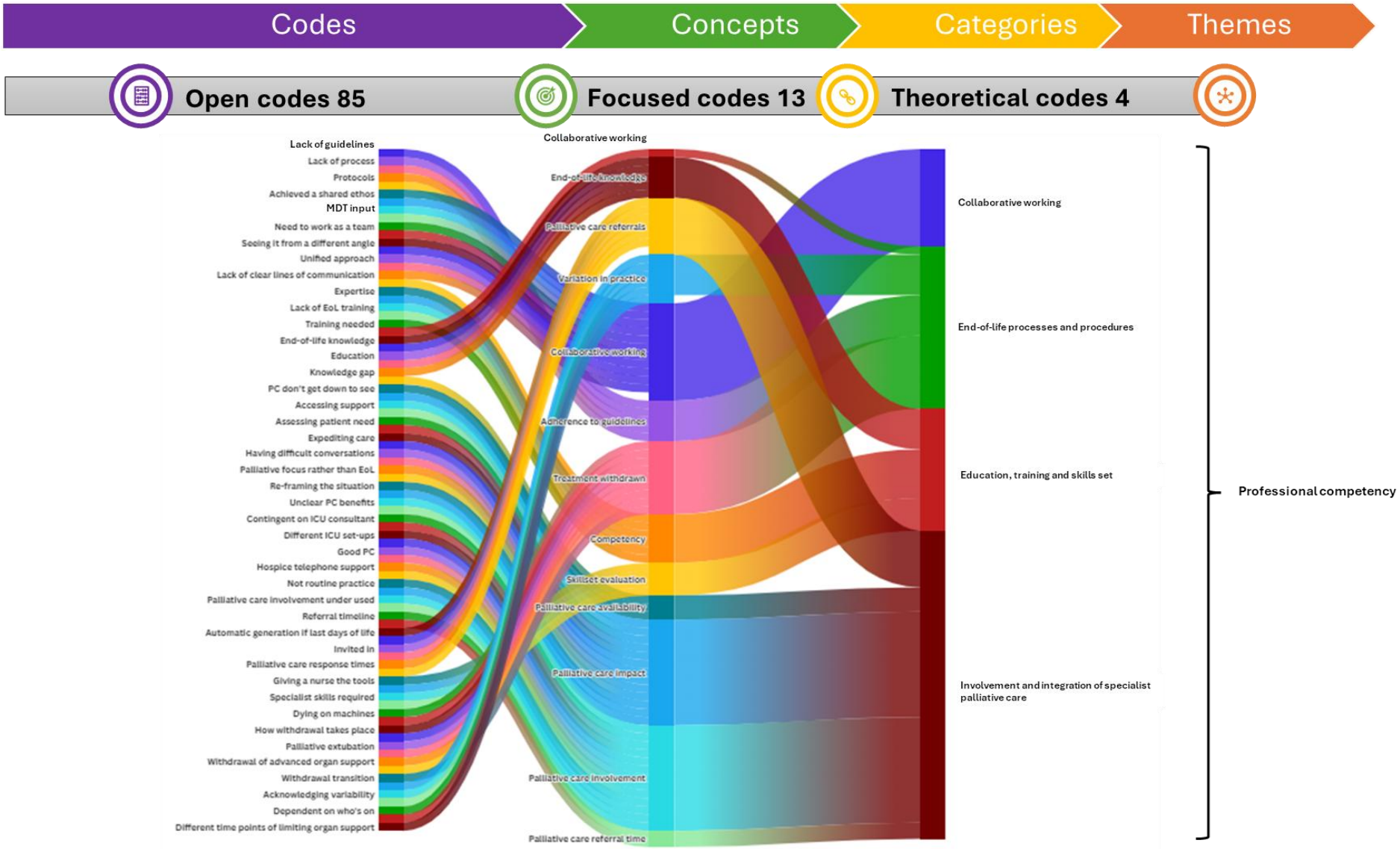
Appendix 33 Theme impact on family coding



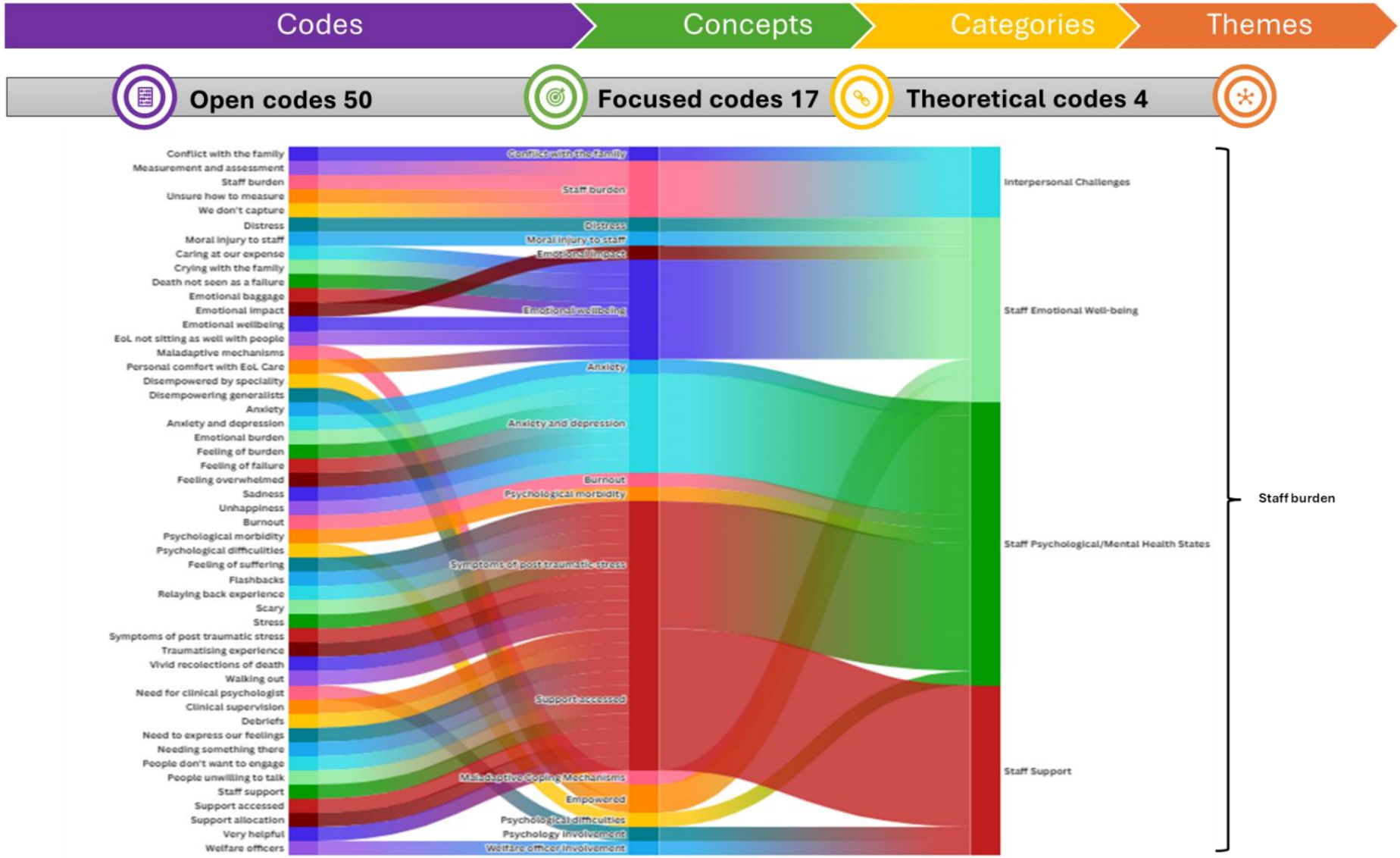
Appendix 34 Theme patient and family centred coding



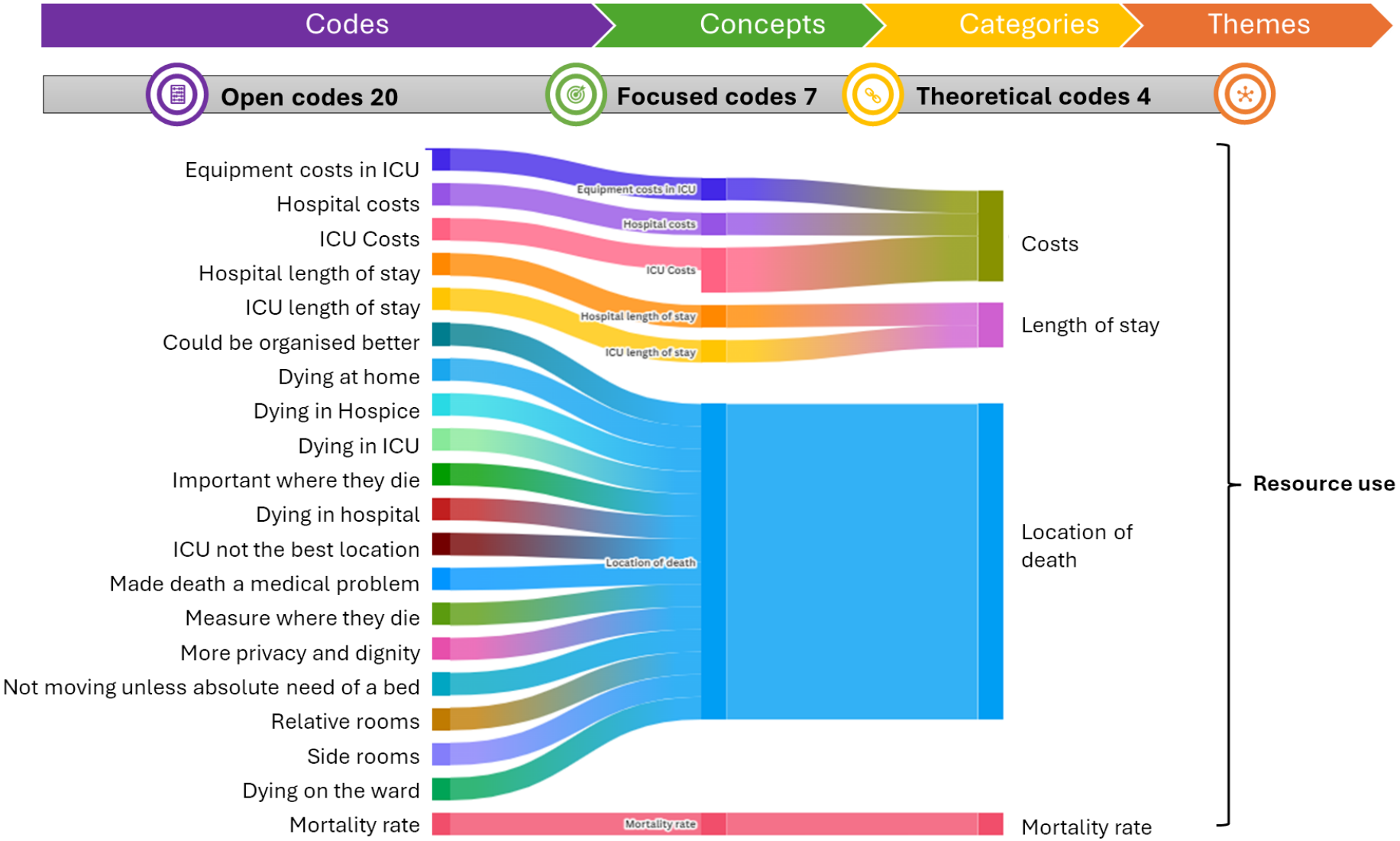
Appendix 35 Theme professional competency coding



Appendix 36 Theme staff burden coding



Appendix 37 Theme resource use coding



Appendix 38 Theme care satisfaction supplementary outcome quotes

Non-beneficial interventions –	Number or percentage of patients who receive no-beneficial interventions or procedures eg antibiotics,
S2I06	*"…I don't think they should be. I don't. I don't think. I think there should be more thought into what exactly that what is beneficial and what isn't. Is taking a patient down for a CT scan really necessary when you've already decided to probably not going to survive. Yeah, I think I think there are cases where less is more in some cases, and what do we actually need to do to keep the patient comfortable? And what do we? What is not, no longer relevant?*
S2I07	*"…I think you should allow peace and why are we pumping them through with medications and, filtering them and, starting new treatments just because it's nighttime?"*
Continuity of care – Satisfaction with the level of continuity of care provided	
S2FG01	*"…And having a rotational system where you have a different consultant come in every week – which is usually how intensive care has been set up, in my experience – you're always going to have that, and it does bring positives but does bring those negatives as well and can be quite confusing and that continuity of care can be really helpful."*
Expectation management	- How patient and family expectations align with the reality of care, treatment and the possible outcomes
S2I03	*"…it's that you've done too much and half the time it's not done enough and umm, and, and, sort of meeting those expectations, expectations or correcting those expectations."*
S2I06	*"…I think the expectations of lay people is very different from those of us who've worked in the setting for a long time, and I think that is media related. You know, you see somebody on the telly having CPR and sitting up 10 minutes later, having a cup of tea, and that's just not real and I think. Expectations are they going to intensive care. They're gonna do all these amazing things and make them better and they'll come home."*
S2I13	*"…So having information around what to expect for some was very important. What to expect, who will be there and yeah, can my family be present with me? Yeah. Can my pets come?"*
Able to be present – Family able to be present during end-of-life	
S2I08	*"…their loved ones would be with them when they passed away, rather than potentially coming into the hospital and their loved one has already passed away."*

S2I09	*"…To keep them away because it could have like long lasting effects."*
S2I13	*"…So giving them time to stay has always been the important thing and then providing comfortable facilities. It's definitely up on the list.."*
Family satisfaction with care – Family satisfaction with the EoL care provided	
S2I05	*"…I suppose it's how the family feel when they leave their relative or the ward, or the environment that they were in for the last time."*
S2I06	*"…I don't know the answer, but yeah, I think I think it's very important to speak. To seek opinions of people who've experienced it from their side."*
S2I07	*"…I think it'd be really difficult to get information from families understandably. But I think it would be helpful.."*
Involvement in care – Family and or patient involvement	
S2I08	*"…We try and involve them and, obviously, we're very open and honest with our conversation."*
Healthcare professional satisfaction with care – Healthcare professionals' satisfaction with care	
S2I07	*"…I think it'd be really helpful professionally from nurses and doctors … And thoughts and feelings of how well do you think this went or how well do you do they think this went."*
S2I09	*"…I do often find, like myself, feeling quite frustrated erm with my unit and how we do end-of-life care."*
S2FG01	*"…I think the other thing that [Name redacted] alluded to there was the importance of how the staff feel providing the palliative and end-of-life care."*
Quality of care – Satisfaction with the quality of care	
S2I03	*"…We're used to routinely ask every patient that died, not just intensive care patients about the quality of care and this was run off the palliative care team much more so than the intensive care team, umm, but would ask every patient's family that died and, we would get the feedback from those, umm, conversations back into the intensive care patients…"*
S2I06	*"…How different people's perceptions of the quality of end-of-life care was in intensive care. Yes, I think it's very important."*

S2I08	*"…You wouldn't get end-of-life care on a ward that would just be one-to-one care. So, it's having that one person, you know, to provide, you know, like, we provide so much care to patients. You know, regular mouth care, hair being washed, eyes being, you know, wiped. And you wouldn't get that somewhere else. So, the care is, you know, is high standard of quality care."*

Quality of death and dying –	Extent to which a person's physical, emotional, social, and spiritual needs are met, aiming to ensure dignity, comfort, and peace during the dying process.
S2I105	*"…They passed away peacefully in a controlled manner. Ideally, if there was any decisions that their particular individual had requested beforehand, we were able to carry it out to the best of our ability …It can be away from the clinical environment as much as we can and do whatever's best for that particular patient to make it calm and relaxed. Dignified. Yeah, with their close loved ones around them. And I would say that was a that was a good one."*

Satisfaction with patient management – Staff satisfaction with patient management

S2I06	*"…Yes, I think I think one of the biggest things I would change, I think often say often on occasion there have been situations where patients are being kept alive with want of a better word until relatives can arrive to say their goodbyes."*
S2I13	*"…The general management maybe something like obviously intubated than suctioning and the rest of them will be done but with families present, sometimes I find that the the die how the dying is the dying process is managed in ICU can be more invasive and aggressive compared with if the patient was a ward and was dying peacefully. So the the dying process in itself can be managed in a different way."*
S2FG05	*"…when you're totally reliant on another service and you don't have all these people that are switched on, with no disrespect to my intensive care colleagues, because some of them are some of the finest clinicians I've ever worked with or ever met, but at the other end of the spectrum you have some that actually are blinded to the fact that there might be, not necessarily better ways, but maybe different ways of doing things."*

Delirium –	Number or percentage of patients with symptoms of delirium eg uncontrolled spontaneous movements, agitation, restlessness
S2I07	*"…Because you can get terminal agitation and things, can't you, if they're, they're doing things like that, it's not. I don't know if it's bothering the patient because they can't tell me but it definitely bothers the family."*
S2I09	*"…Whereas if they're like restless, agitated, like what, what it makes you kind of see like what can I be doing differently to help this person? So I think we're measuring it, it can then like change like how we're gonna make them more comfortable, like can like give us pointers on how to better keep them comfortable."*

Discomfort – Patient's level of discomfort	
S2FG08	*"…And one of the key criteria which we have in our ICU is to stop all monitoring, because any discomfort, any kind of distraction to the patient – the monitors bleeping on the side – it's just a distraction to the nurses and to the families."*
S2I09	*"…Any symptoms like discomfort? I can't really think of anything off the top of my head but pain, nausea, agitation, excessive secretions. I can't really think of anything else."*
Distress – Patient's level of distress	
S2FG08	*"…So there would be a pain score system, we could look at the respiratory rate and how the work of breathing the patient from a respiratory point of view, we can look at signs of, you know, distress in a patient which could be tachycardia, sweating, difficulty in breathing, so those kinds of things."*
S2I03	*"…You're just looking at essentially external signs of distress, which as we all know, are very unreliable."*
Hunger, Hydration and Nutrition - Symptoms of hunger, and hydration	
S2I03	*"…It's various symptoms, nausea, itching. [inaudible]. Hunger. It's thirst, things, things like sort of basic physical symptoms"*
S2FG05	*"..If the patient is conscious the pain, secretions, things that you can actually have a scale there or you can measure management of those symptoms: if the patient was fed, if the patient was hungry, temperature, something like the comfort, the clinical things that we have to measure comfort."*
S2FG07	*"…Have you talked about nutrition and hydration?"*
Physio Involvement – Number or percentage of physiotherapists involved in the patient's care	
S2I05	*"…So yes, usually we get the physios involved to try and assist them and as much as we can through the process, knowing that we're on a bit of a losing battle.*
Level of awareness – Patient's level of awareness	
S2I03	*"…Every now and again there's a little bit of a resurgence of talk about whether we should be, you know, anaesthetising people towards the end of their life or very heavily sedating them for their dignity and for the benefit of the the family."*
S2I09	*"…I think we kind of measure it on like level of awareness. But I'm not sure at the end-of-life whether we document it the same. I mean we should do, but I'm not sure whether that's done."*

Symptom management – Satisfaction with symptom management	
S2I03	*"…I'd say it's generally well handled, but there are symptoms which are not well controlled towards the end-of-life."*
S2I06	*"…I think with any symptom control stuff, you just have to ask the patient that's if if, they're able to communicate. If they're not able to communicate, then there's an element of guesswork. I suppose."*
S2FG01	*"..And so I think there is something in looking at, could we use an outcome set that takes into consideration the nurses' and the families' opinions on how symptom managed the patient is?"*
Pain – Level of pain	
S2I04	*"…Have we documented an assessment of the patients pain? Nobody in hospital should be uncomfortable and distressed it doesen't matter, you don't have to be dying before we treat your pain. It like lets treat pain, that's what you have."*
S2I13	*"…Patient, obviously all of us would not want to be in pain or have uncontrolled symptoms, so that would be some of the things that I would say are priority."*
S2FG08	*"…And family felt very awful, you know, when your loved one is there in pain and there are issues in implementing that care."*
Presence of secretions – Number or percentage of patients who experience respiratory secretions	
S2I01	*"…This patient is on having any secretions or producing or is having, what is that struggling for? Or anything he's moving around. He was making noise. Or how is it's all that thing this is the measuring."*
S2I05	*"…But things like secretions on the chest, you can hear it, so you you deal with it, it's quiet again."*
S2I06	*"…if you look at symptoms like when people get a lot of secretions towards the end-of-life. For some people it's a real problem and, they really don't like it and they find it really uncomfortable and others don't mind at all. Doesn't bother them."*
Respiratory distress – Number or percentage of patient who experience respiratory distress eg breathlessness	
S2I04	*"…Breathlessness is really challenging and it, as I say, I don't quite know how you measure that objectively, but the kind of taking some one particularly off off off high flow or NIV. That sensation of breathlessness can be really troubling. But measuring is really difficult because I think you can have someone with a respiratory rate of 40 who's really comfortable and*

	somebody's got respiratory rate of 25 who's really breathless and really distressed. But I think that would be a really good kind of thing that we look at."
S2I05	*"…Sometimes especially if we've got issues with secretions, it depends on what the end-of-life cause have happened. It's respiratory then yes, because there's nothing worse than someone looking like they're having trouble breathing, you know?"*
S2FG08	*"…We could look at the respiratory rate and how the work of breathing the patient from a respiratory point of view, we can look at signs of, you know, distress in a patient which could be tachycardia, sweating, difficulty in breathing, so those kinds of things."*

Appendix 39 Theme communication supplementary outcome quotes

Able to ask questions – Family satisfaction with opportunities to ask questions concerning the patient's end-of-life care	
S2FG01	*"…Do they feel that they can ask the questions that they want to ask, and that their questions have been met?"*
Accepting being at EoL – Family acceptance of the patient's end-of-life care phase	
S2I07	*"…Everybody's gonna die, it's something well, we all have to accept it, and people just don't want to talk about it and that'd make it easy for everybody."*
Clarity of communication	Family satisfaction with the clarity of communication. Use of clear, concise, simple language that avoids jargon.
S2I05	*"…We go around the bizarres of not actually saying what the relatives wanted to hear or need to hear in terms of we are at end-of-life, we are starting the process of end-of-life."*
S2I06	*"…I think that's often a little bit foggy in that the languages used and the way we speak to relatives. Not we as, as a you know, the whole we, all of us is sometimes a bit difficult and a bit lost in translation sometimes."*
S2FG07	*"…I think from my point of view, the most important thing is clear communication with the patient, with the family, with the team, like the nursing team, the rest of the doctors, everybody to be at the same place. Because it has happened that if one part of the team doesn't agree with that or is not happy with how things are going it can be very frustrating for the family and for the patient."*
Collaborative communication –	Staff satisfaction with the extent of collaborative communication between the healthcare professionals involved in the patient's EoL care
S2I04	*"…it's really fundamental that, you can do it without communicating with people. And it's where a lot of our problems come, I think is is there either we've not communicated well with families or we've not communicated well as a team. People aren't on the same page about what's happening. I think that's generally where we run into difficulties."*
S2I06	*"…but a lot of that work then was to do with kind of coming together more as a team and and listening a little bit more to those flags when you think somebody is approaching end-of-life care and how we communicate that with each other as a team as well."*
Communicated patient is dying	Number or percentage of patient/families who it has been communicated that the patient is dying

S2I05	*"…When they were more lucid, if they're not at that point again for the relatives as well, we're giving them the respect of telling them what's happening, communication and that is being respectful cos there's an element of this is a human being."*
S2FG01	*"…And within that paperwork it has set questions, so have you communicated that the patient is recognised as dying with the family and/or patient if it's appropriate?"*

Communication effectiveness How effective staff communication is	
S2I09	*"…maybe at the end of your shift you can it could be like a little survey saying like, do you feel like, how do you get the communication was or at the end of the patients life but like when they are put on a end-of-life pathway? Maybe at the end of it, like so, the person that was like looking after them for like the last 72 hours or whatever you could have like SurveyMonkey and be like. Just kind of put your thoughts in there anonymously and like write how you could improve and then get feedback."*

Communication understanding - Information presented in a way the family can understand	
S2I05	*"…I think that there's a concern of if you don't have the correct communication, it could be misconstrued that we've given up on them and we are actively wanting them to die."*
S2I13	*"…I think also sometimes is the communication the language used. In ICU, some of the languages, sometimes when you're sitting in some of these meetings, listening to the conversation can be very technically focused. So not all our families would, you know, appreciate or understand some of the technologies used within ICU."*
S2FG01	*"…And I think trying to capture that communication is really important. So what is the understanding of the patient and the family around what is happening."*

Family involvement in EoL conversations- Number or percentage of family members involved in end-of-life communication	
S2I09	*"…Conversations with like the families with the patient. We really don't utilise it that much and it's quite embarrassing because I feel like our consultants kind of want to take their own spin on the end-of-life care pathway. And. Yeah. And just kind of free wheel it."*

Family Satisfaction with communication – Family satisfaction with end-of-life communication	
S2I04	*"…Friends and family questionnaire type things of how well did we communicate with people?"*

S2I06	*"…I suppose you could look at satisfaction of relatives in terms of communication from the team, from the MDT. That would be one thing I think is really important to look at. … So I think you could focus on that if you're going to do a a patient of relative satisfaction survey, as it were, or a questionnaire."*
S2FG08	*"..So I think in those sub-groups of patients it is important that we can have outcome measures or pathway where the feedback between the families is in constant loop."*

Keeping the family up to date – Frequency of updates provided to the family on the patient's end-of-life status	
S2I05	*"…So I like the idea of, of actually telling people what's happening … When they were more lucid, if they're not at that point again for the relatives as well, we're giving them the respect of telling them what's happening, communication and that is being respectful cos there's an element of this is a human being."*
S2I08	*"…Keeping all family members up to date."*
S2FG08	*"…And that way it creates a feedback and listening to the families as to what they want and make sure that we are listening to them."*

Listening to the family – Number or percentage of families who feel their opinions and thoughts have been listened to	
S2I01	*"…Is that important that you listen to the families, what their wish, what they're really, how they want it, is that make any difference to their patients. Wish that's that's, that's important."*
S2I08	*"…And also engaging with the family as well and listening to the family."*
S2FG08	*"…And that way it creates a feedback and listening to the families as to what they want and make sure that we are listening to them."*

Patient involvement in EoL communication – Number or percentage of patients involved in end-of-life communication	
S2I03	*"…I do try and engage with the the families and the and, you know, and the patients if possible umm about where I think things are going usually with patients is much less usual to be able to do it satisfactorily with patients."*
S2I04	*"…I think it's challenging cause a lot of time we get patients and then not in a position to talk to us so they are either intubated on a vent, or they're clapped out and confused and not able to have those discussions."*

S2I13	*"…But if it's this coming in with non malignant conditions, or maybe end stage COPD, sometimes very difficult to then have had the opportunity to have these conversations."*
Satisfaction with online communication –	Staff and family satisfaction with using online communication methods eg Teams, Skype QR codes
S2I04	*"…I think everything looks worse on a screen somehow. I think you seeing a picture of somebody attached to loads of machines looking really poorly I think it's probably worse than seeing them in real life and, you know, being able to hold their hand and interact with them. So it it works if you need to use it, but it's definitely not my preferred way of communicating with people I think you lose a lot. And you lose a lot of the kind of humanity of it through that."*
S2I05	*"…Well, unfortunately, like what we're doing now on TEAMS. It's not ideal but it was better than nothing."*
S2FG05	*"…And for those of you with NACEOL what's even more weird is that to do the quality survey for the bereaved relatives it's a QR code; that's the only way that you can access the survey is by means of a QR code, which is already causing digital exclusion and terrible numbers for us here."*
Do they feel heard – Family members assess whether they feel their views and opinions have been heard	
S2I09	*"…Conversations with like the families with the patient. We really don't utilise it that much and it's quite embarrassing because I feel like our consultants kind of want to take their own spin on the end-of-life care pathway. And. Yeah. And just kind of free wheel it."*
S2FG01	*"…But really what matters, in my mind, is how do patients and families feel that they have been heard and acted on?"*
Staff satisfaction with communication - *Staff satisfaction with end-of-life communication*	
S2I03	*"…I want to do better and I want everyone to do better, I'm also very, very conscious that I'm not that great either."*
S2I09	*"…communication and everything really, I think there's so much that can be done to improve because I definitely don't feel like we're good enough."*
S2FG01	*"…But I think it comes back down to we need to be able to assess our communication."*
Timing of EoL Communication - Time from identification of end-of-life to informing the family	

S2I03	*"…don't think we have it early enough conversations, umm, I don't with patients in particular."*
S2I04	*"..I think probably that earlier the better, I think we we're really good at leaving it really, really late.*
S2I13	*"…If I think sometimes when it's the trajectory of oncology, haematology in a way we can, we know how things will go, but we so we can have those conversations a bit earlier. But if it's this coming in with non malignant conditions, or maybe end stage COPD, sometimes very difficult to then have had the opportunity to have these conversations."*

Appendix 40 Theme decision making supplementary outcome quotes

Advanced directives -	Number or percentage of patients with an advance directive (written legal statement of the patient's wishes regarding medical treatment
S2I03	*"…they come with with law care plans, is what to do about them? They're, they're very, you know, they're very generic not ICU use specific."*
S2I07	*"…Things like advanced directives, we are few and far between and then families don't. It's not discussion people have outside of the hospital."*
S2FG0	*"…But it will definitely add to the uniformity when you are auditing things, to ensure that it's been followed or not."*
Alignment with the law – How the decision process aligns with the law	
S2I13	*"…In the patient capacity consent, all those sort of big, big conversations is probably what we do a lot of in our long term MDT and thinking about the legalities around how we make decisions. How can we measure outcomes of that? In a way, whether we follow due process and whether that process is consistent among the teams."*
Anticipatory medications prescribed	Number or percentage of patients with anticipatory medications prescribed following identification of end-of-life care
S2I04	*"…Anticipatory prescribing is really important … If we've got a patient who's approaching the end-of-life yes, hopefully on ITU you have a doctor somewhere nearby, but that doctor might be intubating someone in resus, in which case we need them there, prescribed, ready to be given just kind of my general opinion."*
S2I08	*"…Get all the anticipatory medications prescribed."*
S2I113	*"…Umm so anticipatory prescribing in ICU, it's done, I think in our ICU it's done quite well. We use the our own version of the individualised care plan for the dying person, so there is one that we use that is specifically designed for ICU and actually that would be a very good measurable outcome."*
Autonomy to make decisions –	Extent to which a person has freedom and authority to make decisions without external influence or control
S2FG01	*"…And I think, in my experience, and I don't know what it is, whether it's just historical hierarchy, but the nurses tend to feel that they are not heard or they don't have enough autonomy around palliative and end-of-life care in the intensive care unit, which is ludicrous really when they're spending so much time with the patient and they're the*

	ones who can see and feel that, sort of, emotive side and assess the symptomology and the needs of the patient, in my opinion, a lot more."
Clarity of decision-making – How clear people perceive the decision-making process	
S2FG08	*"…And what baffles me, and the most important thing is, about decision making where when the active treatment ends and the decision to start comfort care or palliative care begins. I think that clarity around decision-making is important because then the pathway will change completely."*
Collaborative decision-making – How people perceive the level of collaboration in the decision-making process	
S2FG07	*"…So, there are a lot of factors that can count on that. But how to make everybody go on the same page and make a decision I don't know how. I have been working on that for such a long time and it's very difficult."*
S2I05	*"…It's usually a consultant to consultant with the understanding of the team around them in terms of the MDT around them. So you'll have the registrar and the Docs, you'll have the nursing staff as well. But overarching they, they make their decision, they can hear and understand us but they will I feel they make the understanding."*
S2I08	*"…So, obviously, you'd have your, the parent team the patient would be under, whether that be a surgical team or a medical team. But then, also, the patient would be under the ICU team as well. And it's just making, obviously, dietitians would be involved on ICU, and you'd have the physios and then, obviously, we could introduce palliative care as well, and it's just making sure that everybody is on board and everybody is understanding of the situation, and making sure that everyone is in agreement."*
Consistency of decision-making - Are decisions made in the same way, or are they changed?	
S2I07	*"…So you'll have one Doctor who does one thing and, another Doctor who does another thing the day after. And you're like, oh, so you'd think, right, I'll do this well, this 24 hours, if this doesn't work get the family in, we'll withdraw care, we'll put them inside room it was all lovely. And then another consultant come in the morning, like, oh no, we're going to do this now."*
S2I09	*"…one day we might have a decision made so kind of palliate the person and kind of keep them comfortable, you're not treating them anymore. But then maybe the next day a different person would come in and say, let's give them another 24 hours with active treatment and then that kind of as a nurse, it puts you in a position where yeah, kind of torn because you wanna keep the person comfortable and you, you're kind of expecting the worst, but you can't really do that.*

Decision conflict –	Disagreement or tension between healthcare professionals, family or patients involved in making a decision
S2FG01	*"…I would agree that it is an incredibly important thing to capture. And I think [Name redacted] highlighted there that there can often be a conflict within the ICU team, I think, in terms of the nursing staff and the medical staff, which can be really difficult to navigate."*
S2I06	*"…A lot of the time when some members of the MDT feel, you know that, we've, we've reached a plateau here. I think we should stop and other members of the MDT think, no, we're still, you know, we need to give this a shot and that sometimes causes not conflict. That's too strong a word, but it, it can cause tension, I guess within the team when, when those decisions are, are very tricky and, and people have different different opinions over it."*
S2I07	*"…we're like, I think we need to get a family in. I think we need to stop like this isn't fair. This is, this person is, is dying their showing very clear evidence that dying things are not improving. We're doing everything we can. We need to get the family in and give them as much time as we can now because this isn't going to get better. And then you'll have a doctor be like, oh, well, we'll just do this, this and, this first."*
Decision-making processes followed – Has a specific process or method been followed to arrive at a decision	
S2I13	*"…So maybe an outcome I don't know would be looking at the quality of documentation because with that, then the next MDT it's a matter of looking at the decisions that were made earlier on. Have they followed due process and arriving at that discussion to where the withdrawals, withold or whatever that we're going to do has been applied."*
Ethical decision making – Decisions are made using an ethical framework	
S2I13	*"…Where we've got stuck with MDTs or where as difficult it's around the ethical and ethical decision making and especially around the withdrawing, withholding treatment, the ethics of it.* *"I think one of the big things, really big things that we get suck on in intensive care, is ethical decision making in intensive care I would say definitely."*
Family satisfaction with decision-making – Family satisfaction with decision-making	
S2I05	*"…that also then includes the family as well because these are going to be the lasting memories that are going to be held by the relatives as well, so therefore I feel that they need to also be well and truly looked into how they feel about certain decisions that we make. And then understanding the decisions that we're making.*

How quickly end-of-life is identified – Time taken to identify the patient is at end-of-life from admission	
S2I06	*"… think you should be measuring the how quickly the terminal process is identified, so I know that is something that is monitored in quite a lot of centres … it's very clear that some hospitals seem to perform differently in patients who die. Might be there for 10 weeks before they die or sometimes it might be 15 weeks or in some centres it's much shorter period of time where perhaps that recognition of when it's not, it's not working out is made sooner."*
Involvement in decision-making – Whether staff and family members feel involved in the decision-making process	
S2FG05	*"…I appreciate sometimes there's complexity. So, I think that if there was more engagement, more direct engagement with decision making I think that you could literally demonstrate in many cases a significant reduction in length of stay."*
S2FG01	*"…And I think having outcomes that reflect understanding, whether they feel involved and heard and their overall satisfaction with the care, will not only help us see how well the care has been provided but also to pick up on those nuances and highlight where…what do we need to be doing to support nurses, why do they feel unsatisfied, or why do they feel satisfied? And are there those differences?"*
S2I13	*So it it it definitely very important to involve the patient's family members at every stage, but as much as you can if you have an opportunity to get that patients wishes first.*
Organ donation referrals – Number or percentage of patients who were referred for organ donation	
S2FG02	*"…They should be able to make, I mean as they're able depending on their level of consciousness, be involved in all the kind of care decisions. Do you want to be washed and dressed, or do you not? Do you want blood drawn or do you not? You know, and kind of making sure they're able if they're able. If they can communicate able to express their preferences. Very important, I would say the most important thing."*
Organ donors – Number or percentage of patients who become organ donors	
S2FG02	*"… I've picked up one or two from organ donation service who, again, it's voluntary whether or not they say. And they're only the preceding donors that do that survey, so that's far from all the stats, although we've offered that survey.*

S2I04	*"…I think all the kind of patients who then go on to organ donation, they're like a whole different group. Here again, I think there's lots of work that could be done there."*
S2I05	*"…We've got an an end-of-life package which kind of correlates with a little bit of organ donation as well."*

Patient involvement in decision-making – Number or percentage of patients involved in the decision-making process	
S2I06	*"…They should be able to make, I mean as they're able depending on their level of consciousness, be involved in all the kind of care decisions. Do you want to be washed and dressed, or do you not? Do you want blood drawn or do you not? You know, and kind of making sure they're able if they're able. If they can communicate able to express their preferences. Very important, I would say the most important thing."*
S2I13	*"…And at the MDT, the bedside nurse looking at that patient will come and present their view on the care of that patient within the MDT. So in terms of making sure that the patient is well represented, I think the MDT functions quite well. Yeah. So maybe an outcome would. I don't know who who is involved in that decision making.*

Recognition of dying – Identification that the patient is actively dying	
S2FG02	*"…But I think the identification of people who are likely to be dying feels a really, I mean obviously it's the first step really of all this, that often isn't very rigorous."*
S2FG08	*"… And what baffles me, and the most important thing is, about decision making where when the active treatment ends and the decision to start comfort care or palliative care begins*
S2I06	*"…I think the nursing staff are oh, this is going to be controversial. Are quicker to recognise when somebody's reaching end-of-life. I think they are more empathetic with family members … I think you should be measuring the how quickly the terminal process is identified."*

Satisfaction with decision-making – Overall satisfaction with the decision making process	
S2FG05	*"…I think it's more of a suite almost or I mean it's a number of measures. I think sometimes, for example one of the things that strikes me as really interesting with respect to some of the patients we've been involved with is there has sometimes been – and again, not to be critical of any colleagues – a lack of decision making, and sometimes patients have languished on the ITU for a large number of weeks. Sometimes because of different philosophies of care by the leading consultant and what have you, and patients it's literally on occasion been the physiotherapist on*

	the ITU and say, healthcare team, we need you to come and help because everybody's umming and ahing with regards to.
S2I06	*"…we did quite a few kind of VAS scales on people's experiences and of how you know, do you, did you feel comfortable with decision making? Did you feel etc, etc and did it on a kind of one to 10 of always never or whatever in between."*
S2I07	*"…We try to keep people alive at night rather than just saying we need to give them some dignity to die and we need to get the family in … I think they sort of have these little ideas that they don't share and, we try and prepare the family for one thing, and then the next minute, they're not doing it."*
Support in decision making – How supported staff feel in the decision-making process	
S2I13	*"…So that sometimes can be a bit of a barrier when going in and therefore requires someone who's more familiar using the IV route and managing symptoms at the end-of-life to be supporting them and to making those decisions."*
S2FG01	*"…And I think when it's such a, sort of, humane speciality and approach that really does rely on that intuition more than seeing somebody's blood pressure drop and knowing when to go up or down on the support, then it baffles me, really, and I think we really need to be supporting them to do that."*
Time before decision made – Time from identification of end-of-life to decision to withdraw or withhold treatment	
S2I05	*"…I think sometimes the decision to maybe go down the end-of-life just doesn't get spoken about as quickly as probably what we do we yeah.*
S2I07	*"I think for me the the issue is the delay in saying this patient we're going to let them die with like dignity and comfort."*
S2I03	*"…I think some of the things we don't do terribly well as medical professionals are look back and see if there were reasonable stop points sooner. I don't think anybody benefits from having very long periods of intensive care where they ultimately die. I think that just you know is is not that very common, but umm you know people do sometimes die after two or three weeks of intensive care therapy and you sometimes think well would it have been reasonable to have not started or to have stopped sooner."*
CPR status – Number or percentage patients with a documented Cardiopulmonary Resuscitation status	
S2I09	*"…Yeah, definitely. If that's important and that can be communicated with the team."*

DNACPR status –	Number or percentage of patients with a documented Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) status
S2I13	*"…So whether the patient had a TEP, whether the patient had a DNACPR."*
S2FG08	*"…And is there even a need for DNACPR in this subgroup of patients? Because it is the same teams, and once you know that things are going wrong, you can put the ceiling of care in."*
Resuscitation status discussed – Number or percentage of patients with a resuscitation discussion documented	
S2I06	*"…I think the whole DNR conversation I feel quite strongly about that, that people are asked, well, do what do you think? Do you think we should resuscitate and actually it should be a medical decision then making the family think that they have to make a call on that."*
S2I13	*"…Treatment escalation plans would definitely be a good outcome that should look at within that is the DNCPR conversations."*
S2FG01	*"…I do think that would be a helpful outcome set to have that wouldn't involve having to ask anybody's opinions, it's either written out or not, you've either got a documented preferred place of care and death or you haven't. You've either got a documented CPR discussion, you've got a documented, you know, what level of care would be appropriate for this patient. So I think you could look at that.*
RESPECT form use –	Number or percentage of patients with a Recommended Summary Plan for Emergency Care and Treatment (RESPECT) form
S2I07	*"…We do try to use RESPECT forms so you can, so there our do not resuscitate plus discussing quality or the quantity and etc, and limits and things with or without resuscitation. We don't use them very often either, you know, we discuss daily or hourly limits of care."*
S2FG01	*"…I think we're probably getting better at that and ReSPECT forms have really helped with that, as opposed to just the red forms that we used to have which were just literally, do we or do we not perform CPR."*
S2FG04	*"…And interestingly I think hospitals in general we're not very good at using the ReSPECT forms properly. I think everybody has moved to these purple ReSPECT forms, where actually when you're putting things in place to limit escalation of care, you know, there's meant to be a holistic approach to it and ask people really qualitatively what is important in their life, what is important to them, and using some sort of comparison.*

Treatment limitations – Number or percentage of patients with a treatment limitation or escalation plan in place	
S2I05	*"…Cealing of care again, we we talk about futility that needs to be documented and that can also change when they're seriously unwell. And so therefore, that also needs to be recorded, measured if that's the word."*
S2I07	*"…I've told all my family my limits. OK, like you're not doing this to me, you're not doing that to me, you're not doing this to me, absolutely not. But these are conversations people just don't have."*
S2I13	*"…Treatment escalation plans would definitely be a good outcome that should look at within that is the DNCPR conversations. So whether the the TEP. Having conversations around that, the treatment escalation plan. How soon those conversations are had and what sort of measures, what's on there that can inform an outcome."*
Frequency of treatment limitations reviewed – How often treatment escalation plans are reviewed	
S2I13	*"…All those interventions were and that time when that that treatment escalation plan was being put in place and I guess also how often are they reviewed. How often are we reviewing the TEPs?*

Appendix 41 Theme impact on family supplementary outcome quotes

Anxiety – Family member symptoms of anxiety	
S2I13	*"…When the person is dying. What that looks like, how we're going to manage it and understanding of the machinery and especially if we have to turn off some of these monitors. Is doing it with the with the family members understanding of why we're doing it. And how the numbers may be more of a source of anxiety for them. Rather than telling the those, you know the nurses or giving the team an information, it's more of the anxiety that brings."*
Emotional Wellbeing -	Family assessment of their health, tension, energy, cheerfulness, fear, anger, sadness and general wellbeing
S2I01	*"…It is not a straight procedure. Yes, still, it's an emotional process for the family to hear that. But it will be very slow process and sometimes yes, it's very comes very quick but then the family will be have emotional time."*
S2I03	*"…I think families are generally better if and cope with issues better if people come in and die relatively quickly rather than have long periods of uncertainty where they're a bit better today, well, they're a bit worse tomorrow. You know, it's that kind of rollercoaster to sound a bit X factory about all that emotional journey."*
S2I09	*"…Anger because they don't know what's going on and mixed messages and like lack of trust within the people that are providing the care."*
Family Burden – Emotional and physical burden perceived by family members	
S2I03	*"…I think we should look at the burden that puts on to families. I think families are generally better if and cope with issues better if people come in and die relatively quickly rather than have long periods of uncertainty where they're a bit better today, well, they're a bit worse tomorrow."*
S2I04	*"…I think can put a lot of burden on them and as much as you say this is my decision that this is, you know, we're signing information from you. You as a family member would inevitably feel like well, I've said that they wouldn't want this, and so they're not doing it. And so I think that puts people in a really difficult position."*
S2I06	*"… And even if it's even if they're not I think it's often interpreted that they that by families and by members of the public that it is their decision to make. And I think that's a huge burden on people and it shouldn't be their decision to make.*

Family-centredness of care – Family satisfaction with the family-centredness of care	
S2I07	*"…So you're making these decisions when it's happening now under stressful circumstances, and I think we try to do patient-centred care but our opinions on the patient are from the family, not from the patients, so I think it's more family-centred care."*
Family needs – Number or percentage of families who feel that their needs have been met	
S2FG01	*I think then if we're looking at the family needs, so it's assessing…well, first of all we need to ask patients or families, don't we, what are their needs around palliative and end-of-life care, and I'm not sure we know that yet. But once we had that, I feel like we may be able to measure that better. I guess the challenge comes as how do you ask people these questions when they're going through such a turbid time in their life? That's really difficult, isn't it, in terms of an outcome set, and I don't have an answer to that.*
S2I04	*So I think some of that is just going and listening to the nursing staff and saying well, what have you, what do you know about the family? What do you think's important and supporting that moving forward."*
S2I08	*"…You know, making sure they're hydrated, making sure that they've got biscuits. They might…they don't want to eat, I know they don't want to eat, but it's just keeping, you know, are there tissues in the room? Are they aware of where the toilets are?"*
Family Support - Family satisfaction with the emotional and practical support provided	
S2I04	*"…But I suspect there's a huge burden of families who we just don't have anything to offer them support wise."*
S2I13	*"…How their input can be measured. I guess, if they've supported the family as a dying person is, maybe asking about the service and checking with the family members whether they found their input helpful or useful."*
Functional ability - Patient's ability to undertake activities of daily living	
S2I03	*"…I think we should be looking for err, err, functional ability umm, at err, err, probably six months and and the year.*
S2I06	*"…What am I looking at in terms of discharge planning? They're so dependent now. They're so weak. I'm looking at 24 hours in a nursing home."*
Grief – Number or percentage of family members with symptoms of grief	
S2I05	*"…Unfortunately, that then has a a bearing on relative grief, which I'm sure that the person, if they were able to make their decisions. The actual person that's dying would want it to be a bit more controlled and more easing on the families around them, family members around them."*

S2I05	*"…Level of grief is really tricky to manage because it can be so subjective on the individual, the time and how it happened, whether they've had grief somewhere else recently. So it's it's tricky. I don't think you can measure grief. You can only go by what that individual is experiencing at the time. And trying I won't say resolve because you are never going to resolve it, but try and alleviate any of the symptoms they may be experiencing and offer any support that you can within the remit of your abilities."*
Level of disability – Patient's level of disability post critical care	
S2I03	*"… I don't want to be left with somebody, you know, wiping my bum. You know, they they're they're the sorts of, like outcomes of which they imagine are worse than death, or sometimes people, perhaps relatively commonly in these sorts of conversations, people will say I don't want someone to have to look after me."*
S2I07	*"…Some just want them to survive. Some people just think if the hearts beating they're alive or like, oh yeah, can't we take them home on a ventilator forever? And you're like, well in theory you can, but would you want to? Would you want that?"*
Mental impairment – Patient's level of cognitive impairment	
S2I03	*"…So most people will tolerate or, or believe they'll be able to tolerate a certain amount of physical disability afterwards, but very afraid of umm, being left with serious mental impairment."*
Post-intensive care syndrome in family –	Number or percentage of family members who develop post-intensive care syndrome
S2I04	*"…So there's a bit of evidence isn't there about post-intensive care syndrome and how that affects family."*
Psychological well-being – Family members assessment of their psychological well-being	
S2I01	*"…So they they will look at the money, but the, the psychological side of occasion, their families, they don't measure it.*
S2FG02	*"…So, a measure is, have they assessed holistic needs, so have they looked beyond the, kind of, critical care things but have they actually thought about how emotional needs, psychological needs, social needs and all that stuff … And actually, the demanding families are actually demonstrating their unmet need of these are distressed people with psychological and social support needs that are not being met, and that's why they come across as demanding or difficult."*
Psychologist involvement - Number or percentage of family members who were seen by a psychologist	

S2I06	*"…Well, she's involved with the patients who are able to communicate. So I don't know what care she offers to the families, I don't know."*
S2I13	*"…And then also the ward will give them they've got ward psychologists who would the ICU psychologist and the team if they've been very much involved with that family, they would give them a ring as a follow up to see how they're getting on."*
Quality of survival – Quality of the patient's life post-critical care	
S2I03	*"…I think most people, if they were thinking about a quality of survival would want to be them. Umm. They want that be the person they are today to have their personality intact and they want to have the level of mental functioning that goes along with that."*
Relative morbidity -	Number or percentage of family members who develop new or worsening health conditions (morbidity) as a consequence of their loved one being in ICU
S2I03	*"…To, to imagine a different way of doing it, but must lead to some some morbidity amongst the, the people who are left."*
Survival - Number or percentage of patients that are alive at ICU discharge or after hospital discharge	
S2I03	*"…So survival both at unit discharge and and at 30 days. Umm, both of which are important in one sense but they're not, they don't, they certainly do not tell the complete story of somebody who survived and an ITU admission … At the moment we record survival as our primary outcome and we record most of the stuff goes through ICNARC."*
S2I06	*"…Some just want them to survive. Some people just think if the hearts beating they're alive or like, oh yeah, can't we take them home on a ventilator forever?*

Appendix 42 Theme patient and family centred supplementary outcome quotes

Comfort – Patient level of comfort	
S2I01	*"…Some patients, some patients, families, they don't want anything, they just want very comfortable. They want their dad or mum to be very comfortable and they're very happy with that and some staff so pleased with the families are so pleased with the staff because they feel comfortable that their dad has had a very pleasant, very happy kind of end-of-life, so they're very pleased."*
S2I04	*"…think that would be a really good kind of thing that we look at kind of how we, how we are keeping people comfortable."*
S2I06	*"…We could ask people how comfortable. Yeah, again, there's very few objective measures I would say but all have to be be very subjective … Keeping the patient as comfortable as possible, as as far as our interpretation of comfort goes, keeping them as comfortable as we can."*
Compassion -	Family satisfaction with compassion provided eg understanding concerns, distress, pain or suffering and the staffs empathetic and caring behaviour towards these
S2I07	*"..I think it's the most important part. Genuinely, I think umm, just understanding that the family go through probably the worst day of their life. Umm, just really allows you to just look after them and I think you need to be compassion, compassionate and caring without sort of letting the emotions take over you."*
Concordance of care –	Number or percentage of patients receiving EoL care consistent with the patient's and family's preferences or wishes
S2I01	*"…So he came and he thought his wish was never intubate him. Never put any tube on. He don't want any of that thing. He don't want any suffering. He want to us normally. He don't want to go through. So the next moment the doctors had a conversation and then less than 24 hours but they listen to the family, the next of kin."*
S2I05	*"…So you you still have to be that advocate for what that relative would have wanted, so the patient would want for their relatives."*
S2I07	*"…And they've got the people there that they want there. Do they want music on and, just making it more person-centred about what they want, not just let's turn all this life support off and go."*

End-of-life care wishes and preferences	Patient and family EoL preferences are sought, discussed and documented in their medical record
S2I08	*"…It's absolutely massive, because we don't…we don't know that person in that bed, we can only go by, obviously, what we've been told, and we need to know what's their last wishes."*
S2I13	*"…So, it it it definitely very important to involve the patient's family members at every stage, but as much as you can if you have an opportunity to get that patients wishes first … I think simple things about have we actually recorded what's important to the patient and what what they value have we asked."*
S2FG01	*"…Definitely something about do they feel that their goals and wishes have been respected and heard, actually, I think it's firstly to be able to enact on those wishes we need to ascertain what they are. And so, I think the best way to capture that would be…I guess you could do it by documentation, isn't it, so are we documenting patients' wishes? … And so, I think you can more easily objectively measure whether goals have been ascertained in terms of the documentation."*
Dignity – Satisfaction with dignified care. This includes if the patient was respected and treated with dignity	
S2I03	*"…understanding what are important outcomes for the patient, you know what's important to you if you were left in a situation where your personal dignity was compromised, you receive personal care would that be an acceptable way of living your life?"*
S2I05	*"…Respecting everything and dignity in terms of maintaining privacy and maintaining what the patient would have wanted."*
S2FG01	*"…Do they feel that their family member has been treated with dignity?"*
Individualised Care Plan – Number or percentage of patients with an individualised EoL care plan in place	
S2I13	*"…We use the our own version of the individualised care plan for the dying person, so there is one that we use that is specifically designed for ICU and actually that would be a very good measurable outcome."*
S2FG04	*"…I think what potentially you know would help the critical care community manage death better for our patients is, kind of, adopting a framework on which we can adapt a really individualised plan for people, that still is of a protocol that everyone understands because that's everyone's happy place. And I think that's what would translate into real-life effectiveness."*

S2FG05	*"…The metrics I'm trying to remember exactly what things were that we used to look at, but one of them certainly was the number of deaths on the individualised end-of-life care plan."*
Holistic needs assessment – Occurrence of a holistic needs assessment	
S2I01	*"…when you look at it as a holistic approach, we need to be have like it's a social, religious, familywise, comfortable, its pain, it's a physical training, reduce everything. All that things, it's important."*
S2FG02	*"…In my current MDTs I go to now, are pretty much all doctors, mainly me being the SNOD, but I'm adding some palliative care, but often there's no palliative care; there's certainly no chaplain, there's certainly no social worker. So, how holistic is the MDT and the working of the unit? … So, a measure is, have they assessed holistic needs, so have they looked beyond the kind of, critical care things but have they actually thought about how emotional needs, psychological needs, social needs and all that stuff."*
S2FG04	*"…. there's meant to be a holistic approach to it and ask people really qualitatively what is important in their life, what is important to them, and using some sort of comparison.*
Patient-centred care -	Family patient-centredness of care includes how communication, empathy and shared decision-making
S2I04	*"…have we actually engaged in this person as a human being?"*
S2FG03	*"…I think there is a risk that we end up changing metrics and you end up with a very transactional package of care that just fits some sort of measures, rather than an individualised and compassionate care that we're supposed to be providing."*
S2FG04	*"…in critical care sometimes the things that people struggle with is creating really individualised non-protocolised ways of approaching the management of these patients."*
Personalising the environment – Presence of personal items eg photos, blankets, pets, removal of monitoring	
S2I03	*"…We've encouraged animal visiting people, bringing pets in at the end, at the end-of-life and and so on."*
S2I05	*"…Sometimes we just need to get the environment as you would just be quiet space available first for them and the necessary care that goes with that before we start talking about candles and romance and all that kind of thing."*
S2I06	*"…We always try and talk to our patients or they're conscious or about things they're interested in. Put music, they might enjoy on the radio, that kind of thing. So, to an extent it is personalised as much as as possible in that environment."*

Preferred place of death and dying	Number or percentage of patients who had their preferences regarding place of care and place of death met
S2I06	*"…I think particularly the critical care setting it's it's a very negative place it's very noisy, it's very invasive, a lot of the monitoring tools are painful and it's it's horribly unpleasant. And I don't think anybody would choose to die there if they had that choice."*
S2I07	*"…Something like 80 or 70% of people when you ask them when they're able to communicate with you, don't want to die in hospital, they want to die at home."*
S2FG01	*"…Have you talked about preferred place of death and dying? And care. So, there are those measures where you could see whether those have been documented and then that can often reflect whether they've been communicated … I do think that would be a helpful outcome set to have that wouldn't involve having to ask anybody's opinions, it's either written out or not, you've either got a documented preferred place of care and death or you haven't."*
Preparation for death and dying – Patient and family are prepared for the possibility that the patient will die	
S2I03	*"… We commonly find families using expressions like they were shocked to find that their patient, that their relatives were close to death in our complaint letters and things like that … So, I think there's something perhaps we could do with that which would be measurable."*
S2I06	*"…And whether they feel their expectations of the service were whether they were prepared for kind of the end-of-life process how they were prepared for that. Were they pleased with the way that they were prepared for that?"*
S2I13	*"…But they also very good in giving a step-by-step approach in how they communicate, dying to a patient because because they have, I guess, a bit of control over what's happening, death and dying conversations can be staggered."*
Privacy - Satisfaction with the level of privacy provided	
S2I01	*"…It is very important because when end-of-life happens if it's in a common or shared area people want to have a religious prayers or whatever is happening or evenly, consciously or unconsciously, other patients may be listening all these things or when we discuss some things, there won't be much privacy regarding other patients' conditions or anything. It will be heard by the other families."*
S2I07	*"…Space is limited, then you've got visitors having normal conversations with their relatives next to somebody that's dying, and, it's just doesn't seem to be privacy, the curtains aren't soundproof."*

S2I08	*"…So, it just makes it a little bit more privacy, much more privacy, lots more dignity for patients, and obviously, family members are able to sit in that room as well."*
Religious/Spiritual leader involvement – Number or percentage of patients who were seen by a religious or spiritual leader	
S2I01	*"…I have respect the patients don't involve in any religious things, but we will have a it's it's it's we will discuss with the patients, families and patients sometimes patients' family said I'm religious, but he don't believe in this, so don't call them. But some people they believe in religious, so we will make an arrangement. We will."*
S2I05	*"…I think sometimes when the question on that spirituality would you like chaplaincy to come around?"*
S2I07	*"…We ask the question when we admit them, if they're aware of if they're religious or spiritual and, then when it comes to end-of-life, we ask the family if there's anybody who they want, want them to come and see."*
Respect for religious beliefs - To what extent the religious beliefs of the patient/family included in the care	
S2I01	*"…I'm very religious, so I give high priority locations to the religion. The same time I have respect the patients don't involve in any religious things."*
S2I05	*"…Again, going back to my own previous partner, experienced my grandparents was a Jehovah's Witness, but in her later years as she her dementia came more apparent. Her beliefs were less orthodox. And felt like she was moving away from her religion. And and there's an element of. So do you go by what she was when she was lucid, or do you go by what she is now? … I have thoughts on this from previous grief and they are a great comfort, regardless of the fact that I am not a religious lady."*
Respect for spiritual beliefs - To what extent the spiritual beliefs of the patient/family included in the care	
S2I05	*"…Maybe not chaplaincy of of we've got a really good chaplaincy but although it's not necessarily religious, it's all come with a lot of and ability of spirituality and time to reflect, like music or anything else that maybe that individual liked doing and make them the person who they are."*
S2I07	*"…We offer things that are a bit, they're not religious, just things like Reiki and, music and, things like that to help the patient. We've had people come in with umm, sage."*
S2I09	*"…we've got documentation of there like religion. Or anything like that so we could get that person involved and we had a patient recently who was on the end-of-life care and his partner did complementary therapies and she would be doing like Rakki on him and so that was really nice."*

Awareness of cultural, religious and spiritual beliefs – Cultural, religious or spiritual beliefs sought	
S2I03	*"...You know, do you know do you need help with writing wills, spiritual matters, whatever it is. Umm. And err. And sometimes I think if we were a little bit more up front about those sorts of questions. We, we could not just measure our success against them, but it would bring families into line with the reality of what the future might be for, for, for those patients and we'd get less of that to always really shocked that they died."*
S2I07	*"…And be able to talk to you about what would happen should they reach the end of their life. And we use that and discuss it with the family of things like medications and then we look at religion, spirituality."*
S2I13	*"…And they key thing another area that we're focusing on is also looking at the cultural and spirituality. So, management of, you know, culture sensitive and departing in the ICU is one of our, the things where I would really highlight."*

Appendix 43 Theme professional competency supplementary outcome quotes

Adherence to protocol/guidelines – Number or percentage of patients receiving EoLC compliant with an EoL guideline	
S2I03	*"…And so we don't really have a process that fits those patients who come in very sick and continue to deteriorate and die very soon after..."*
S2FG04	*"…So, I think what potentially you know would help the critical care community manage death better for our patients is, kind of, adopting a framework on which we can adapt a really individualised plan for people, that still is of a protocol that everyone understands because that's everyone's happy place."*
Collaborative working –	Staff satisfaction with their ability to work collaboratively with member of the ICU and multi-disciplinary team
S2FG01	*"…And I think that is a huge advantage in intensive care, that you get multiple skillsets and viewpoints, but can also be a huge hinderance, especially when end-of-life and palliative care is concerned."*
S2FG05	*"…And sometimes I think there's, not necessarily resentment because that sounds like a hard line to take with some of the colleagues in intensive treatment, particularly the anaesthetists who will sometimes take issue in the fact that hey, we've been doing this for a little while so we can do this."*
S2FG08	*"…And hence, some form of a unified approach, a multidisciplinary approach, where teams in ICU, the teams who are looking after that patient, whether medical or surgical, all be sat down and discusses about end of active treatment and start of the palliative care."*
Consistency of care planning - Number or percentage of changes made to the patient care plan	
S2I06	*"…Consistency was one of the things kind of consistency in a plan. So is the plan continuously changing? Is it adapting to patient needs, or is it changing because of differing opinions?"*
S2I13	*"…There's more of team decision making and having that consistent approach, as you know in ICU consultants change on a weekly basis."*
Competency – Level of confidence, skills and expertise in end-of-life care	
S2I09	*"…I think we should be checking up and making sure that they feel like they have like the necessary like the the confidence and they have the knowledge to be able to like give good care."*

S2I13	*"…One will be the confidence to manage a dying patient and ICU in terms of managing their symptoms, their physical symptoms. How confident they are in doing that in managing and supporting families."*
S2FG01	*"…And I think there's something there to be used in ICU, and I think that would, in a way, also feed into what [Name redacted] said about that training and experience and give people the confidence."*
End-of-life knowledge level – Level of knowledge of end-of-life care among staff	
S2I01	*"…What is end-of-life? Or how you manage general knowledge and everything should be advised."*
S2I08	*"…So, it's just all about education though, isn't it? Educating people to think.."*
S2I09	*"…Just the expertise and knowledge that I, I'm not familiar with."*
End-of-life skillset – End-of-life care skills among staff	
S2I01	*"…Critical care end-of-life is very difficult I think is that the end-of-life patients to be looked after by specialised critical care staff, any palliative staff involved in that one and they should and it should be a specialist skill and specialist area because it needs a lot of time patients and staff needs to be trained very well, regarding end-of-life."*
S2I09	*"…make sure that the nurse has got the tools to feel supported and looking after that person."*
Palliative care team availability – Time from palliative care referral to palliative care review	
S2I04	*"…It's it's generally the ones who you know we've decided to withdraw at 2 o'clock and then we withdraw at 4 o'clock but palliative care don't get down to see."*
Palliative care involvement – Number or percentage of patients who palliative care were involved with eg visit, consultation, advice	
S2I03	*"…I keep sort of trying to chip away at is greater involvement … It's not, they won't come. It's not they won't come. They're not being awkward. It's just I think everyone's, it's just not in a routine at the moment."*
S2I07	*"…We very rarely get them involved. Umm, we just don't. We, you can refer to them if you think we're going to survive, sort of a couple of hours, maybe a bit longer, but our patients don't always survive that long and we tend to manage it on us own."*
S2FG05	*"…And if consultant X is on or whatever then it's oh yes, we might see an influx of referrals or what have you; whereas it switches to consultant Y and then it goes all dry for a little bit."*

Palliative care impact – Palliative care impact on patient care eg change in symptom management, access to additional support for families, facilitation of patient transfers	
S2I05	*"…So the palliative care team came in and they organised beds, they organised TTOs, ICU don't do TTOs or medications to take home. It was a bit of a new one for me for a number of years. Getting an ambulance that was suitable for them. Make sure there's a bed at home for them. It was turned around within my long day shift and he went home just as I was about to leave the shift, and that felt satisfying that I did right by that particular patient in the most horrible of circumstances. And he passed away three days later at home."*
S2FG05	*"..if we are saying that there is benefit for patient outcome or for patient experience in having for example a palliative care presence in the ITU on a regular basis how do you know that we've made a difference?"*
S2FG08	*"…You know, traditionally we hardly used to see the palliative care team coming in ICU. But nowadays, as [Name redacted] has said, they can add so much of value in terms of communication, they can add so much of value with comfort care, especially even in patients who are being treated."*
Palliative referrals – Number or percentage of patients referred to palliative care	
S2I06	*"…The nursing staff can seek advice from the palliative care nurses, but in terms of the whole service being involved, it would definitely be a consultant to consultant referral."*
S2FG02	*"…Palliative care referrals and whether or not you have an engaged palliative care team."*
S2FG04	*"…either a referral to the service or whatever palliative care, you know, champions you've got in the unit. And if that was adopted nationally as a standard, then that would be potentially something to measure."*
Palliative care referral time – Time from admission to palliative care referral	
S2I13	*"…But that is the speciality of palliative care and that's why we ask them to, we make that referral early and then they can come and advise us as to what we're giving, when we're giving."*
S2I13	*"…Another thing we should probably be useful is measuring, especially in terms of outcomes, is and that's the piece of what we're looking at at the moment is when is this patient referred to for palliative and end-of-life care input. So.looking at when a patient is admitted to the ICU and then how long does it take for that patient to be there, refer to palliative care or end-of-life care."*

Treatment withdrawn –	Number or percentage of patients who had a active life-sustaining treatments stopped or decision not to start or increase a life-sustaining intervention
S2I07	*"…I'd say 80 to 90% of what we do is we withdraw the care. And that's, it's something that I don't think you do all that well."*
S2FG02	*"…Have people looked at how withdrawal takes place and whether it's possible to, kind of, define how it should take place?"*
S2FG04	*"The other thing I guess I see a lot in clinical practice, you know, there's not only different opinions in the consultant body about when to say a patient is dying and when to either limit or withdraw, but I've seen huge variations in practice."*
Variations in practice – How practice varies between health professionals and across critical care	
S2I07	*"…So you'll have one Doctor who does one thing and, another Doctor who does another thing the day after. And you're like, oh, so you'd think, right, I'll do this well, this 24 hours, if this doesn't work get the family in, we'll withdraw care, we'll put them inside room it was all lovely. And then another consultant come in the morning, like, oh no, we're going to do this now."*
S2FG01	*So I think [Name redacted] just raised a really important point there, is the sort of variety and different approaches in intensive care units. And I think that is a huge advantage in intensive care, that you get multiple skillsets and viewpoints, but can also be a huge hinderance, especially when end-of-life and palliative care is concerned.*
S2FG08	*"…Because every patient may be different, some people may be intubated and they will probably want to palliate them, some people would like to extubate them, some people would like to keep them on the ventilator and then come down on all support. So the way of palliation or end-of-life care in critical care patients will depend on what sort of organ support they are, and how quickly and what symptoms they are having."*

Appendix 44 Theme staff burden supplementary outcome quotes

Anxiety– Number or percentage of staff with symptoms of anxiety	
S2I09	*"…I've felt anxious about coming back to work."*
Anxiety and depression – Number or percentage of staff with symptoms of anxiety and depression	
S2I01	*"…whatever happens, whether it's always in the end-of-life care very sad feeling created … So many incidents that so many and end-of-life we've gone through in our departments in various, various times and none of the staff was happy after passing out, after the patient passed away. They all others looking sad and very traumatised."*
S2I13	*"…For staff it's more individualised, so they might speak to their units psychologist for support if they feel something has been overwhelming or speak to the palliative care team, or use any of our chaplains to service or the trust driven to trust, support for their own well-being."*
S2FG08	*"…And then, you know, seeing their journey in a downward descent, as they've seen in young patients going off in COVID, has a massive, massive emotional impact on them."*
Staff Burden – Accumulation of unresolved thoughts and feelings from providing/being involved in EoLC	
S2I01	*"Staff working in critical care normally is don't have that feeling of a burden because they want to, they enjoy and they, they, they are looking forward. I don't think that if we will we make any measurement to measure the burden."*
S2I07	*"If you are here for a long time, the emotional burdens bigger. Umm, and if they're younger, that always seems to sort of strike it more."*
Burnout – Symptoms of burnout reported by staff	
S2I09	*"…monitoring burnout, so I think if they've been like looking after the same patient for like a few days they end up dying they should definitely kind of have like a little bit of a flag to say this person's been through a lot of emotionally."*
Conflict with the family - Conflicts with family members reported by ICU staff	
S2I07	*"…then you obviously have the issues of family dynamics. I don't want them in the room, and I don't want them. And I'm not, don't talk to them. We have that quite frequently, which is also very difficult."*
S2I13	*"…Sometimes it's very difficult when when the patients wishes are not known and the family member really wants to I guess, override what the what the team are trying to say is in the best interest of that person."*

S2FG02	*"…And actually, the demanding families are actually demonstrating their unmet need of these are distressed people with psychological and social support needs that are not being met, and that's why they come across as demanding or difficult."*
Distress – Staff members' symptoms of distress	
S2I03	*"…People become a bit attached to and and then experience some distress. So, yeah, I think that might be something to capture."*
S2I04	*"…But I think there's a huge burden of kind of distress amongst staff from doing that again and again and again during COVID."*
S2FG08	*"…So you've asked a very important topic, [Name redacted], because post-COVID we've seen so much distress, not only in the nursing staff but all medical staff who are working, all medical and non-medical staff who are working in ICU."*
Emotional impact – How providing EoLC impacts on the staffs feelings and experience	
S2I13	"*So supporting the families of the dying person is how how confident they are in doing that. How? Then looking at the impact that this has on them."*
Emotional well-being – Self-reported emotional well-being in staff	
S2I05	*"…we do have the ability to give the patient dignity respect sometimes at the expense of her own and emotional baggage load where you want to call it."*
S2I13	*"…So looking at the impact that these these sort of patients have on them. Their own emotional and psychological well-being and and how they cope with those sort of cases that they come across."*
S2FG01	*"…I know that we see a lot of differences culturally, so it's just not…so for some people nurses, doctors, all allied healthcare professionals, if it's not, sort of, culturally…there are big cultural differences that mean that providing palliative and end-of-life care may not sit as well with people."*
Staff empowerment – Staff reported level of personal empowerment includes their perception of autonomy	
S2I03	*"…They don't feel empowered to make recommendations, they're, they're out of their comfort zone on the intensive care units."*

S2I06	*"…Depending on who's working that day and what people's experiences and what people's wishes are make that end-of-life experience better or worse."*
S2FG02	*"…I think what you were just saying, is that that to me is exactly the difference between end-of-life care and specialist palliative care, and we mustn't disempower generalists."*
Maladaptive coping mechanisms – Behaviours or thoughts that provide temporary relief	
S2I03	*"…We do tend to get all of the sort of well-described gallows humour, umm, type coping mechanisms, which are a bit maladaptive, umm, err, and, and things like that."*
Moral injury – End-of-life situations that conflict with their personal values, leading to feelings of failure, guilt or moral dissonance	
S2I03	*"…you sometimes hear people saying they think they've failed if patients die and and, things like that."*
S2I06	*"…if we do continue with care it can be very uncomfortable … You keep going in this horrendous, invasive awful situation and I think it feels like a lot, a lot more of a failure in some cases."*
S2I09	*"…I think it's horrific. I think it's horrific because it just it feels cruel. Especially when you can see that the patients agitated like you're just keeping them alive. It it's very frustrating. That's one of my biggest issues."*
Psychological morbidity - Presence of mental health disorders and psychological distress in staff	
S2I03	*"…I was expecting a lot more psychological morbidity amongst everyone, err doctors, nurses, the, the lot and umm, err, and it didn't ever really materialise, apart from for very few people."*
Psychological difficulties -	Persistent emotional, cognitive, or behavioural challenges that significantly interfere with a member of staff ability to undertake their role
S2I03	*"…But I like to say about four nurses that came to my attention as having psychological difficulties with, with what they were dealing with to the point of, It'd be obvious enough to everyone else, so that, for whatever reason that they got formal help if you like, and and maybe a couple more that walked out and just said can't do this anymore*.."
Psychologist involvement - Number or percentage of staff members who were seen by or spoke to a psychologist	
S2I13	*"…For staff it's more individualised, so they might speak to their units psychologist for support if they feel something has been overwhelming or speak to the palliative care team, or use any of our chaplains to service or the trust driven to trust, support for their own well-being."*

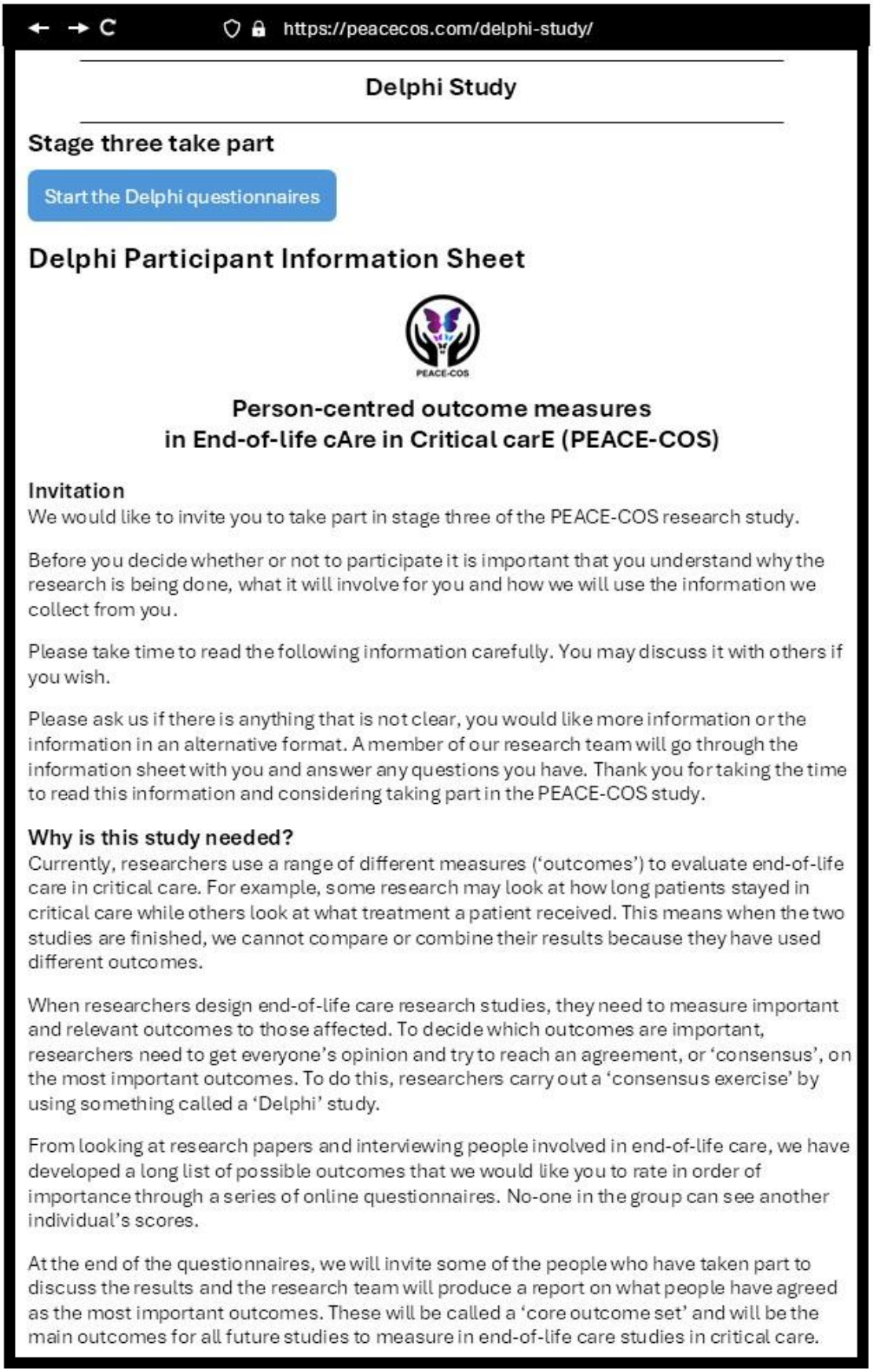
S2FG08	*"…So you've asked a very important topic, [Name redacted], because post-COVID we've seen so much distress, not only in the nursing staff but all medical staff who are working, all medical and non-medical staff who are working in ICU, to the point where the Faculty of Intensive Care found that there was a need for a clinical psychologist to support not only the patients and the families but also the staff working in ICU."*
Support accessed – Number or percentage of staff who access emotional support	
S2I05	*"…So yes, I do think you do need something there, but not all the time because some are good and some are bad."*
S2I06	*"…I don't think we have anything specific for critical care necessarily, but there's there's plenty of things to access at the Trust … It would be interesting to to see if those staff members who were feeling, feeling the burden of those situations are then accessing the support or not."*
S2FG08	*"…And the kind of support they get in the stressed environment where workforce is dwindling, I think that is something which we all need to look at."*
Post-traumatic stress – Symptoms of post-traumatic stress in staff	
S2I01	*"…But when I came to critical care, we very close to the patients and patients in different age, they will have sad endings and, it caused so much to traumatise me."*
S2I08	*"…And I remember having one that stuck with me for years and years. I remember the day like it was yesterday … I think it's just maybe a topic that is maybe too upsetting or, you know, brings back maybe some trauma."*
S2I09	*"…Like recently on my last shift, it happened where the goal posts were moved and it caused like a lot of stress for me personally."*
Welfare officer involvement – Number or percentage of staff who were seen by a welfare officer	
S2FG08	*"…They could be, obviously, it is confidential, but we do have, what are they called now, they're like welfare officers, I suppose, that we speak to that's part of…part of the trust. But I know that would be like a confidential, you know, they could be asked as to how many people have come to them..."*

Appendix 45 Theme resource use supplementary outcome quotes

Hospital costs - Total cost of hospital stay	
S2I01	*"…I think the management and management normally look at the financial side other than the. Other, other outcomes, how they implement when they implement, they look at the finances at how financially cost the press, how financially over credit for the you need all these things and that they don't care about until their parents come."*
S2I05	*"…I think sometimes that's not necessarily shared amongst bed applications and for the politics of money and the involvement or cost of getting someone back home."*
S2I08	*"…It's quite interesting, isn't it, the finances are a hot topic everywhere, there's not enough money anywhere within the trust."*
ICU costs - Total cost of ICU stay includes staffing and equipment associated with ICU care	
S2I01	*"…Or if you say we want a side room, building a side room, and it's only for end-of-life that cost an extra bit and one staff need to look after that patient, so it's an extra room, extra everything. It's cost some money … Also staff need not working so it cost the money. Other thing equipments they need equipment. Other thing is junkyard and end-of-life patient and they have a traumatising and they need to give an extra day or for that day it goes from. Money.*
S2I08	*"…I suppose, the only thing that springs to mind with regards to finances, and I don't know whether I'm completely off topic here, would be obviously, keeping a patient in an ICU bed. So, you know, quite often there is a push for beds, and if you've got a patient that's in A&E that needs an ICU bed, then it's automatically a swap. As in, right, this patient can go to the ward. But that's where finances would just, in my mind, I don't really have much to do with finances. Obviously, an ICU bed is very expensive."*
Hospital length of stay - Number of days the patient is alive in the hospital	
S2FG02	*"…So, stuff like length of stay is more applicable to the whole service and the quality in general."*
S2FG05	*"…Unfortunately, they listen to bottom-line metrics with respect to length of stay."*
S2FG07	*"…But one of the things that we can actually measure is length of stay."*
ICU length of stay - Number of days (duration) the patient is alive in the ICU	
S2FG04	*"I looked at the data that we had in 2018 of all the deaths on the unit and compared that to the Ethicus data and we were noticing there was a significantly longer length of stay."*

S2I06	*"…I've seen this before. When you have have, you look at how long people have spent in ITU before they die and the and the differences between different centres is really interesting … I think it's a good measure. I think it's. I think it's very helpful."*
S2I07	*"…So, one of the things I was actually going to talk about, length of stay as one of the things to measure, like once the patient had been decided that we are going to start this process, the end-of-life care, what is the length of stay of this patient."*
Location of death - Location where the patient died eg hospital, hospice, home	
S2I03	*"… I think I think where people die is important. Umm to them and to their families and the families memories umm and, the intensive care unit and all that when it comes to where where people should be doing it?"*
S2I07	*"…I've heard time and, time again of well, we can't get into a Hospice because they'll not survive the ambulance and yeah, but you know. Do you know that? And then they might last for another 48 hours in a side room so you're like they could have."*
S2I13	*"…With the exception of, I'd say a handful of patients most people die in ICU when it's recognised that they're dying ... I think we've managed to get probably a couple of people into a Hospice from ICU."*
Mortality – Number or percentage of patients who die	
S2FG07	*"…And sometimes for example if I have a patient who was operated on a few days ago, like some of the surgeons they don't accept that this patient is end-of-life care because it comes into their 30 day morality."*

Appendix 46 Stage Three participant information sheet



https://peacecos.com/delphi-study/

Delphi Study

Stage three take part

Start the Delphi questionnaires

Delphi Participant Information Sheet

Person-centred outcome measures in End-of-life cAre in Critical carE (PEACE-COS)

Invitation

We would like to invite you to take part in stage three of the PEACE-COS research study.

Before you decide whether or not to participate it is important that you understand why the research is being done, what it will involve for you and how we will use the information we collect from you.

Please take time to read the following information carefully. You may discuss it with others if you wish.

Please ask us if there is anything that is not clear, you would like more information or the information in an alternative format. A member of our research team will go through the information sheet with you and answer any questions you have. Thank you for taking the time to read this information and considering taking part in the PEACE-COS study.

Why is this study needed?

Currently, researchers use a range of different measures ('outcomes') to evaluate end-of-life care in critical care. For example, some research may look at how long patients stayed in critical care while others look at what treatment a patient received. This means when the two studies are finished, we cannot compare or combine their results because they have used different outcomes.

When researchers design end-of-life care research studies, they need to measure important and relevant outcomes to those affected. To decide which outcomes are important, researchers need to get everyone's opinion and try to reach an agreement, or 'consensus', on the most important outcomes. To do this, researchers carry out a 'consensus exercise' by using something called a 'Delphi' study.

From looking at research papers and interviewing people involved in end-of-life care, we have developed a long list of possible outcomes that we would like you to rate in order of importance through a series of online questionnaires. No-one in the group can see another individual's scores.

At the end of the questionnaires, we will invite some of the people who have taken part to discuss the results and the research team will produce a report on what people have agreed as the most important outcomes. These will be called a 'core outcome set' and will be the main outcomes for all future studies to measure in end-of-life care studies in critical care.

https://peacecos.com/delphi-study/

Why have I been invited?

You have been invited to participate in this study because we think it is important to include the opinions of:

- family members and friends of patients who received end-of-life care in critical care
- health professionals providing end-of-life care
- researchers
- critical care survivors who were given a limited chance of survival whilst in critical care

Do I have to take part?

No. It is up to you to decide whether or not to take part. This information sheet will describe the research study and help you decide. You can also discuss taking part with your friends and family.

If you decide to take part, you are still free to withdraw at any time and without giving a reason. You can do this by exiting the questionnaire or consensus meeting.

What will happen if I take part in the study?



You will need to confirm that you have read the participant information sheet and that you meet the study criteria by completing an online form.



On the same form, you will be asked to consent to participating in two questionnaires and to keep the questionnaire results confidential. You will be invited to answer mandatory demographic, accessibility and contact questions (age, ethnicity, gender, profession, experience and email address).



You will be asked to consent to receive an invitation to be part of a MS Teams video-conference consensus meeting. Consenting to be approached for the consensus meeting does not mean that you are obliged to take part nor that you will be approached to do so. Not everyone who consents to take part will be invited to attend as we need to ensure we include a diverse range of participants and places are limited.



We will contact you via the email address you provided with a link to start the first questionnaire.



The questionnaire involves reviewing lists of outcomes and rating their importance. Instructions will be provided. You have up to three weeks to complete the questionnaire.



The research team will use your feedback and other experts' feedback to revise the outcome list.



You will be sent a link to a revised questionnaire, together with a summary of the results from the previous questionnaire, and asked to rate each outcome. Each questionnaire should take no more than 30 minutes to complete and will be sent out approximately four weeks apart. Submitting your completed questionnaire indicates your ongoing consent to take part.



If you are not selected to participate in the consensus meeting your involvement in the study will finish following the submission of the second questionnaire. We will write up the results and may use anonymised direct quotes (where your identify is not disclosed) in publications.

https://peacecos.com/delphi-study/

Consensus Meeting (additional optional component by invitation only)



You will receive an email inviting you to take part in an online consensus meeting. Participants will be selected to represent the different organisations and perspectives.



You will need to confirm that you have read the information sheet by completing an online form.



On the same form, you will be asked to consent to participating in the online video conference consensus meeting. You will be invited to answer six mandatory demographic, accessibility and contact questions (age, ethnicity, gender, profession, experience and email address).



We will contact you via the email address you provide to let you know the date and time of the consensus group meeting together with the information you will need to join. The meeting will take place using MS Teams.



When you join, you will be entered into a virtual waiting room until everyone has joined. There will be a maximum of 40 people. We will guide you through the end-of-life outcomes we want to explore. There are no right or wrong answers we are simply interested in your opinions.



The consensus group meeting will last a maximum of three hours with breaks. We will take notes and make an audiovisual recording. The meeting will be written up (professionally transcribed or transcribed by the research team). All transcripts will be pseudonymised (real names replaced) and the recording deleted.



Your involvement in the study will finish following the consensus group meeting. We will write up the results and may use anonymised direct quotes in publications.

Possible benefits

Participating in this study may not help you directly but will allow us to develop a clearer understanding about what end-of-life outcomes truly matter to patients and their families, which will improve future research together with patient and family care.

Possible disadvantages



We understand that thinking about and talking about end-of-life care and the death is likely to be emotional or stressful experience for you. It can make you feel upset, angry, sad and cry. These powerful feeling can occur before, during or after the interview.

Each outcome description has been written sensitively by a researcher with appropriate training. If you do feel upset or distressed at any point, you can pause, take a break or stop altogether, depending on your wishes.

A list of bereavement support services is also available on the study website.

https://peacecos.com/delphi-study/

What if there is a problem?



If you have any concerns about any aspect of the study then you can speak with the researchers in the first instance who will do their best to answer your questions or concerns.



If you have any complaints or concerns about any aspect of the way you have been approached or treated during this study, you can also write to the University's Secretary and Registrar at the following address:
Sharon Harrison-Barker Secretary and Registrar, University of Hertfordshire, College Lane, Hatfield, Hertfordshire, AL10 9AB.

Email Sharon Harrison-Barker

How we use your data



In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write.

We will need to use information from you for this research project. This information will include your name and contact details. People use this information to do the research or check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all your information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our report in a way that no-one can work out that you took part in the study.

What are my choices in how my information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study in the secure University data systems. Your data will be anonymous, meaning you will not be identified.



https://peacecos.com/delphi-study/

More information

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients
- by asking a member of the research team
- by sending an email to dataprotection@herts.ac.uk

Organisation and funding

The research is being organised and run by the University of Hertfordshire. The study is led by Sally Humphreys, a PhD research student at the University of Hertfordshire and NHS critical care research nurse. She is supervised by Professor Natalie Pattison and Dr Rosemary Godbold at the University of Hertfordshire and Dr Nazir Lone at the University of Edinburgh, all of whom have extensive experience in conducting research.

The day-to-day conduct of the study will be managed by Sally Humphreys and the study will contribute towards Sally's PhD thesis.

Expenses and payments

None of the study team are paid for you participating in this study. You will not be paid for participating in this study. Participation is entirely voluntary.

Who has reviewed the study?

To protect your interests this study has been looked at by an independent group of people, called a Research Ethics Committee (REC). All the study information has been reviewed and given a favourable opinion by North East – Tyne & Wear South REC and the Health Research Authority (HRA). It has also been reviewed by the University of Hertfordshire Health, Science, Engineering and Technology Ethics Committee with Delegated Authority.



Study results

The results of the study will be written up and published in a professional journal and will form part of Sally Humphreys' PhD thesis. The results will also be presented at conferences. The data will be anonymous, meaning none of the people involved in the study will be identified in any report or publication.

A summary of the Delphi results will be provided to all participants via email.

Our contacts

You are encouraged to ask any questions you wish, before during or after the study. If you have any questions or require further information about the study please contact one of the following people:

Lead Researcher	Sally Humphreys	
Primary Supervisor	Natalie Pattison	
Independent Contact	Melanie Handley	01707 289375

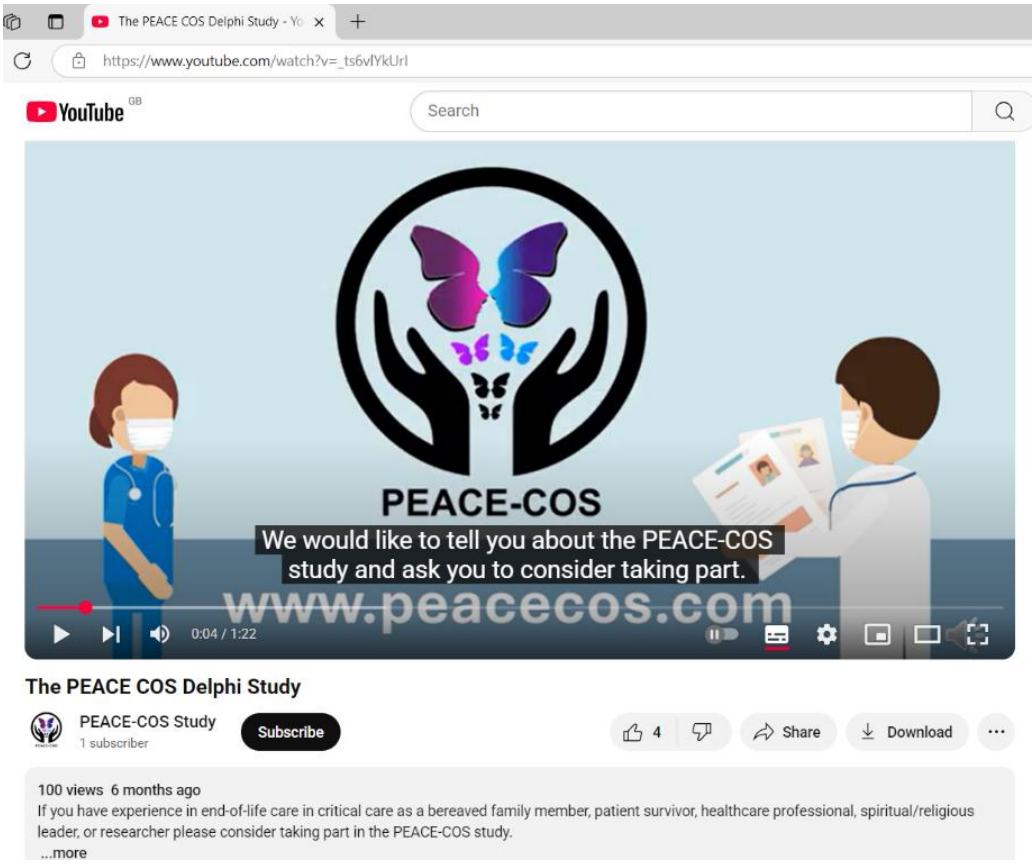
Start the Delphi questionnaires

Appendix 47 Stage Three social media adverts





[The PEACE COS Delphi Study]



Appendix 48 Stage Three recruitment poster example

University of Hertfordshire UH

Developing person-centred outcome measures in end-of-life care in critical care (PEACE-COS Study)



Help identify what matters most

Researchers at the University of Hertfordshire are conducting a study to find out which outcomes should be included in a core outcome set on end-of-life care in critical care.

Bereaved Family members

Had direct experience of an adult (>18 years) family member receiving end-of-life care in critical care within the last 10 years

Patients

Patients who within the last 10 years have recovered from critical care but had a limited chance of survival whilst in critical care

Healthcare professionals

All healthcare professionals (including all members of the multi-disciplinary team) with at least 1 year postgraduate experience of which 1 year has been in critical care involved in the provision of end-of-life care

Researchers

All researchers actively conducting research in critical care or end-of-life related fields who have published within the last 5 years

Taking part involves completing two online questionnnaires
Each questionnaire should take no longer than 30 minutes.

TAKE PART

SCAN ME

Version 1.0

PEACE-COS

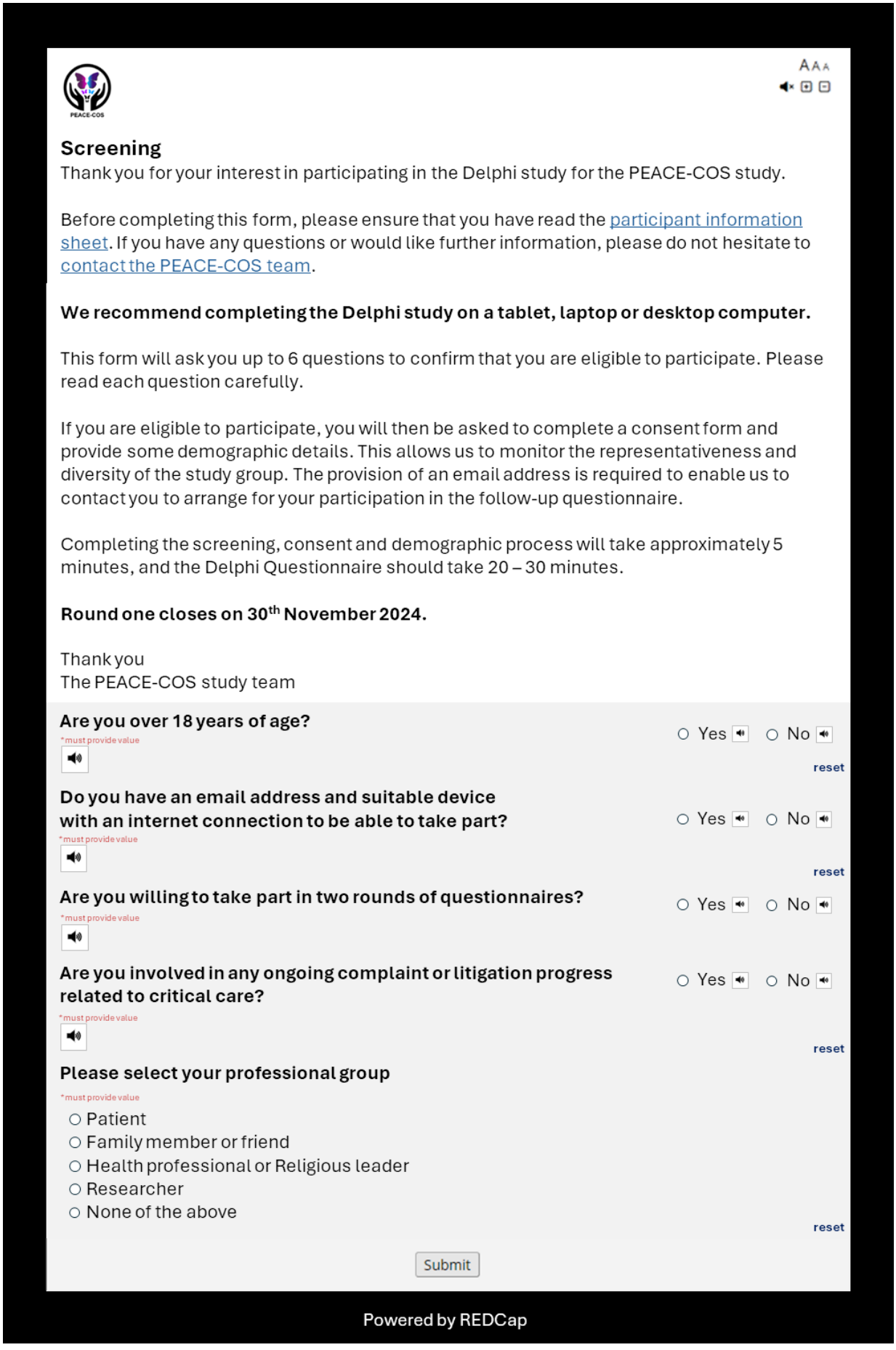
www.peacecos.com

PEACE_COS_Study

Ethical approval obtained from the HRA and the University of Hertfordshire

IRAS 306272

Appendix 49 Stage Three screening questionnaire



AAA

Screening

Thank you for your interest in participating in the Delphi study for the PEACE-COS study.

Before completing this form, please ensure that you have read the participant information sheet. If you have any questions or would like further information, please do not hesitate to contact the PEACE-COS team.

We recommend completing the Delphi study on a tablet, laptop or desktop computer.

This form will ask you up to 6 questions to confirm that you are eligible to participate. Please read each question carefully.

If you are eligible to participate, you will then be asked to complete a consent form and provide some demographic details. This allows us to monitor the representativeness and diversity of the study group. The provision of an email address is required to enable us to contact you to arrange for your participation in the follow-up questionnaire.

Completing the screening, consent and demographic process will take approximately 5 minutes, and the Delphi Questionnaire should take 20 – 30 minutes.

Round one closes on 30th November 2024.

Thank you
The PEACE-COS study team

Are you over 18 years of age? ○ Yes ○ No
*must provide value
reset

Do you have an email address and suitable device with an internet connection to be able to take part? ○ Yes ○ No
*must provide value
reset

Are you willing to take part in two rounds of questionnaires? ○ Yes ○ No
*must provide value

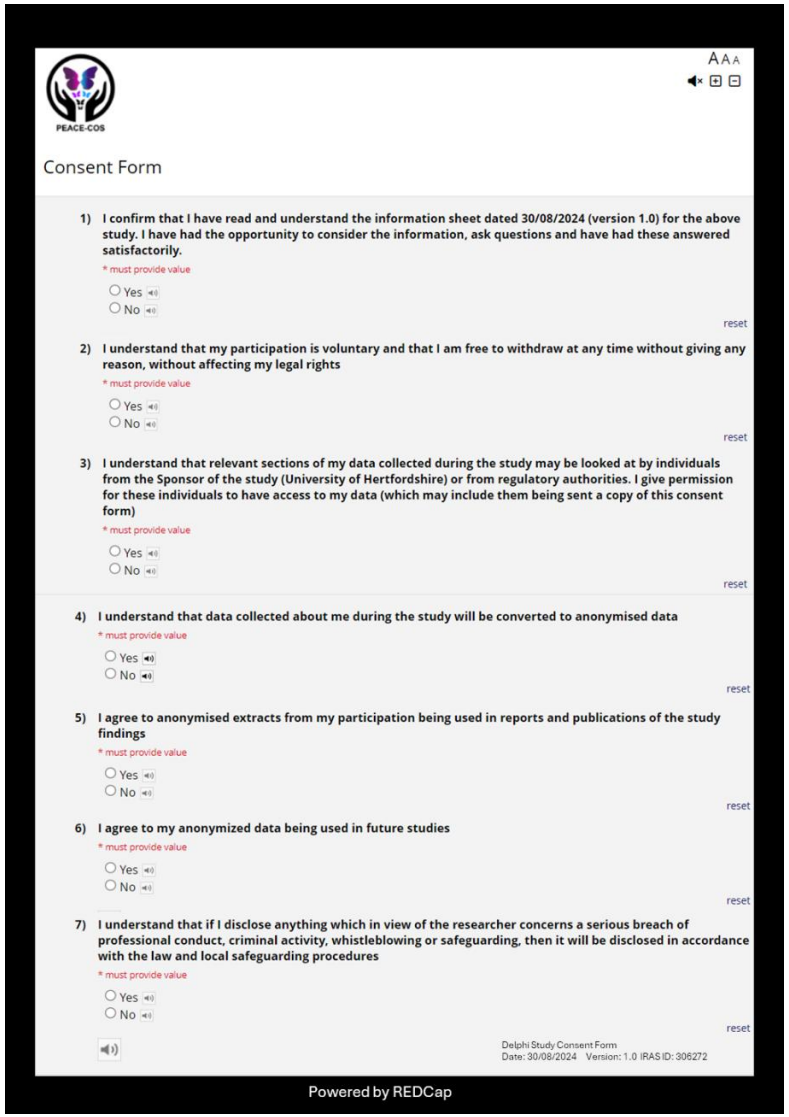
Are you involved in any ongoing complaint or litigation progress related to critical care? ○ Yes ○ No
*must provide value
reset

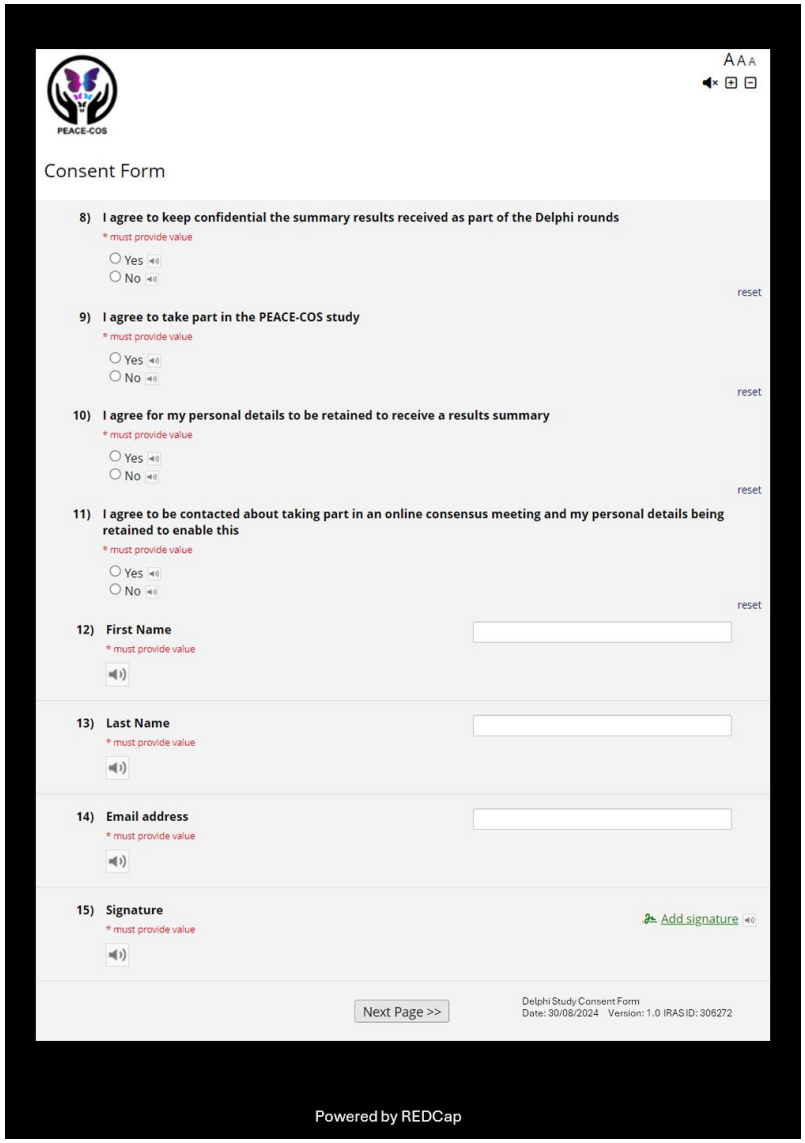
Please select your professional group
*must provide value
○ Patient
○ Family member or friend
○ Health professional or Religious leader
○ Researcher
○ None of the above
reset

Submit

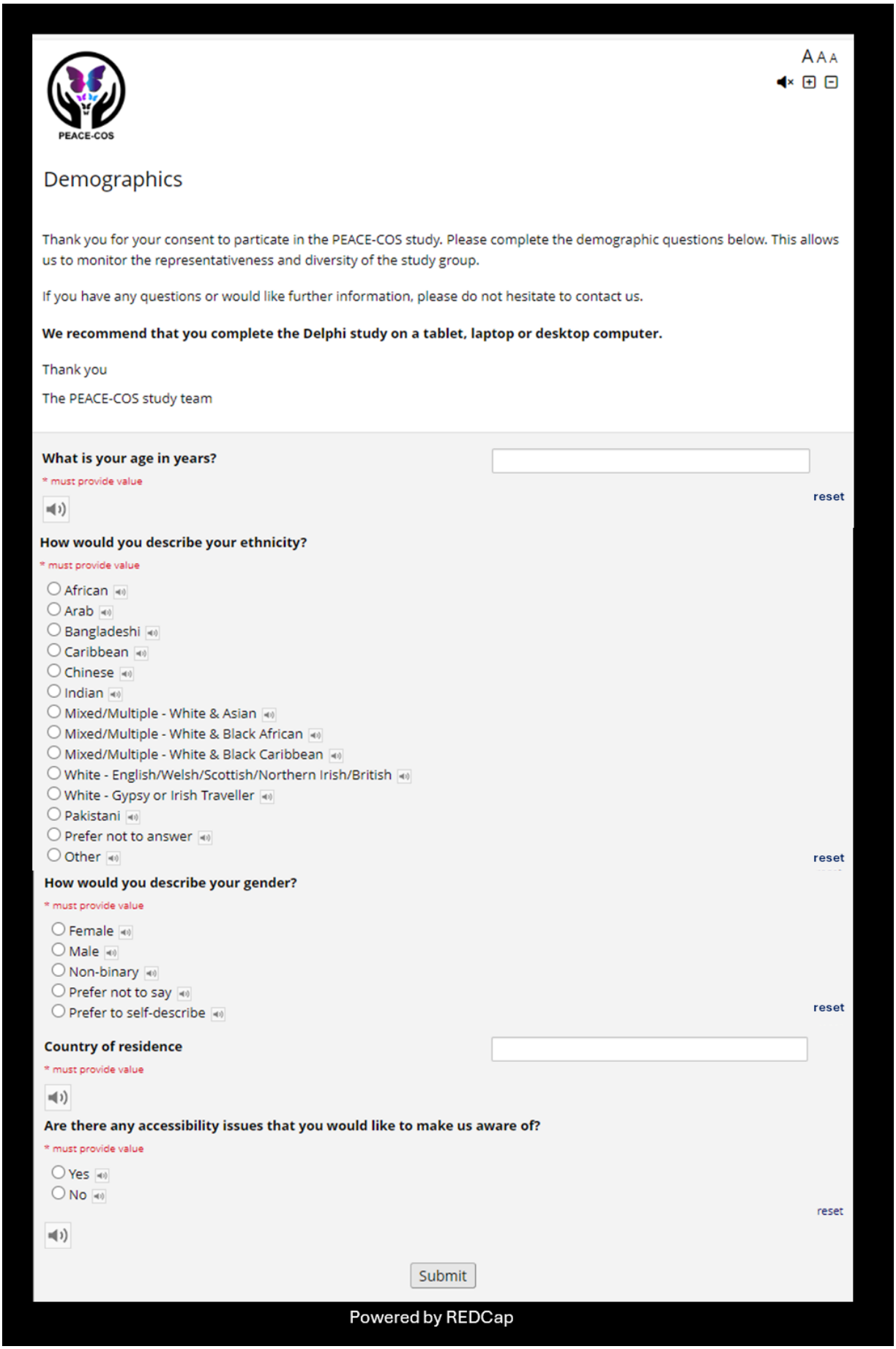
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Appendix 50 Stage Three e-Consent form





Appendix 51 Stage Three demographics questionnaire



PEACE-COS

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Demographics

Thank you for your consent to particate in the PEACE-COS study. Please complete the demographic questions below. This allows us to monitor the representativeness and diversity of the study group.

If you have any questions or would like further information, please do not hesitate to contact us.

We recommend that you complete the Delphi study on a tablet, laptop or desktop computer.

Thank you

The PEACE-COS study team

What is your age in years?

* must provide value

reset

How would you describe your ethnicity?

* must provide value

- African
- Arab
- Bangladeshi
- Caribbean
- Chinese
- Indian
- Mixed/Multiple - White & Asian
- Mixed/Multiple - White & Black African
- Mixed/Multiple - White & Black Caribbean
- White - English/Welsh/Scottish/Northern Irish/British
- White - Gypsy or Irish Traveller
- Pakistani
- Prefer not to answer
- Other

reset

How would you describe your gender?

* must provide value

- Female
- Male
- Non-binary
- Prefer not to say
- Prefer to self-describe

reset

Country of residence

* must provide value

Are there any accessibility issues that you would like to make us aware of?

* must provide value

- Yes
- No

reset

Submit

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Appendix 52 Round One instructions

PEACE-COS

AAA

Round One Instructions

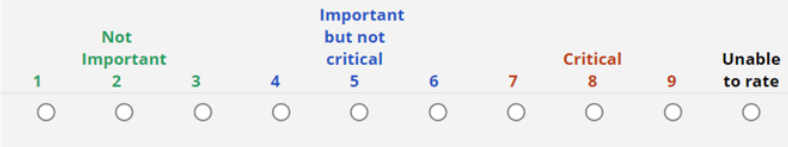
Your input will play a significant role in shaping the future of end-of-life care research in critical care. We are eager to know which outcomes you believe are the most important and should be included in all future research studies as part of a core outcome set.

A core outcome set aims to measure the most important outcomes.

We recommend that you complete the Delphi study on a tablet, laptop or desktop computer. Using a mobile phone will not allow you to see all the rating scale.

Questions to answer

Please look at each outcome in the list and answer **how important you feel it is that the outcome is included in all research.**
Please rate each outcome using the scale of 1 (not important) to 9 (critically important) to include in all research.



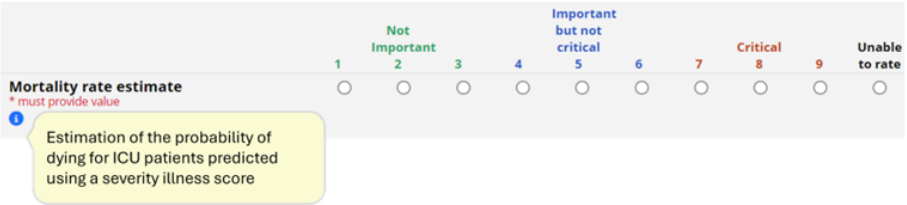
If you think an outcome is **not important** you should score between **1 to 3**.

If you think an outcome is **important but not critical** score between **4 to 6**.

If you think an outcome is **critical** you should score between **7 to 9.**

You can select *'unable to rate'* if you feel unable to rate the outcome. Please add any comments you have about the outcomes in the comment box.

A description of each outcome is available when you select the icon



Additional support

We understand that thinking about end-of-life care might be emotional or distressing for some people. It can make you feel upset, angry, sad and cry.

Each outcome description has been written sensitively by a researcher with appropriate training and with patient and public involvement. If you do feel upset or distressed at any point, you can pause, take a break or stop altogether, depending on your wishes.

A list of bereavement support services is also available on the study website.

Thank you for your time.

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Appendix 53 Public Involvement in Research group (PIRg) in eDelphi study

Research Area	Comments	How PIRg informed and/or influenced the research
	I did notice that the wording (range of people/participants) rather than (a diverse range of people/participants) was used. Was there a reason behind this?	Wording changed to include the word diverse in the sentence a diverse range of people/participants
	There are also two words that should be changed; anonymised and pseudonymised. I am not exactly sure what they mean	The following was added: • All transcripts will be pseudonymised (real names replaced). • We will write up the results and may use anonymised direct quotes (where your identity is not disclosed) in publications.
Participant information sheet	"Patients who were given a limited chance of survival" I'm not sure this sentence helps the paper at all. It simply reminds/confirms the participants or their loved ones of the situation they are in. Even worse it could provide some false hope.	*"Patients who were given a limited chance of survival*" changed to critical care survivors who were given a limited chance of survival whilst in critical care. This population has been added as there has previously been no response from family members, so we need to look at additional proxy measures.
	In the opening section you offer a "different format". Someone who is not familiar with PCs may not know what this can be. Would it be possible to provide some examples?	The format of the participant information sheet would depend on the participants' accessibility needs. In line with the accessibility statement of the study website, we would explore with the individual and try to facilitate accordingly. So, if someone wanted large text or a voice recording, we would provide this as a reasonable adjustment.
	The sheet is certainly readable and understandable although I think consideration needs to be given to who will participate and the mental stress that person may be experiencing at the time of the study.	We have developed a range of support documents and sign-post participants to relevant charities and health organisations. REDCap set up to enable people to pause and return at a later date. Participants are able to contact the study team.

	I do wonder though if it is not too long for someone who does not have English as a first language, or is for example dyslexic. Could it therefore inadvertently filter out some groups of people? Personally, I find that the researchers who have to cover themselves legally give far more information than people with lived experience feel that they need, but there's probably not much you can do about that.	
Participant information sheet	All understandable and easy to read	
	The participant information sheet is both clear and understandable	No changes
Social Media assets	I'd choose a picture which had actual people in, since this is a person-centred study (not the one with medical machines only) and personally one with an older person as again that more relates to the topic.	Social media graphics chosen using people
	I like opinion 1,3,5,6 and 7	Social media graphics chosen to use 1,3,5,6,7
	All images show collaboration.	
	All very readable and understandable	No changes
	All understandable and easy to read.	
Round 1 questions	Individually, in the delphi questions document, the descriptions all look fine. But there is a lot to read.	We have been trying to reduce the number and will continue to try to reduce it. It has to be balanced with the granularity of the data which is challenging.
	In the section social burden. Stress	Horror is one of the key measures used to assess symptoms of peritraumatic distress. Other synonyms were discussed but the overall consensus was to use horror.
	The use of the word Horror doesn't seem right	
Overall	All understandable and easy to read	
	While the content and actual questions were difficult to come to terms with (my own personal memories I'm afraid) I cannot think of anyway that could be changed for the better.	No changes

Appendix 54 Stage Three organisations approached

Location	Acronym	Organisation	eDelphi promotion route
		Promoting eDelphi	
France	FAMIREA	Groupe de Recherche Famirea	Membership
UK	ACPRC	Association of Chartered Physiotherapists in Respiratory Care	Membership
UK	APM	Association for Palliative Medicine	Membership
UK	BACCN	British Association of Critical Care Nurses	Membership, social media, website
UK	CC3N	Critical Care National Network Nurses Lead Forum	Membership, social media
UK – England	EOECCN	East of England Critical Care Network	Membership
UK	EPCIN	End-of-Life and Palliative Care in the ICU Network	Membership, social media
UK	FICM	Faculty of Intensive Care Medicine	Newsletter, social media and website
UK	ICS	Intensive Care Society	Newsletter, membership, social media, web
UK – England	NWLCCN	North West London Critical Care Network	Social media
UK	RCN	Royal College of Nursing	Social media
UK – England	SWCCN	South West Critical Care Network - Pharmacy	Membership
UK – England	TVWCCN	Thames Valley and Wessex Critical Care Network	Membership
UK	UKCCRG	UK Critical Care Research Group	Membership
UK – Wales	WICSART	Welsh Intensive Care Audit and Research Trainee Network	Membership
UK		ICU Steps	Membership, social media
UK - England		NHS England Palliative and End-of-Life Network	Membership
UK		Sepsis Trust UK	Newsletter, membership, social media
UK		The Brain Tumour Charity	Newsletter, membership, social media
USA	AACN	American Association of Critical Care Nurses;	Membership

Location	Acronym	Organisation	eDelphi promotion route
		Unable to support eDelphi	
Australia	ACCCN	Australian College of Critical Care Nurses;	None ACCN membership required
Australia/New Zealand	ANZICS	Australian and New Zealand Intensive Care Society	None no response to application
Canada	CCCS	Canadian Critical Care Society	None cost prohibitive
Canada	CACCN	Canadian Association of Critical Care Nurses	None cost prohibitive
Europe	EfCCNa	European Federation of Critical Care Nursing Associations	None no response to application
Europe	ERS	European Respiratory Society	None no response to application
Europe	ICSI	Intensive Care Society of Ireland	No response to application
Europe	ESICM	European Society of Intensive Care Medicine;	None ESICM unable to process within timelines
New Zealand	MRINZ	Medical Research Institute of New Zealand	None no response to application
UK	CCSN	Critical Care Support Network	None no response to application
UK	CHCC	College of Health Care Chaplains	None no response to application
UK	CRUISE	CRUISE Bereavement support	None no response to application
UK	ICNARC	Intensive Care National Audit and Research Centre	None no response to application
UK	KSSCCN	Kent, Surrey and Sussex Critical Care Network	None no response to application
UK	NECCN	North of England Critical Care Network	None no response to application
UK	NIHCA	Northern Ireland Hospital Chaplains Association	None no response to application
UK - Scotland	SICS	Scottish Intensive Care Society (SICS)	None no response to application
UK - Wales	WICS	Welsh Intensive Care Society	None no response to application
UK	UKCPA	UK Clinical Pharmacy Association (UKCPA)	None UKCPA membership required
USA	SCCM	Society of Critical Care Medicine	None cost prohibitive

Appendix 55 Round One no consensus outcomes amended

Original outcome	Original description	Participant comments	Action
Core outcome domain: 25: Physical functioning outcomes			
Functional status	The patient's ability to undertake activities of daily living independently eg bathing, dressing, toileting, feeding, continence and bed mobility	• *"Unable to rate this unless a better definition is provided."* [S3R109] • *"Not sure to what that outcome refers".* [S3R124]	**Description amended:**The patient's ability to undertake activities of daily living independently eg bathing, dressing, toileting, feeding, continence and bed mobility **using a validated tool**
Core outcome domain: 29: Cognitive functioning outcomes			
Delirium	Number or percentage of patients with symptoms of delirium eg uncontrolled spontaneous movements, agitation, restlessness	*"Delirium is too vague - needs clarification."* [S3R124]	**Description amended:**Number or percentage of patients with symptoms of delirium **assessed through a validated delirium screening tool**. **The word "delirium" is used to describe a severe state of confusion**. eg uncontrolled spontaneous movements, agitation, and restlessness

Original outcome	Original description	Participant comments	Action
Core outcome domain: 32: Delivery of care – care satisfaction			
Caregiver Self-Efficacy in the ICU	Family member assessment of their ability to contribute to patient care	• *"Self-Efficacy is a technical social sciences term that's not going to be well-understood be a lot of respondents to this survey."* [S3R109] • *"I don't understand what caregiver self efficacy is."* [S3R136HP] • *"Caregiver self efficacy - a better question would be whether they were invited to be involved in patient care should they so wish eg mouthcare, washing patient."* [S3R166]	**Outcome renamed: Caregiver belief in their ability to contribute to patient care**
Satisfaction with continuity of care	Satisfaction with the number of doctors and nurses looking after the patient and the ability of the ICU to provide continuing care for the patient	• *"Difficult to answer because it wasn't always clear if the outcome was measured from the family or clinician perspective."* [S3R143] • *"Whose satisfaction is being measured for the outcome? Service user/family/MDT? All have value."* [S3R146]	**Outcome renamed: Family** satisfaction with continuity of care
Satisfaction with quality of care	Family member and/or staff satisfaction with the quality of care delivered to the patient and their family	• *"Being able to deliver a high standard of care is very important. Knowing you did a good job can be very important and satisfying to the individual nurse."* [S3R174] • *"Would be much clearer to have separate sections for patient, family and staff satisfaction."* [S3R166]	**Outcome split and renamed:** i) **Family** satisfaction with quality of care ii) **Staff** satisfaction with quality of care **Description split and amended:** i) **Family** satisfaction with the quality of care delivered to the patient and their family

			ii) **Staff** satisfaction with the quality of care delivered to the patient and their family
Satisfaction with emotional and practical support	Family satisfaction with the emotional and practical support provided whilst in ICU. Examples include accommodation, counselling, orientation to the ICU, and information, being attentive to the distress of the family member	• *"Better to separate emotional and practical support"* [S3R166].	**Outcome renamed:** **Family** satisfaction with emotional and practical support
Satisfaction with collaborative working	Staff assessment of the process of working with members of the ICU and multi-disciplinary team to achieve a common goal.	• *"Would be much clearer to have separate sections for patient, family and staff satisfaction."* [S3R166]	**Outcome renamed:** **Staff** satisfaction with collaborative working
Satisfaction with patient management	Staff satisfaction with the total overall care provided to the patient	• *"Whose satisfaction is being measured for the outcome?"* [S3R146]	**Outcome renamed:** **Staff** satisfaction with patient management
Core outcome domain: 32: Delivery of care – decision making			
Satisfaction with decision-making	Satisfaction with decision-making processes	• *"Difficult to interpret what is being asked."* [S3R1135] • *"Satisfaction in relation to decision making is not reflective of conflict resolution or barriers, I think the correct measure would be 'information provision and understanding of rationale in relation to decision making."* [S3R146]	**Outcome split and renamed:** i) **Family** satisfaction with decision-making processes ii) **Staff** satisfaction with decision-making processes

Patient and family involvement	The number or percentage of patients/family members involved in communication and decision-making processes includes being able to be present at end-of-life	• *"I would rate patient and family involvement much higher if it were worded ' to the extent that they wish to be involved."* [S3R172]	**Outcome description amended**: The number or percentage of patients/family members involved in communication and decision-making processes **to the extent that they wished to be involved,** includes being able to be present at end-of-life
Concordant care	To what extent the patient's treatment is aligned (matched) with their preferences, values and beliefs (eg measured through indication of cardiopulmonary resuscitation, dialysis, mechanical ventilation, chemotherapy, parenteral nutrition, and palliative care in the medical record)	• *"Concordant care - important but likely impossible to measure."* [S3R166] • *"Questions about concordant care should also put decisions in to context of what treatment would offer symptom control or improve chances of survival. A patients wishes may not reflect what is possible."* [S3R173] • *"I think concordant care is what is being aimed for but I don't think it is possible to objectively measure."* [S3R1117]	**Outcome renamed:** **Care aligned with patient preferences, values and beliefs**
Do Not Resuscitate (DNR) orders	The number or percentage of patients with a DNR order documented in the patient record. A DNR order simply states that no attempts should be made to restart breathing or restart the heart if it stops	• *"As a footnote can we change DNR to DNACPR."* [S3R1124]	**Outcome renamed:** Do Not **Attempt Cardiopulmonary** Resuscitation (DNACPR) orders **Description amended**: The number or percentage of patients with a **DNACPR** order documented in the patient record. A **DNACPR** order simply states that no attempts should be made to restart breathing or restart the heart if it stops

Core outcome domain: 32: Delivery of care - withdrawal			
Withdrawal of mechanical ventilation (terminal wean)	The number or percentage of patients who had mechanical ventilation withdrawn through terminal wean. Terminal wean is a gradual decrease in ventilatory support over a period of time	• *"Consider using a different term for withdrawn."* [S3R143] • *"Terminal wean, what would be measured?"* [S3R146]	**Outcome renamed: Withdrawal by gradual decrease in ventilatory support** **Description amended**: The number or percentage of patients who had mechanical ventilation **discontinued** through terminal weaning. Terminal weaning is a gradual decrease in ventilatory support over a period of time, **then the ventilation support is discontinued**.
Core outcome domain: 36 Further investigation - MDT			
Pastoral care involvement	Number or percentage of patients who received pastoral care involvement as documented in the medical record whilst in ICU. Pastoral care includes spiritual and religious leader involvement	• *"Involvement-a referral, a telephone consultation, regular and lengthy involvement?"* [S3R146] • *"I would like to capture them by a general measure of the appropriateness of involving various HCPs / specialists, which will include different combinations."* [S3R172]	**Description amended:** Number or percentage of patients who received pastoral care involvement as documented in the medical record whilst in ICU. Pastoral care includes involvement from spiritual and religious leaders**. Examples of involvement include consultation, review or advice**
Physiotherapist involvement	Number or percentage of patients who received physiotherapist involvement as documented in the medical record whilst in ICU	• *"Involvement-a referral, a telephone consultation, regular and lengthy involvement?"* [S3R146]	**Description amended:** Number or percentage of patients who received physiotherapist involvement as documented in the medical record whilst in ICU. Pastoral care includes involvement from spiritual and religious leaders**. Examples of**

			involvement include consultation, review or advice
Core outcome domain: 36 Further investigation -			
Modalities of end-of-life processes	The number of changes to end-of-life care after a decision to withhold or withdraw treatment	• *"'Modalities of end-of-life processes' I don't understand the outcome measure."* [S3R146]	**Outcome renamed: Changes to end-of-life processes**
Rate of decision to withhold and withdraw therapies	The frequency with which certain treatments are withheld or withdrawn. Withholding refers to not starting specific treatments while withdrawal involves stopping ongoing treatments.	• *"'Rate of decision'-I do not understand what rating is used."* [S3R146] • *"What do you mean by "Rate of decision to withhold and withdraw life-sustaining therapies"?"* [S3R1123]	**Description amended:** The frequency **within a given population** where certain treatments are withheld or withdrawn. Withholding refers to not starting specific treatments while withdrawal involves stopping ongoing treatments
Core outcome domain: 37 Social burden – anxiety and depression			
Symptoms of anxiety	Family member or staff symptoms of anxiety eg excessive worry, fear, or nervousness about future events or situation	• *"I would separate family and staff symptoms."* [S3R143] • *"It would also be of value to consider whether this is a pre-existing symptom, related to death and dying or environmental."* [S3R146] • *"Combine anxiety and depression."* [S3R1123]	**Outcome split and renamed:** i) **Family** symptoms of anxiety ii) **Staff** symptoms of anxiety **Description split and amended:** iii) **Number or percentage of family members with** symptoms of anxiety eg excessive worry, fear, or nervousness about future events or situations. iv) **Number or percentage of staff with** symptoms of anxiety eg excessive worry,

			fear, or nervousness about future events or situations
Symptoms of depression	Family member symptoms of depression eg persistent feeling of sadness, hopelessness, and a lack of interest or pleasure in activities	• *"It would also be of value to consider whether this is a pre-existing symptom, related to death and dying or environmental."* [S3R146] • *"Combine anxiety and depression."* [S3R1123]	**Outcome rename:** **Family member** symptoms of depression **Outcome split and renamed:** **i)** **Family** symptoms of anxiety and depression **ii)** **Staff** symptoms of anxiety and depression **Description split and amended:** **iii)** **Number or percentage of family members with** symptoms of anxiety and depression **using a validated tool** eg excessive worry, fear, or nervousness about future events or situations, persistent feeling of sadness, hopelessness, and a lack of interest or pleasure in activities **iv)** **Number or percentage of staff with** symptoms of anxiety and depression **using a validated tool** eg excessive worry, fear, or nervousness about future
Symptoms of anxiety and depression	Family member or staff symptoms of anxiety and depression	• *"I would separate family and staff symptoms."* [S3R143] • *"Need to separate out family member and staff mental health issues*." [S3R166] • *"This would be quite difficult to quantify - everyone that goes through grieving will have transient signs of depression/anxiety to a certain degree."* [S3R1127]	

			events or situation, **persistent feeling of sadness, hopelessness, and a lack of interest or pleasure in activities**
Symptoms of depression, anxiety, and stress	Family member and/or staff symptoms of anxiety, depression and stress	• *"I would separate family and staff symptoms."* [S3R143] • *"Need to separate out family member and staff mental health issues*. Need to also ensure that these relate specifically to clinical work, not background status." [S3R166] • *"There is a lot of overlap in the first 4 terms"* [S3R172] • "Combine anxiety, depression and stress." [S3R1123]	**Outcome split and renamed:** **i)** **Family** symptoms of depression, anxiety and stress **ii)** **Staff** symptoms of depression, anxiety and stress **Description split and amended:** **iii)** **Number or percentage of family members with** symptoms of depression, anxiety and stress **using a validated tool** **iv)** **Number or percentage of family members with** symptoms of depression, anxiety and stress **using a validated tool**
Core outcome domain: 37 Social burden – stress			
Symptoms of peritraumatic distress	Family member symptoms of peritraumatic distress eg fear, helplessness or horror	**No comments but outcome amendment in line with other outcome changes to ensure consistency across the outcome set**	**Outcome renamed:** **Family member** symptoms of peritraumatic distress **Description amended:** **Number or percentage of** family members with symptoms of peritraumatic distress eg fear, helplessness or horror
Symptoms of dissociation	Family member symptoms of a sense of detachment, altered	**No comments but outcome amendment in line with other outcome changes to ensure consistency across the outcome set**	**Outcome renamed:** **Family member** symptoms of dissociation

	perception, or feeling disconnected from reality		**Description amended:** **Number or percentage of** family members **with** symptoms of a sense of detachment, altered perception, or feeling disconnected from reality **Outcome split and renamed:** **i)** **Family** symptoms of post-traumatic stress disorder (PTSD) **ii)** **Staff** symptoms of post-traumatic stress disorder (PTSD) **Description split and amended:** **iii)** **Number or percentage of family members with** symptoms of post-traumatic stress disorder (PTSD) **using a validated tool** **iv)** **Number or percentage of family members with** symptoms of post-traumatic stress disorder (PTSD) **using a validated tool**
Symptoms of post-traumatic stress disorder (PTSD)	Family or staff member symptoms of post-traumatic stress disorder (PTSD)	*"Need to separate out family member and staff mental health issues. Need to also ensure that these relate specifically to clinical work, not background status."* [S3R166]	
Emotional and psychological well-being	Self-reported emotional and psychological well-being in family members and/or staff. Includes an assessment of their health, tension, energy, cheerfulness, fear, anger, sadness and general wellbeing	**No comments but outcome amendment in line with other outcome changes to ensure consistency across the outcome set**	**Outcome split and renamed:** **i)** **Family members** emotional and psychological well-being **ii)** **Staff** emotional and psychological well-being **Description split and amended:** **iii)** Self-reported emotional and psychological well-being in **family members**. Includes an assessment of their health, tension, energy, cheerfulness, fear, anger, sadness and general wellbeing

			iv) Self-reported emotional and psychological well-being in **staff**. Includes an assessment of their health, tension, energy, cheerfulness, fear, anger, sadness and general wellbeing
Morbidity	Presence of new or worsening health conditions (morbidity) in family members or staff as a consequence of their ICU experience	**No comments but outcome amendment in line with other outcome changes to ensure consistency across the outcome set**	**Outcome split and renamed:** **i)** **Family** morbidity **ii)** **Staff** morbidity **Description split and amended:** **iii)** **Number or percentage of family members with** new or worsening health conditions (morbidity) as a consequence of their ICU experience **of a family member receiving end-of-life care or dying in ICU** **iv)** **Number or percentage of staff with** new or worsening health conditions (morbidity) as a consequence of their ICU experience **of being involved in patients receiving end-of-life care or dying in ICU**
Core outcome domain: 37 Social burden – grief			

Symptoms of prolonged grief	Number or percentage of family members with symptoms of prolonged grief. Prolonged grief is characterised by a persistent and pervasive grief response that lasts for an extended period, typically more than six months after the loss. Family member symptoms of complicated grief. Complicated grief involves intense and persistent feelings and responses related to the loss. These emotions can be debilitating and interfere with daily functioning	**No comments but outcome amendment in line with other outcome changes to ensure consistency across the outcome set**	**Outcome renamed:** **Family member** symptoms of prolonged grief
Symptoms of complicated grief		**No comments but outcome amendment in line with other outcome changes to ensure consistency across the outcome set**	**Outcome renamed:** **Family member** symptoms of complicated grief
	Core outcome domain: 37 Social burden		
Difficulty in managing family in end-of-life issues	Staff overall rating of the difficulty in interacting with the family in the patients end-of-life management	**No comments but outcome amendment in line with other outcome changes to ensure consistency across the outcome set**	**Outcome renamed:** **Staff** difficulty in managing family in end-of-life issues
Decision regret	Family assessment of distress or remorse after a healthcare decision	**No comments but outcome amendment in line with other outcome changes to ensure consistency across the outcome set**	**Outcome renamed:** **Family** decision regret

Decision conflict	Disagreement or tension between healthcare professionals, family or patients involved in making a decision	• *“Decision conflict hard to measure - or are you suggesting these for prospective as well as retrospective studies?” [S3R166]*	**No change to the outcome or description but the explanation of scope of COS and participant instructions**

Appendix 56 Round One outcomes proposed actions

Proposed outcome	Participants proposing outcome N	Mapped to existing outcome	Existing outcome description	Steering group agreed proposed outcome included in Round Two
		01: Mortality		
Actual cause of death	2	None	N/A	No – inconsistent international approaches
Adjusted mortality rate	1	None	N/A	No – inconsistent international approaches
How people die	1	None	N/A	No – inconsistent international approaches
All cause mortality	1	Mortality rate	Number or percentage of patients who die within 60 and 90 days after a specified event	No but **description modified**: Number or percentage of patients who die within 60 and 90 days after a specified event **from any cause**
DNR mortality	1	None	N/A	No – only proposed by one participant
Long-term mortality 6 -12 months	1	Morality rate	Number or percentage of patients who die within 60 and 90 days after a specified event	No – Time point of measurement does not make an outcome unique and only proposed by one participant
Palliative care mortality	1	Outside of COS scope	N/A	No – outside of COS score

Time between identification of dying and death	1	Survival time	Median time in days until death	No - covered by existing outcome
Time between withdrawal and death	1	Duration of end-of-life processes	Number of days from the decision to forgo life-sustaining treatments to death	No - only proposed by one participant
14: Metabolism and nutrition outcomes				
Signs of dehydration	1	None	N/A	No – only proposed by one participant
22: Respiratory, thoracic and mediastinal outcomes				
Laboured breathing	1	Respiratory distress	Number or percentage of patients who experience respiratory distress eg breathlessness	No - covered by existing outcome
Secretion burden	1	Respiratory comfort	Patient's breathing comfort evaluated by healthcare professionals observation includes pain, presence of respiratory secretions	No - covered by existing outcome
25: Physical functioning outcomes				
Disability	1	Functional status	The patient's ability to undertake activities of daily living independently eg bathing, dressing, toileting, feeding, continence and bed mobility	No - covered by existing outcome and only proposed by one participant
28: Emotional functioning outcomes				

Distress levels at the time of withdrawal	1	None	N/A	No – only proposed by one participant
30: Global quality of life outcomes				
Patients' and families' perception of quality of life	1	Patient quality of life	Family assessed patient quality of life	No - covered by existing outcome
Perceived future quality of life	1	Patient quality of life	Family assessed patient quality of life	No - covered by existing outcome
32: Delivery of care – End-of-Life				
Any death preparation	1	Preparation for dying	Family are informed about the possibility that their loved one could die from the illness during the last hospitalisation	No - covered by existing outcome
Personalisation of care and intervention	1	Personalising dying	Recognising and understanding the unique experiences and needs of the patient as an individual during the dying phase. This includes personalising the environment, individual care plan	No - covered by existing outcome
Attempt to increase awareness	1	Preparation for dying	Family are informed about the possibility that their loved one could die from the illness during the last hospitalisation	No - covered by existing outcome
32: Delivery of care – Care Satisfaction				

Oral care plan or plan for oral care	1	None	N/A	No – only proposed by one participant
NACEL measures in terms of information sharing:				
- Possibility that the patient may die had been discussed with the patient	1	None	N/A	No – only proposed by one participant
- Possibility that the patient may die had been discussed with families and others	1	Preparation for dying	Family are informed about the possibility that their loved one could die from the illness during the last hospitalisation	No - covered by existing outcome
32:Delivery of Care - Communication				
Information needs met	1	Satisfaction with end-of-life communication	Satisfaction with the communication and support provided to the patient, their family and all the medical staff (including ICU, other teams, eg, cardiology, palliative care), involved in the patient's care. This includes online communication methods such as video calls, as well as frequency of communication.	No - covered by existing outcome

Satisfaction with information provision	1	Satisfaction with end-of-life communication	Satisfaction with the communication and support provided to the patient, their family and all the medical staff (including ICU, other teams, eg, cardiology, palliative care), involved in the patient's care. This includes online communication methods such as video calls, as well as frequency of communication.	No - covered by existing outcome
Communication of dying	1	None	N/A	Yes - Families and others were notified that the patient was about to die
Families and others were notified that the patient was about to die	1	None	N/A	Yes - Families and others were notified that the patient was about to die
32: Delivery of care – Decision making				
Patient was involved in discussing the individualised plan of care	1	Patient and family involvement	The number or percentage of patients/family members involved in communication and decision-making processes includes being able to be present at end-of-life.	No - covered by existing outcome
Families and others were involved in discussing the individualised plan of care	1	Patient and family involvement	The number or percentage of patients/family members involved in communication and decision-making processes includes being able to be present at end-of-life.	No - covered by existing outcome

Documented decision on why extubation/sedation reduction is not possible	1	None	N/A	No – only proposed by one participant
Identification of dying	1	None	N/A	No – only proposed by one participant
Understanding of rationale in relation to decision-making	1	None	N/A	No – only proposed by one participant
34: Economic				
Hospice transfer cost	1	None	N/A	No – only proposed by one participant
Re-orientation to home palliative care cost	1	None	N/A	No – only proposed by one participant
35: Hospital				
Discharge home	1	Discharge location	The location where the patient is discharged from ICU and hospital	No - covered by existing outcome
Hospital free days	1	None	N/A	No – only proposed by one participant
Length of ICU admission prior to ICU mortality	1	ICU length of stay	Number of days (duration) the patient is alive in ICU	No - covered by existing outcome

Length of ICU admission prior to hospital mortality	1	Hospital length of stay	Number of days the patient is alive in the hospital. This includes the length of time the patient spends in the ICU until hospital discharge or death	No - covered by existing outcome
Side room use	1	None	N/A	No – only proposed by one participant
36: Further investigations processes, procedures				
Number of PRNs at time of withdrawal	1	None	N/A	No – only proposed by one participant
Pain-relieving drugs consumption	1	None	N/A	No – only proposed by one participant
Re-admission rate	1	Hospital readmission rate	The number or percentage of patients who are readmitted to the hospital after hospital discharge	No - covered by existing outcome
Re-intubation	1	Non-beneficial interventions	Number or percentage of patients receiving nonbeneficial interventions e.g., mechanical ventilation, cardiopulmonary resuscitation, acute dialysis, tracheotomy, surgical feeding tube placement, antibiotics	No - but description amendment adapted to include re-intubation
37: Social burden - stress				
Emotional well-being	1	Emotional and psychological well-being	Self-reported emotional and psychological well-being in family members and/or staff. Includes an assessment of their health, tension,	No - covered by existing outcome

	energy, cheerfulness, fear, anger, sadness and general wellbeing

Appendix 57 Round One description exemplar quotes

Theme sub theme	**Description**		***Illustrative quote***
Assessor			
Assessor subjectivity	Comments about the subjectivity of the assessor	S3R146HP	*"One professionals interpretation of nonbeneficial intervention, is another professionals essential intervention."*
		S3R174HP	*"However, collecting data on good communication skills can be challenging as everyone's impression of good communication skills can be different."*
		S3R186HP	*"Would need to really define "beneficial interventions" as this could conflict between patient, family and staff."*
Proxy assessor	Comments about proxy assessors	S3R172HP	*"Important but very difficult to reliably measure, especially when done by proxy (family), so most studies will not be able to do this well."*
		S3R112HP	*"Important to recognise that only the patient themselves can describe this (similar to ethnicity) - impression of professionals or advocates is not reliable or meaningful."*
		S3R1135HP	*"This is important but as it needs to be subject to the individual not the health care professional."*
Who is assessing	Comments about who is the outcome assessed by	S3R109HP	*"Who's assessing this - often the patient won't be able to communicate so is this professional or relative?"*
		S3R166HP	*"Are you asking for staff to rate their satisfaction and competency or for relatives to rate staff competency?"*
		S3R143R	*"This page was difficult to answer because it wasn't always clear if the outcome was measured from the family or clinician perspective."*

P = Patient/family HP = Health professional R = Researcher

Theme sub theme	**Description**		***Illustrative quote***
Clarity			
Context	Comments that the description needs context	S3R131HP	*"Some context is needed - to understand whether those with high expected mortality get different treatment for those with initial low mortality predictions."*
		S3R136HP	*"This question lacks context to frame the response."*
		S3R173HP	*"Withhold and withdraw questions needs to be in context of situations such as waiting for close family to arrive and be with the patient."*
Needs defining	Comments that the description needs further defining	S3R109HP	*"Unable to rate this unless a better definition is provided."*
		S3R131HP	*"These should have a clear defined measure, but important to assess."*
		S3R186HP	*"Would need to really define "beneficial interventions" as this could conflict between patient, family and staff."*
Needs rewording	Comments that the description should be reworded	S3R108HP	*"This outcome should be reworded to simply 'Comfort' or Pain Control and Comfort' because pain and comfort are opposites."*
		S3R166HP	*"Quality of death and dying is a clumsy phrase and therefore prob meaningless."*
		S3R143R	*"Consider using a different term for withdrawn."*
Unclear	Comments on the description being unclear	S3R109HP	*"I presume these are in family members not the patient?? not very clear."*
		S3R166HP	*"Patient and family involvement - really unclear and depends on so many factors!!"*
		S3R1123P	*"That patients/relatives should be made aware of costs? That costs (which clearly are very high in ICU) should influence the care provided?"*

Theme sub theme	**Description**		***Illustrative quote***
Focus			
Format	Comments on how the description is presented	S3R136HP	*"These are not metabolism and nutrition outcomes."*
		S3R143R	*"Some of these measures were patient level were as others were defined as a percentage of family members. I would recommend that the definitions are formatted similarly."*
Requires expanding	Comments that the outcome is too narrow and needs to consider other aspects	S3R131HP	*"Awareness should include a measure of if there has been an attempt to increase awareness. For example, any patient sedated and ventilated - is there a documented decision on why extubation/sedation reduction is not possible."*
		S3R146HP	*"It would also be of value to consider whether this is a pre-existing symptom, related to death and dying or environmental."*
		S3R187HP	*"Under preparation for dying; needs to consider timing and chance for questions to be answered."*
Separate outcome	Comments on the need to separate outcomes	S3R146HP	*" I would also suggest that these are two separate outcomes and should not be measured together."*
		S3R166HP	*"Better to separate emotional and practical support."*
		S3R143R	*" I would separate family and staff symptoms."*
Granularity	Comments on the level of detail	S3R146HP	*"I don't think these outcomes are specific enough."*
		S3R1117HP	*"Some measure of satisfaction is important but don't think it should be so granular."*
		S3R214R	*"Delirium is too vague."*

Theme sub theme	**Description**		***Illustrative quote***
OMI			
Which instrument or tool	Comments on which instrument or tool	S3R109HP	*"on EQ5D or SF36 of using a specific palliative care type instrument?"*
		S3R146HP	*"It is not specified what tools, if any would be used to measure these outcomes."*
		S3R167R	*"These are all important outcomes although many don't have corresponding adapted tools."*
Reliability	Comments on the ability to produce consistent and stable results	S3R109HP	*"How good are the tools available to consistently assess these - very poor I think."*
		S3R131HP	*"Respiratory secretions can often be seen as distressing to ICU staff despite evidence they are not."*
Timepoint			
Timing	Comments on the timing of the outcome	S3R109HP	*"When hoe [sic] long and who's opinion."*
		S3R166HP	*"It would be really important to specify QOL over what period."*
		S3R1117HP	*"I would expect these to change over time and so be very sensitive to when the questionnaire was administered."*
Needs multiple timepoints	Comments on expanding the description to include multiple time points	S3R131HP	*"This should be looked at, at multiple times: prior to admission, at time of enrollment to research."*
		S3R117HP	*"I think longer term mortality 6 - 12 months is also important for patients and their families."*
		S3R1117HP	*"Survival time would be useful to have at 30, 60, 90 days + 1 year, 3yr, 5yr."*

Theme sub theme	**Description**		***Illustrative quote***
Understanding			
Instructions	Comments relating to not understanding questionnaire instructions	S3R1117HP	*"Not clear to me whether these metrics are about the general ICU care or the care around EOL."*
		S3R164HP	*"Not really sure what's being asked here."*
		S3R166HP	*"Are you asking which are most important? which are easiest to measure? which would most likely guide future care? Which are most modifiable?"*
Terminology	Comments relating to not understanding the terminology	S3R109HP	*"Self-Efficacy is a technical social sciences term that's not going to be well-understood be a lot of respondents to this survey."*
		S3R136HP	*"I don't understand what caregiver self efficacy is."*
		S3R1123P	*"Apologies but I am not clear what you mean by "use of nonbeneficial interventions". Aren't mechanical ventilation, resuscitation, etc. used only if they benefit the patient?"*

Appendix 58 Round One reasons critical for inclusion exemplar quotes

Theme	Description		*Illustrative quote*
Aids funding and service provision	Comments where the outcome is considered to facilitate funding and service provision	S3R146HP	*"These outcomes when compared to other outcomes mentioned here e.g. preparedness of dying, quality of dying would be helpful in identifying areas that are costly and not serving service users or service delivery."*
		S3R173HP	*"All critical to evidence the effects on family members and need for additional resources to support such as funding for psychologists."*
		S3R174HP	*"As a nurse and in terms of ICU costs, I think it's extremely important for people to understand how much an ICU nurse *actually* does and to value our worth. Looking after one critically ill ICU patient can be extremely difficult and the high level of knowledge we need to have on certain medications and machinery cannot be overlooked as just a 'cost'."*
		S3R1131HP	*"Value for money is very important."*
Critical/essential aspect of EoLC	Comments where the outcome is considered a critical/essential or considered to be a priority in EoLC	S3R146HP	*"It is generally accepted that, as oppose to the general medical outcomes such as mortality or quantity of time beyond estimated prognosis, PEOLC prioritises quality of life as an outcome for service users and so I would state this is the MOST critical outcome."*
		S3R147P	*"Awareness of pain is most important. I do not remember much of my time in critical care, including pain levels."*
		S3R160R	*"A MDT approach to EoLC would be considered as the gold standard."*
		S3R1132HP	*"This is probably the most critical value to measure as pain at end of life is one of the most feared aspects of dying."*

P = Patient/family HP = Health professional R = Researcher

Theme	Description		*Illustrative quote*
Supports evidence-based decision-making	Comments on how the outcome supports evidence-based decision-making	S3R1104HP	*"I think more important to consider location of death (potentially important to family), survival (are we getting the diagnosis right in ICU?)."*
		S3R1117HP	*"Ethics consultation would need to be clearly defined. But would be good to have an understanding of the decision-making process."*
		S3R1127R	*"Where, when and how patients die following ICU admission is key to aid in accurate prognostication and increasing options for patients."*
		S3R146HP	*"Improvement or deterioration in function are important measures for PEOLC patients and a good signifier to professionals of increasing needs."*
Determines effectiveness	Comments on how the outcome would determine effectiveness	S3R130HP	*"If we are to understand the overmedicalisation of death and the unnecessary treatments/tests performed when the patient is in the last 12 months of life then a look at the number of procedures may provide vital data."*
		S3R146HP	*"vital data capture to measure the efficacy of care provision in response to patient needs."*
		S3R168R	*"These are all crucial factors, either to epidemiologists/ONS & specialist needs in certain areas."*

Theme	Description		*Illustrative quote*
Measures an existing gap or need	Comments on how the outcome measures an existing gap or need	S3R130HP	*"Not all respiratory outcomes are measured effectively or managed accordingly … Delirium again another under measured and treated symptom …Nausea and vomiting is often an overlooked symptom that can have significant impact on any outcome and experience."*
		S3R133P	*"I had the most awful abdominal pain and begged them for analgesia."*
		S3R152P	*"QOL is hugely underrated. As an ex-patient, I often find myself grieving for myself- yes, my life has been saved, but at what cost?"*
		S3R1124HP	*"Complicated grief is often unrecognised and requires more input."*
Impact on patient and/or family	Comments referring to the impact on the patient and/or family	S3R127R	*"Hunger/thirst/Nausea can be very difficult for family to see and experience and can be seen as pain."*
		S3R145HP	*"A focus on comfort, dignity and the relief of pain is, in my opinion, crucial to end-of-life care, for both the dying person and the soon-to-be bereft family and their memories of the end of their loved one's life."*
		S3R133P	*"I was very confused and the fact that I was in so much pain and that they kept telling me they'd given me the maximum added to my confusion and belief I'd been kidnapped by aliens who were lying to me."*
		S3R199HP	*"I always strive for pain free, not only is this kinder to the patient but it gives family's final memories of their loved ones as peaceful."*

Theme	Description		*Illustrative quote*
Perceived importance to the patient and family	Comments pertaining to the perceived importance to the patient and/or family	S3R1104HP	*"I think more important to consider location of death (potentially important to family)."*
		S3R168R	*"These are all crucial factors, either to epidemiologists/ONS & specialist needs in certain areas. Or to patient/family and ensuring a 'good death' and providing patient preferences at the EOL."*
		S3R172HP	*"Of vital importance to patients, loved ones and staff caring for EOL patients … To measure what is important to the patient."*
		S3R174HP	*"A patients' quality of life and what matters most to them and their family is one of the most important aspects in EOL care."*
Impact on staff	Comments referring to the impact on the staff	S3R166HP	*"Need to also ensure that these relate specifically to clinical work, not background status."*
		S3R174HP	*"Burnout of ICU staff is exceptionally high, and can be contributed due to EOL care."*
		S3R198HP	*"I have personally found that in our ITU, the palliative care team are often uninterested in supporting our nurses at EOL."*
		S3R199HP	*"Psychological support is often difficult for staff to access."*

Appendix 59 Round One reasons not critical for inclusion exemplar quotes

Theme	Description		*Illustrative quote*
Description	The outcome lacks clarity or specificity and can not be clearly operationalised	S3R166HP	*"Quality of death and dying is a clumsy phrase and therefore prob meaningless. Better would be quality of care given during the dying phase? Palliative care needs is an almost impossible term for families and even health care professionals to understand, much better to break it down."*
		S3R199HP	*"Often asked by relatives what a score means this score is mainly used by the medical teams. In my experience, Relatives find this information confusing and more often than not will ask what my personal experience is of a death."*
		S3R112HP	*"Difficult to define non beneficial interventions so limited use."*
Frequency of occurrence	The outcome is rare or considered part of the dying process	S3R186HP	*"Deaths in critical care usually happen in ITU/HDU with a small number in other locations and usually limited readmission."*
		S3R172HP	*"From my experience most of the ethics deliberations will be embedded in routine clinical care, and it is very rare for an ethics consultation to be summoned as a stand-alone event."*
		S3R112HP	*"Hunger and thirst are interesting but hopefully rare symptoms - would really hope food/drink would never be withheld from someone experiencing hunger or thirst. More likely to complain of reduced appetite or dry mouth."*
		S3R1124HP	*"Reduced functional status invariably forms part of dying … Dulling the senses may form part of EoLC."*

P = Patient/family HP = Health professional R = Researcher

Theme	Description		*Illustrative quote*
Limited importance or relevance	The outcome is not considered a priority, relevant or considered to be meaningful or of benefit	S3R133P	*"Respect for culture and religion isn't as important to patients at this time so much as it is important to NoK, virtue signallers or other worthies. When the patient is in ICU at death's door survival is more important than religion and culture. Religion is for the living, not so much for the dying."*
		S3R172HP	*PPD [preferred place of dying] is almost irrelevant in most ICU scenarios as options tend to be very limited."*
		S3R1127R	*"Caregiver Self-Efficacy in the ICU is more important in PICU setting."*
Feasibility of measurement and collection	Concerns about whether an outcome can be practically and consistently measured	S3R167R	*"These are all important outcomes although many don't have corresponding adapted tools."*
		S3R186HP	*"Given usual time frame of ITU admissions, depression unlikely to be diagnosed. Also limited given usually reduced consciousness … Would be difficult to assess preparation for dying for the patient given the nature of people dying in critical care."*
		S3R112HP	*"Difficult to measure duration of eol processes as likely to be a gradual transition from active to palliative approach."*
		S3R1127R	*"This are important but will be difficult to collect once the patient and family are no longer in the hospital."*
Not person-centred	The outcome is not person-centred, impacting on individualised care	S3R130HP	*"I appreciate costs are important and play a factor in all elements of care however if too high a priority is placed on them there is a risk of losing the individuality of care."*
		S3R131HP	*"Overall in previous ICU mortality studies I feel there has been too much focus on mortality/length of stay statistics rather than patient focused outcomes."*

Theme	Description		*Illustrative quote*
Measurement quality	Concerns about bias, validity, and reliability	S3R131HP	*"Family and caregiver perspective is important - timing of any data collection in this area could bias data."*
		S3R172HP	*"Important but very difficult to reliably measure, especially when done by proxy (family), so most studies will not be able to do this well."*
		S3R1124HP	*"Respiratory distress is another difficult one to gauge as what appears distressing to the uniformed observer may be a sign of comfort and dulled upper airway reflexes in the dying. Note Kathryn Mannix's comments on the " death rattle."*
Variability	Concerns about applicability to different study designs and patient variability	S3R136HP	*"Some end of life studies may be very qualitative and mortality rates/survival time nto [sic] be so important."*
		S3R146HP	*"N+V should be assessed however not ALL EOL patients experience these symptoms and asking unnecessarily is not conducive so needs to be holistic."*
		S3R172HP	*"If the study isn't at all about symptoms (e.g. it is about attitudes of staff) then this can be left out … should be addressed by some - not all – studies."*
		S3R186HP	*"Important but outcomes will depend on type of study and duration of follow up."*

Appendix 60 Round Two reasons for score change exemplar quotes

Theme sub theme	**Description**		***Illustrative quote***
Importance	Comments on the significance, importance, or priority of the outcomes	S3R283P	*"Cultural spiritual and religious beliefs may be of extremely importance to some people and should be fully considered."*
		S3R272HP	*"The key factor is that good ethical decisions are made and that care is delivered by a wide range of professionals as appropriate in each case."*
		S3R210R	*"But religious, cultural, and spiritual belief should be prioritised because they are strongly related to the EOL process."*
Comparative importance	Comments comparing or contrasting the importance of one outcome with another as a rationale for score modification	S3R52P	*"Location of death: I think the more important question would be if the people died in line with their wishes versus where they eventually died."*
		S3R39HP	*"Although the numbers and data for these questions are useful, i think the reasons behind / quality of a pts life is more important."*
		S3R253R	*"Although important, one -year mortality and functionality would be better."*
Relevance	Comments regarding whether the outcome aligns with the scope, purpose, or concept of EoLC	S3R252P	*"Awareness: with EOL I expect patients to have reduced awareness as they are made comfortable."*
		S3R2112HP	*"Preferred place of death is often irrelevant in ICU scenarios as options tend to be very limited."*
		S3R267R	*"Concerning ethics consultations (with external consultants) = relevant when there is tension/conflict among the team and/or with patient/family."*

P = Patient/family HP = Health professional R = Researcher

Theme sub theme	**Description**		***Illustrative quote***
Human consequences		S3R2123P	*"While in an induced coma on a ventilator, I felt incredibly thirsty, which also fed into delirium. It is still a very vivid memory."*
Effect on the patient	Comments on the immediate or direct consequence for a patient	S3R208HP	*"It has implications for identifying discriminatory practices in healthcare for specific populations e.g. are we quicker to withdraw treatment in black people."*
		S3R2130R	*"These outcomes will directly relate to the comfort of the patient and thus should be prioritised."*
Impact on family members	Comments on the long-term profound or significant influence on the patient's family	S3R283P	*"Time in mechanical ventilation may be correlated with post-ICU conditions."*
		S3R299HP	*"Nausea and vomiting have a significant impact on how a patient feels and if the patient is vomiting this also significantly impacts how their visitors experience the dying process."*
		S3R2127R	*"For families the reduced mobility/daily function knowledge on reflection may help with future decision making of where EoL care is best provided."*
Impact on staff	Comments on how the outcome can impact on the staff providing EoLC	S3R252P	*"Highlight staff anxiety and fear for more support in the role."*
		S3R2124HP	*"Survival and readmission to hospital and then ICU has the potential (regardless of outcome) to destroy staff morale."*
		S3R299HP	*"I feel that if staff are confident in end of life care then they feel less anxious about delivering end of life care."*

Theme sub theme	**Description**		***Illustrative quote***
Comprehension	Articulating a shift in the comprehension of the COS scope or outcome definition since the preceding round	S3R283_	*"Lowering scores on a better understanding of the questions!"*
		S3R208HP	*"Have carefully re-read the explanatory statements and adjusted scores accordingly."*
		S2R3267R	*"I have lowered the score as originally I think I didn't fully understand the scope of the question."*
Ambiguity or clarity	The outcome or construct is poorly phrased or defined	S3R208HP	*"Ethics consultation: I don't think you can include this in COS unless you define it clearly. Many palliative care consultations requiring consultant input could be regarded as an ethics consultation. If this was clearly defined, my score might increase. E.g. if you mean complex, conflict-ridden decisions going through an ethics committee, my score would be higher."*
		S3R2127R	*"Pastoral care needs clear definition and whether the family is spiritual/religious. Was it requested by the family or organised by the family or suggested/organised by healthcare professionals and frequency/benefit or other formal markers to quantify use."*
Correction	Score changed to correct an error, incorrect score or mis-selection in the previous round	S3R267R	*"I have changed the score - I'm thinking that originally I should maybe have rated "unable to rate" as I have no bedside clinical experience so no "hands on" experience of these symptoms."*

Theme sub theme	**Description**		***Illustrative quote***
Participant influence	Comments relating to seeing the distribution, central tendency, or reasoning of other panel members	S3R252P	*"I was trying not to have everything as critical or very important but seems everyone thinks every question is very-critical so I'll revise my responses."*
		S3R2139HP	*"I thought that families and patients would be more interested to know where they were going to die. Being as the aim of this is patient centred, I think its important to look at what patients feel would be beneficial for their end of life care."*
		S2R2127R	*"Not ALL EOL patients experience these symptoms and asking unnecessarily is not conducive - this is an interesting concept that I had not considered."*
Frequency	Comments that the outcome is rare, common or is considered part of the dying process.	S3R252P	*"Conflicts will naturally arise with heightened emotions and perception."*
		S3R208HP	*"Patient-reported hunger and thirst are not symptoms I see frequently in palliative critical care patients."*
	Frequency varies across the critical care population.	S3R2127R	*"Going through an EoL process will naturally have periods of increased anxiety/grief at the loss of a loved one."*

Theme sub theme	**Description**		***Illustrative quote***
Research awareness	Comments acknowledging relevant research, empirical evidence or research gap	S3R2123P	*"What do current stats suggest? Are all ICU deaths preceded by low functional status?"*
		S3R230HP	*"With the concept of total pain and the potential for complex grief I think this is crucial research at present to determine the evidence for further teaching/ reinforcement of the importance of cultural/spiritual needs on the patient and family outcomes."*
		S3R267R	*"I have changed the last scores to 7 as research shows how interdependent family and staff satisfaction can be."*
Personal experience	Comments based on participant's lived, professional or practice-based experience	S3R2123P	*"This is based on my own experience of delirium while in an induced coma in ICU, which was highly distressing, horrific and upsetting."*
		S3R208HP	*"Mortality Scores - my score has decreased because I am becoming more aware of young patients with terminal illness (such as those in their 20s with genetic abnormalities) whose care is (sometimes negatively) influenced by attention to these scores, but who require a very different model of ICU/palliative care than the 'usual' adult population."*
Cognitive incubation	Comments pertaining to having time, space or opportunity to reflect and reconsider reasoning between rounds	S3R233HP	*"My altered scores benefit from further reflection."*
		S3R299HP	*" Having thought more on this answer the score carries weight for the medical team but less so for nursing staff and patients families."*

Theme sub theme	**Description**		***Illustrative quote***
Measurement quality	Comments about bias, validity, and reliability of the outcome	S3R2123P	*"Time from end-of-life decision to withhold or withdraw therapies", wouldn't it depend on what state the patient is in…"*
		S3R299HP	*"Grief is difficult to quantify and therefore very complex to measure."*
		S3R2127R	*"What is satisfaction in the mindset of a family/carer who is losing a loved one?"*
Feasibility	Concerns about whether the outcome can be practically and consistently measured	S3R252P	*"I think similarly to birth plans- when it comes down to dying sometimes the plans go out of the window depending on the situation."*
		S3R208HP	*"It would take scrutinising the medical notes carefully to identify all instances of this. Not practically feasible all the time."*
		S3R253R	*"Satisfaction is important, however depend on what the individual wants and what the team cargiver [sic] are able / in power to offer."*
Resource constraints	Comments referring to the how resources can impede achieve the outcome resulting in a score change	S3R2124HP	*"Ideally this should be in a familiar environment, but the state of play in the UK at present can often make this difficult to provide."*
		S3R2223HP	*"Whilst important to discuss options for PPD are limited in ICU so someone not dying in a previously stated PPD should not necessarily be seen as a failure."*

Appendix 61 Round Two reasons critical for inclusion exemplar quotes

Theme	Description		*Illustrative quote*
Aids funding and service provision	Comments where the outcome is considered to facilitate funding and service provision	S3R252P	*"Highlight staff anxiety and fear for more support in the role. … ventilation length impacts on other areas "*
		S3R230HP	*"Analysis of trends is important as they can give support to service provision, funding etc but there are many factors involved that these statistics on their own may be of limited value - for example place of death indicates percentages of deaths in hospital etc but this needs to be coupled with preferred places of death in my opinion to show whether we are meeting PPD and the potential impact this may have if PPD is not met."*
Critical/essential aspect of EoLC	Comments where the outcome is considered a critical/essential or considered to be a priority in EoLC	S3R229HP	*"End-of-life care is so important; we need to get it right."*
		S3R272HP	*"In my opinion it is of utmost importance that staff and families, when reflecting back, can be confident that decisions taken were the best possible in those circumstances, and I would like to see more evidence in how to achieve this."*
		S3R2131HP	*"Prevention of Nausea and Vomiting is very crucial in the management of patients."*
		S3R2130R	*"All of these should be prioritised but systems factors often impede success here."*

P = Patient/family HP = Health professional R = Researcher

Theme	Description		*Illustrative quote*
Supports evidence-based decision-making	Comments on how the outcome supports evidence-based decision-making	S3R217HP	*"This helps with determining that a person is dying over weeks to months."*
		S3R2124HP	*"Is it our/ families' perception of hunger thirst or the biochemical disturbances that make us think that a dying patient is hungry/thirsty, when in reality the patient is unaware, with issues such as uraemia/hypernatraemia potentially contributing to comfort care?"*
		S3R2127R	*"For families the reduced mobility/daily function knowledge on reflection may help with future decision making of where EoL care is best provided."*
Determines effectiveness	Comments on how the outcome would determine effectiveness	S3R223HP	*"A valid DNACPR is a useful measure but even so it is appropriate that a small number of patients will always die following an attempt at CPR. This can be seen as a failure but this is not always the case."*
		S3R233P	*"ADLs are brilliant ways to monitor a wide variety of patient features. Mood, dexterity, fine finger movements, balance, coordination, cognition, etc etc so I see huge value in these."*
		S3R252P	*"Number of DNAR- does this link with education and awareness, does it link with the rate of survival score."*
		S3R2130R	*"Location of death is important because it shows how quickly EOL care and planning was put into action to meet the patient's goals and create a therapeutic death."*

Theme	Description		*Illustrative quote*
Measures an existing gap or need	Comments on how the outcome measures an existing gap or need	S3R252P	*"As someone who continues to fight to get any sort of support as an ex patient."*
		S3R230HP	*"With the concept of total pain and the potential for complex grief I think this is crucial research at present to determine the evidence for further teaching/ reinforcement of the importance of cultural/spiritual needs on the patient and family outcomes."*
		S3R272HP	*"In my opinion it is of utmost importance that staff and families, when reflecting back, can be confident that decisions taken were the best possible in those circumstances, and I would like to see more evidence in how to achieve this."*
Impact on patient and/or family	Comments referring to the impact on the patient and/or family	S3R299HP	*"Nausea and vomiting have a significant impact on how a patient feels and if the patient is vomiting this also significantly impacts how their visitors experience the dying process. Staff stress and anxiety impacts on our patients and their families stress and anxiety. I believe that in the context of end of life care both are equally significant."*
		S3R2103R	*"For me, success is when the dying process is consistent with family and patient wishes and in a way that it will be remembered favorably and with at least trauma as possible."*
		S3R2123P	*"While in an induced coma on a ventilator, I felt incredibly thirsty, which also fed into delirium. It is still a very vivid memory."*

Theme	Description		*Illustrative quote*
Perceived importance to the patient and family	Comments pertaining to the perceived importance to the patient and/or family	S3R217HP	*"I think hunger and thirst are perceived as important symptoms by families and therefore it is important to measure this."*
		S3R272HP	*"In my experience, the possibility of hunger or thirst are very much on carers' minds, therefore evidence of its existence is paramount to the provision of useful information."*
Impact on staff	Comments referring to the impact on staff	S3R252P	*"Delirium: hugely important because that could form how distressing a death can be."*
		S3R372HP	*"In my opinion it is of utmost importance that staff and families, when reflecting back, can be confident that decisions taken were the best possible in those circumstances, and I would like to see more evidence in how to achieve this."*
		S3R2124HP	*"Survival and readmission to hospital and then ICU has the potential (regardless of outcome) to destroy staff morale and place increasing burdens on patients and their families."*

Appendix 62 Round Two reasons not critical for inclusion exemplar quotes

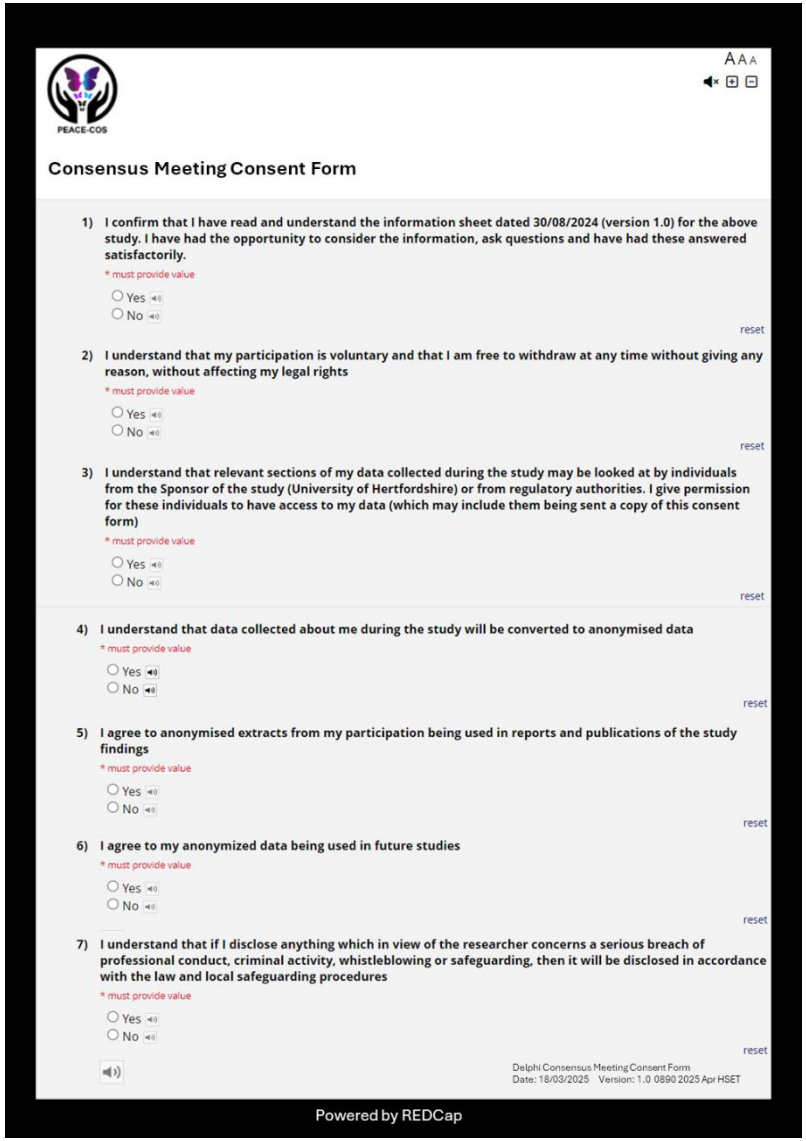
Theme	Description		*Illustrative quote*
Description	The outcome lacks clarity or specificity and can not be clearly operationalised	S3R208HP	*"Ethics consultation: I don't think you can include this in COS unless you define it clearly. Many palliative care consultations requiring consultant input could be regarded as an ethics consultation. … This type of measure provides data, but doesn't address nuance."*
		S3R2127R	*"Symptoms of anxiety - again should be clearly defined."*
		S3R2272HP	*"It feels like too many items: either measure depression, anxiety and stress individually or as a cluster - and I personally feel measuring them individually is more helpful."*
Frequency of occurrence	The outcome is rare or considered part of the dying process	S3R208HP	*"Patient-reported hunger and thirst are not symptoms I see frequently in palliative critical care patients."*
		S3R233P	*"Having cared for dying patients as a nurse, loss of hunger and thirst are both normal features of the dying process."*
		S3R2127R	*"Going through an EoL process will naturally have periods of increased anxiety/grief at the loss of a loved one."*
Limited importance or relevance	The outcome is not considered a priority, relevant or considered to be meaningful or of benefit	S3R233P	*"Patients deserve the best care especially at the end of life, and where there's a risk that religion gets in the way of that then the patient must come first. Religion and funerals are for the benefit of the living, not the dying and the dead."*
		S3R267R	*"Concerning ethics consultations (with external consultants) = relevant when there is tension/conflict among the team and/or with patient/family."*
		S3R272HP	*"Mortality estimate rate is interesting but less important in my opinion because the care provided should take into account uncertainty and the possibility of less expected outcomes for individuals."*

Theme	Description		*Illustrative quote*
Feasibility of measurement and collection	Concerns about whether an outcome can be practically and consistently measured	S3R252P	*"You're not able to make a lot of decisions as a relative."*
		S3R208HP	*"MDT communication is not documented well in critical care - I find these conversations very useful but they often happen in corridors or huddles and are not necessarily actually documented/flagged up as an 'MDT' communication episode. It would take scrutinising the medical notes carefully to identify all instances of this. Not practically feasible all the time."*
		S3R288HP	*"Location of death is important in terms of the patient's wishes. However, in critical care there is often no time to transfer the patient to a more suitable environment so it is more important to focus on symptom control, comfort and support to relatives."*
Not person-centred	The outcome is not person-centred, impacting on individualised care	S3R252P	*"Everyone is different and their ICU journey could be longer or shorter than the norm."*
		S3R2130R	*"This outcome is important but not critical. This outcome would need to be catered to each individual patient."*
		S3R2139HP	*"I think it is very difficult to classify non-beneficial interventions as this a very personal decision/patient specific."*
Measurement quality	Concerns about bias, validity, and reliability	S3R252P	*"Reality and perception are very different."*
		S3R223HP	*"Timing of withdrawal often depends on families attending, religious needs etc and so I am not sure that timing gives us useful information on quality of care, the time is however long a patient and their family needs. Similarly ICU patients change rapidly upon withdrawal and so changes in management are needed often."*
		S3R299HP	*"Some of the length of time to withdraw is dictated by family's especially of they are widespread as a nurse I would advocate for my patient that family*

Theme	Description		*Illustrative quote*
			be allowed to visit to be given the chance as far as possible to visit before withdrawal of care."
Variability	Concerns about applicability to different study designs and patient variability	S3R208HP	*"There's often an assumption behind such measures that hospital is a place to be avoided. This is not necessarily the case for all groups of patients. … Whilst nausea is an important symptom to identify and treat at the end of life in critical care, I do not think that all research in this domain must include."*
		S3R272HP	*"Conflict is interesting and should be studied but I wouldn't say that all research studies in this area should address this … It is an interesting detail to be looked at by some but not all studies."*
		S3R2127R	*"Not ALL EOL patients experience these symptoms and asking unnecessarily is not conducive - this is an interesting concept that I had not considered."*

P = Patient/family HP = Health professional R = Researcher

Appendix 63 Stage Four consent form



PEACE-COS

Consensus Meeting Consent Form

1) I confirm that I have read and understand the information sheet dated 30/08/2024 (version 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
* must provide value
Yes
No
reset

2) I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without affecting my legal rights
* must provide value
Yes
No
reset

3) I understand that relevant sections of my data collected during the study may be looked at by individuals from the Sponsor of the study (University of Hertfordshire) or from regulatory authorities. I give permission for these individuals to have access to my data (which may include them being sent a copy of this consent form)
* must provide value
Yes
No
reset

4) I understand that data collected about me during the study will be converted to anonymised data
* must provide value
Yes
No
reset

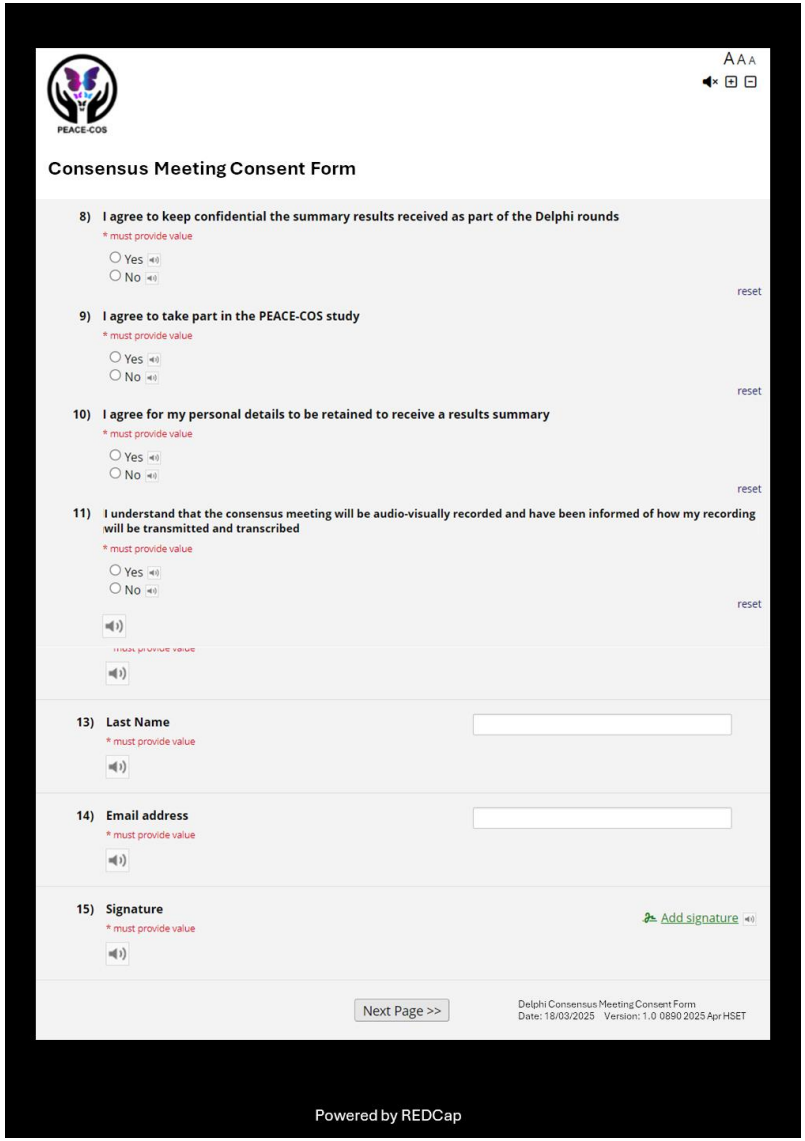
5) I agree to anonymised extracts from my participation being used in reports and publications of the study findings
* must provide value
Yes
No
reset

6) I agree to my anonymized data being used in future studies
* must provide value
Yes
No
reset

7) I understand that if I disclose anything which in view of the researcher concerns a serious breach of professional conduct, criminal activity, whistleblowing or safeguarding, then it will be disclosed in accordance with the law and local safeguarding procedures
* must provide value
Yes
No
reset

Delphi Consensus Meeting Consent Form
Date: 18/03/2025 Version: 1.0 0890 2025 Apr HSET

Powered by REDCap



PEACE-COS

Consensus Meeting Consent Form

8) I agree to keep confidential the summary results received as part of the Delphi rounds
* must provide value
Yes
No
reset

9) I agree to take part in the PEACE-COS study
* must provide value
Yes
No
reset

10) I agree for my personal details to be retained to receive a results summary
* must provide value
Yes
No
reset

11) I understand that the consensus meeting will be audio-visually recorded and have been informed of how my recording will be transmitted and transcribed
* must provide value
Yes
No
reset

13) Last Name
* must provide value

14) Email address
* must provide value

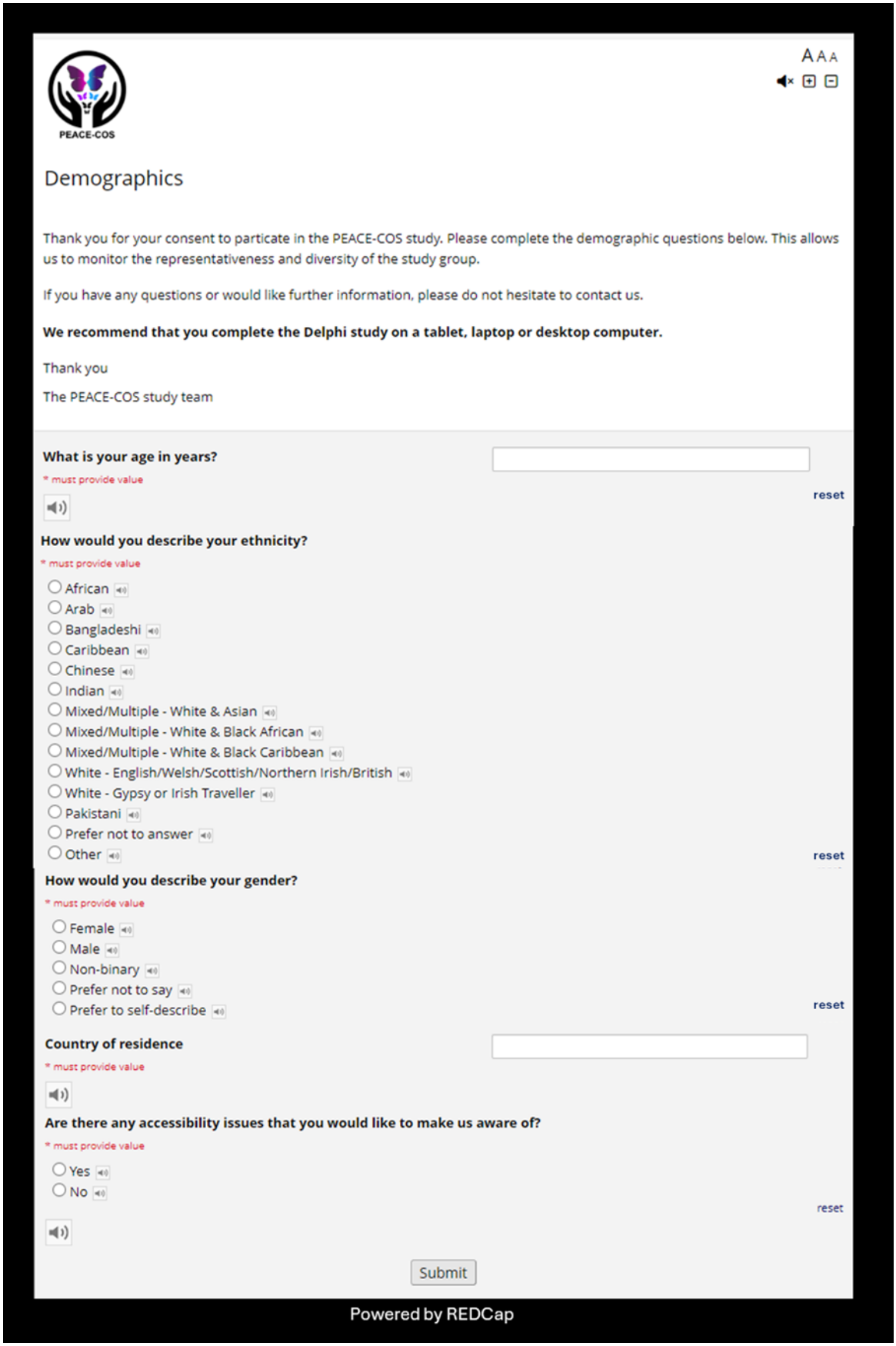
15) Signature
* must provide value
Add signature

Next Page >>

Delphi Consensus Meeting Consent Form
Date: 18/03/2025 Version: 1.0 0890 2025 Apr HSET

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Appendix 64 Stage Four demographics form



Appendix 65 Consensus meeting participant pack

PEACE-COS

Email: peace-cos@herts.ac.uk

Consensus Meeting What to Expect

Introduction

Thank you for agreeing to take part in the PEACE-COS consensus meeting. This information pack outlines why the meeting is being held and your important role.

What is the aim of the PEACE-COS study?

At the moment, researchers use a range of different measures ('outcomes') to evaluate end-of-life care. For example, research may look at how long patients stay in critical care or what treatment a patient receives. The PEACE-COS study aims to create a Core Outcome Set (COS) for future research studies that accurately reflect the outcomes that matter most to the patients, their families, health professionals and researchers.

What is a Core Outcome Set (COS)?

A Core Outcome Set (COS) is a small, standardized set of key outcomes that should be measured and reported in all studies within a specific research area. It ensures that studies can be compared. For an outcome to be considered 'core', it needs to be relevant to patients, their families, healthcare professionals and researchers.

How are Core Outcome Sets developed?

To decide which outcomes are important, researchers need to get everyone's opinion and try to reach an agreement, or 'consensus', on the most important outcomes. To do this, we have carried out a 'consensus exercise' by using something called a 'Delphi' study.

From looking at research papers and interviewing people involved in end-of-life care, we developed a long list of possible outcomes that we asked people to rate in order of importance through a series of online questionnaires. This showed us which outcomes people agree are important and areas where people's opinions differ.

The online consensus meeting is the last stage of the consensus process where patients, their families, healthcare professionals and researchers come together to discuss the outcomes in more detail and agree which outcomes should be included in the COS.

Preparing for the consensus meeting

You don't need to do anything to prepare for the meeting. If you took part in the Delphi process, we will send you a summary of how you rated each outcome. This is just to remind you of what was included and your previous ratings—you may find it helpful to have it with you at the meeting. If you didn't take part, we will send you a list of the outcomes that were rated. This is to give you an idea of what we will be discussing during the meeting.

Who will be at the consensus meeting?

There will be a maximum of 40 people. This will include a chairperson, members of the PEACE-COS study team, and representatives of stakeholder groups - patient and family members, health professionals, researchers and guideline/policymakers/support groups.

How long will the meeting last?

The consensus group meeting will last two hours with additional breaks.

What will happen at the consensus meeting?

There will be an informal introduction by the chairperson who is independent from the PEACE-COS study team. We will present the background to the Delphi study and share the results from the Delphi process. We will guide you through the end-of-life outcomes we want to explore. There are no right or wrong answers we are simply interested in your opinions. The chairperson will ensure that everyone who wants to, has an opportunity to speak. Participants are encouraged to ask questions at this stage so that everyone has the same understanding of each outcome.

After each discussion, you will be asked to vote (anonymously) on whether that outcome should be included in the core outcome set.

We will take notes and make an audiovisual recording to help us remember what is said. When the meeting is written up, we will use pseudonyms (real names replaced).

How will voting take place?

We will ask each stakeholder group to vote for each outcome. This ensures that each group's views are considered equally, as there may not be the same number of people in each stakeholder group. When your group is called, you will be asked to vote online on how important that outcome is to include in the core outcome set. The voting will use a 1 – 9 scale where 1 is not important and 9 critically important. No-one in the group can see another person's scores.

How will you decide what is included in the core outcome set?

Once everyone has scored each outcome, we will add up everyone's score for each of the outcomes. We will include an outcome in the core outcome set if 70% or more of people in each stakeholder group rate the outcome between 7-9.

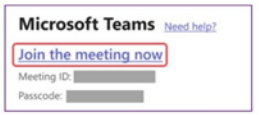
It is recommended that a core outcome set has a maximum of 10 outcomes. If we have more than 10 outcomes, we may ask people to vote for their top 10.

What will happen to the results of consensus meeting?

We will use the information from the consensus meeting to create a core set of outcomes that should be measured and reported in all future research studies evaluating end-of-life care in critical care. The results of the study will be written up and published in a professional journal and will form part of Sally Humphreys' PhD thesis. The results will also be presented at conferences. The data will be anonymous, meaning none of the people involved in the study will be identified in any report or publication. If you would like a copy of the overall study results or publication, please let a member of the study team know.

How to join the consensus meeting

The meeting will take place online via Microsoft Teams. For the best experience, we suggest joining from a desktop, laptop or tablet. Please join the meeting a few minutes before the scheduled start time to ensure that your device is working. In your meeting invite, select **Join the meeting now**



You may be held in the lobby until we admit you. We ask that you mute your microphone when you are not required to speak/interact. We ask you do turn on your video when responding to the facilitator or your peers. This enhances the experience for everyone.

While you're in the Teams meeting, you can access different functions from the meeting controls at the top of your screen.



Raise your hand

Raise your hand to let others know you have something to share without interrupting the speaker. To raise or lower your hand: select (raise hand icon)

Others will see that your hand is raised, and in which order it was raised if others have their hands raised.

Mute or unmute your mic

If you're already muted in a meeting and you'd like to speak: Select **Mic** to turn it on.

To mute your mic, select **Mic** again.

Turn your camera on or off

To turn your camera on: Select **Camera** to turn it on.

To turn your camera off, select **Camera** again.

Leaving the meeting

To leave a meeting, select **Leave**.

Appendix 66 Reasons for core

Theme	Description		*Illustrative quote*
Addresses existing gap or need	Comments where the outcome addreses a gap or need	PCM_52_P	*"I think sometimes, pains underestimated, but I guess for me the fact that I was on fentanyl, morphine and ketamine shows how serious the pain is."*
		FCM_72_HP	*"So to include in the outcome set, not only because I think it's very distressing, but also because I think it's under recognised as so distressing."*
Aids funding and service provision	Comments where the outcome is considered to facilitate funding and service provision	PCM_33_P	*"I would say this is important, on the basis that the nature of or the quality of palliative of care generally speaking in the country is is very much a post code lottery and because of that, because people cannot rely on the quality of palliative care."*
		FCM_07_HP	*"We are missing that service and obviously we need the evidence to actually get that service."*
Supports evidence-based decision-making	Comments on how the outcome supports evidence-based decision-making	PCM_33_P	*"It's important that we gather this data because policies and laws are made based upon data, such that this would provide in a core outcome set."*
		PCM_52_P	*"If it was a high number, you'd think well, then are we getting our predicting people's dying stages is are we getting that wrong."*
		FCM_72_HP	*"But at the point of the communication, there is value in having some research data that aids for prognostication."*

P = Patient/patient representative HP = Health professional R = Researcher

Theme Subtheme	Description		*Illustrative quote*
Importance			
Comparative importance	Comments referring to the outcome being considered more important when compared to another outcome	PCM_142_P	*"I would agree that it's, it's actually quality of death that's the most important, not quality of life at this particular time."*
		FCM_72_HP	*"But I don't think it's less important than the two others we've talked about personally."*
Critical/essential aspect of EoLC	Comments where the outcome is considered a critical/essential or considered to be a priority in EoLC	PCM_47_P	*"The comms is so important and I think, yeah, I just think it's for me, it's the most important side."*
		FCM_72_HP	*" … but certainly there's something about symptom management that it's that is crucial in the dying phase."*
		FCM_152_R	*"I would say conceptually compassion and end-of-life care is extremely important … I think it conceptually, I think it definitely should be there."*
Perceived importance to the patient and family	Comments pertaining to the perceived importance to the patient and/or family omments	PCM_47_P	*"I think it's important to follow the request of the patient."*
		PCM_143_P	*"We're looking obviously at outcomes for the patient here. So I think it is absolutely critical that it's always included from the patient's angle obviously as well."*
		FCM_52_P	*"I think it's really important for the patient."*

Theme Subtheme	Description		*Illustrative quote*
Human consequences			
Effect on the patient	Comments referring to the effect on the patient	PCM_123_P	*"It's horrendous and maybe it's in a way it is physical pain, I guess, but it's just terrifying because you feel like you're going to die and you're helpless. And yeah, I think it's definitely key to to include there."*
		FCM_33_P	*"Pain is one of the, as you say, most feared things and speaking from personal experience of intensive care whereby I had a considerable amount of pain."*
		FCM_52_P	*"I totally agree. They should be included. I remember all of my pain from my time in hospital and it's awful."*
Impact on the family	Comments referring to the impact on the family	PCM_143_P	*"But I think also from what is reported to me from the family and the trauma that they experience in what they're witnessing as well, obviously to see your family member, the person you love the most feeling any discomfort is utterly torturous and has lifelong repercussions, if it's not managed well."*
		FCM_72_HP	*"And I think it's the uncertainty that we always need to carry, but also the responsibility to say that it's really, really important to manage it regardless of whether the person lives on or not for them and for those who stay behind."*
Impact on staff	Comments referring to the impact on the staff	PCM_52	*"So for me, I think having the palliative team that's supporting the nurses."*
		FCM_33_P	*"Having been a staff nurse and witnessed respiratory distress, it can be the most appalling experience for people to have not to be able to breathe and the degree of anxiety and panic and fear that creates."*
		FCM_143	*"If we have any query about medication, or we need advice, we have them come and visit the ICU, and they're fantastic because they have a different view on things than we do."*

Appendix 67 Reasons for non-core

Theme	Description		*Illustrative quote*
Description comprehension	Comments referring to understanding the outcome due to ambiguity or terminology	PCM_123_P	*"I just don't think it's phrased very accurately or very, very helpfully rather."*
		FCM_123_P	*"I just think it's difficult from a patient perspective unless you're a qualified clinician understanding all the, you know, different aspects of of care."*
		FCM_72_HP	*"I think palliative care is a poorly understood term generally, so probably I wouldn't choose it as a term, although I, you know, that's my profession, but I probably wouldn't choose it because I think people don't quite understand what it is."*
Comparative importance	Comments referring to the outcome being considered less important when compared to another outcome	PCM47_P	*"But I think also the other factors that we've already talked about, certainly for me things like pain management, dignity, all that, that sort of goes ahead of whether you're in a white room or you're wherever you know that."*
		FCM_33_P	*"I think less support over the other things that have been discussed."*
		FCM_72_HP	*"We need to accept that quality of life in intensive care is not going to be good. Therefore we need to focus on other things to optimise in that context."*
Frequency	Comments referring to the outcome being rare, usual practice or part of EoLC	PCM_52_P	*"I would just hope that this was just normal."*
		FCM_142P	*"A lot of people kind of have this feeling that if there's some noisy breathing, it's automatically going to be distressed and pain for their loved ones when actually, that isn't always the case. It can be a natural part of the dying process that has to be discussed at an earlier stage."*
		FCM_142R	*"Although pain is a consideration, breathlessness for sure, delirium not so much because the majority of our patients will die sedated on a ventilator and with sedation still on."*

P = Patient/patient representative HP = Health professional R = Researcher

Theme Subtheme	Description		*Illustrative quote*
How			
Confounders	Comments on how variables can impact the outcome	PCM_33_P	*"You know, there are so many potential variables. I think this is really, really unwise. And I would, I think they should be dismissed with great haste."*
		FCM_54_HP	*"Can we, can all this data just be related to the experience that they had in the ICU?"*
		FCM_23_HP	*"I think it's a different study because actually your family morbidity is going to be so kind of contingent on so many different things."*
Subjectivity	Comments on how the outcome is interpreted	PCM_33_P	*"And clinical because there are so many clinicians involved in the care of the ITU patient, the quality of compassion of 1 member of staff could differ considerably from another."*
		FCM_07_HP	*"But compassion looks like something different for lots of different people. So for some patient people, compassion is a hug. If that was me, I'd be like, don't touch me."*
		FCM_144_R	*"It's something that everybody says they want, it's something that means everybody something different to everybody else, and I would very heist. I would be very hesitant to include this."*
Precision	Comments relating to the outcome being too broad	PCM_143_P	*"It's very woolly, and it's sort of too big. It's too big a subject, isn't it? And too complex."*
		FCM_23_HP	*"… but I think I agree in that palliative care needs just so broad as a term. And I think if you're trying to come up with an outcome set, what you're trying to do is to define what good palliative care looks like. So that's sort of too big of a question. I think it, I think breaking it down into those key aspects is probably more useful."*

Theme Subtheme	Description		*Illustrative quote*
How			
Reliability	Comments referring to the reliability of the outcome	PCM_33_P	*"So in terms of a core outcome set, I don't think this is a good enough reliable measure to be worth including as a core outcome set."*
		FCM_23_HP	*"The struggle is going to be how do you assess that or in a kind of consistent way."*
		FCM_72_HP	*"I think the difficulty with delirium is possibly the reliable measurement of it."*
		FCM_152_R	*"So from a research perspective, there are tools for measuring it. I'm not sure how reliable those are."*
Timing	Comments referring to concerns how the outcome is affected across different time points.	PCM_142P	*"But for some people it could be 5-6 years down the line, and they've very clearly got complicated grief and are really struggling with suicidal thoughts and things like that. So it's how long you follow people and how do you portion it to that experience of somebody dying in intensive care? So it's a technically very difficult, but also very woolly."*
		FCM_53_R	*"A couple of days before the quality of life is important, but certainly when it takes months its not".*
		FCM_144_R	*"So it feels like there needs to be a natural line time point in the sand where the notion or the anticipation of death is going to happen, where we've moved into palliative care or end-of-life care, so that these outcomes are all anchored in that time frame, not broadly symptom management."*

Theme Subtheme	Description		*Illustrative quote*
How			
Feasibility	Comments referring to the feasibility, practicality and implementation	PCM_142_P	*"So really, all it's actually measuring is how feasible it is to do any of this. So, I'm not sure it's really relevant in this situation."*
		FCM_23_HP	*"Whereas ICU patients often just don't die that way. Can you get somebody who's been taken off a ventilator home? Very occasionally, but often not."*
		FCM_72_HP	*"I just worry that the number of different scenarios is going to make it impossible to apply it clinically. Therefore I'm probably more in favour of losing it."*
Outcome measurement instrument	Comments referring to the outcome measurement instrument	PCM_33_P	*"What clinical tool are you going to use to measure patient-centred care? What tool are you going to use to measure dignity?"*
		FCM_23_HP	*"But I think if this is looking at kind of End-of-life care rather than palliative care, then it's about kind of quality of death and quality of life is quite a blunt instrument, isn't it?"*
		FCM_152_R	*"But if you think about the kind of traditional tools that we use to assess it in in other contexts a lot of the domains of those wouldn't be relevant in an end-of-life care setting, but others would."*
Human consequences			
Effect on patient	Comments referring to the impact on the patient	PCM52_P	*"I've been on the receiving end of because people do it. That's what you Google. What is the prognosis of the sepsis survivor? How long do you survive after critical care? And it's pretty damaging."*
		PCM143_P	*"Just the presence of the word starts to put doubt in people's heads. It either puts fear and in a in a survivor or doubt in a survivor or, you know, or it puts doubt in a grieving relatives. So I just think you've got to be proceed with massive caution with including something like that."*

Theme Subtheme	Description		*Illustrative quote*
Human consequences			
Impact on family	Comments referring to the impact on the family	CM52_P	*"And I just think survival all these stats, these survival percentages, they are so, so damaging and I absolutely hate them."*
		FCM_123_P	*"Family might be emotionally drained, distressed and also it might burden them too much with these kind of things."*
Redundancy			
Alternative route	Comments referring to the outcome being available by alternative routes	FCM_142_P	*"I think the other thing is we I know we have been able to access some of that data through other routes. So whether it necessarily needs to kind of be in this core outcome set and as I say, part of it's been as kind of a bit of a surrogate for some of the other more specific outcomes that we've got that somebody's death and the communication."*
		FCM_23_HP	*"This data already exists, so I'm not sure it is massively necessary to collect it again."*
Overlaps	Comments referring to the outcome or construct overlapping with another outcome or construct	PCM143_P	*"For me it this is a bit repetitive what we've so which kind of makes me think, do we need to include it because we've included a lot of these core things already with what we've looked at."*
		FCM_142_P	*"I think if there's too much overlap and this is perhaps a reason for to consider removing this one as a core outcome."*
		FCM_07_HP	*"I think a few other things actually overlap, if I'm honest."*
		FCM_144_R	*"It feels like this is this is captured elsewhere … I can't quite see how this is delineated from some of the other aspects that we've captured in in the previous one."*

Theme Subtheme	Description	*Illustrative quote*	
Outside COS scope			
Health condition	Comments referring to the health condition	PCM_123_P	*"I'm still not clear as to what this has to do in the set of outcomes we're looking at, we're looking at end-of-life care in ICU."*
		FCM_72_HP	*"I just think this isn't specific to end-of-life care."*
Population	Comments referring to the population	PCM_33_P	*"This is not a part of a core outcome set that belongs in this particular topic because we're only talking about intensive care."*
		FCM_72_HP	*"So it's not generic to intensive care."*
		FCM_144_R	*"Is outside of the scope because that's to do with general ICU management."*
Intervention	Comments referring to the intervention	FCM_152_R	*"I mean, presume interventions in end-of-life care are not attempting to change whether patients die. I would presume because we're already in an end-of-life care situation."*
Setting	Comments referring to the setting	FCM_152_R	*"I think similar to the DNACPR, and I'm I'm not clear that it's kind of appropriate as a trial outcome measure."*
		FCM_144_R	*"So for me this would be, you know again scope of this core outcome set, end-of-life research, it must be mortality, it must be the mortality around patients within that end-of-life experience or kind of window for me."*
		FCM_140_R	*"Again, there are some countries where dying patients can't from ICU, can't go anywhere else to die but ICU. So I think if we want to be relevant to all, I'm not sure how this is relevant."*