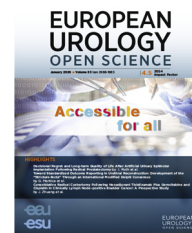




European Association of Urology

**Trial Protocol**

# The CAMUS Initiative: A Multiphase, Multicentre International Collaboration to Redefine Risk Stratification, Reporting, and Grading of Surgical Complications in Urology

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**Abstract**

Surgical complications remain a major source of preventable morbidity, mortality, and health care expenditure, but existing frameworks such as the Clavien-Dindo classification and Comprehensive Complication Index are clinician-centred and intervention-focused and fail to capture cumulative patient-centred outcomes. This protocol outlines the Complications After Major and Minor Urological Surgery (CAMUS) initiative, a global, multiphase effort to redefine complication reporting, risk stratification, and outcome measurement in urological surgery. CAMUS aims to address these limitations via an integrated, seven-arm programme combining retrospective and prospective data analysis, consensus development, and digital infrastructure design. Arm 1 has assembled a retrospective data set of 130 034 major urological procedures from 180 centres across 33 countries, the largest of its kind. Arms 2 and 3 have completed Delphi surveys with physicians ( $n = 1113$ ) and pilot nursing participants ( $n = 20$ ) and has generated consensus on novel grading domains and highlighted the importance of multidisciplinary perspectives. Arm 4 will incorporate patient-reported outcomes and behavioural economics methods to quantify subjective burdens, while arm 5 will develop the CAMUS Intraoperative and Postoperative Risk and Difficulty Estimation Index (IPRADES) for surgical risk and difficulty prediction. Arms 6 and 7 will build a secure e-database and dictionary and prospectively validate the system using >2000 new cases. Statistical methods include multivariable regression, meta-analysis of individual patient data, and machine-learning approaches to model predictors of morbidity and mortality. Outputs will be benchmarked internationally to facilitate both clinician- and patient-driven definitions of complication severity.

<sup>†</sup> The CAMUS Study Group Collaborators are listed in the Supplementary material.

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Ultimately, CAMUS will deliver a reproducible, patient-inclusive classification system with broad applicability to clinical practice, audits, education, and policy. By integrating more than 130 000 procedures with global Delphi consensus, CAMUS represents the most comprehensive complication classification initiative undertaken in surgery. Its outputs are expected to improve transparency, standardise reporting, and inform patient-centred risk stratification worldwide.

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## 1. Introduction and hypotheses

Surgical complications remain a leading cause of preventable morbidity, mortality, greater health care costs, and lower patient satisfaction [1,2]. As the global volume of surgical procedures continues to rise [3], the consequences of complications for both patients and health care systems are becoming increasingly prominent. Complications can result in prolonged hospital stays, unplanned readmissions, additional interventions, long-term disability, and even death. From a health-care system perspective, these events increase costs and place additional pressure on resources. For clinicians, they represent missed opportunities to deliver safe, high-quality care; for patients, they may significantly reduce trust in surgical services and contribute to physical and emotional distress.

Despite advances in surgical techniques, anaesthesia, and perioperative medicine, a critical issue persists: the lack of a universally accepted, consistent, and patient-inclusive system for classifying and reporting surgical complications. Accurate and reproducible classification is not only essential for benchmarking and quality improvement but also fundamental to effective patient counselling and informed consent. The absence of a standardised, comprehensive complication classification system limits our ability to compare outcomes across centres, identify areas for improvement, and ensure transparency in academic reporting and clinical decision-making [4–7].

While systematic registration of complications may initially be perceived as burdensome, much of the current workload arises from fragmented, duplicative documentation across multiple parallel systems. CAMUS aims to consolidate complication reporting into a single structured framework that will allow one high-quality record to serve clinical documentation, audits, education, and research simultaneously. Experience from early adopters suggests that after an initial learning phase, this approach reduces the overall workload rather than increasing it.

Standardised complication registration also plays a critical role in surgical training and education. Transparent documentation of perioperative morbidity exposes trainees to the full spectrum of surgical risk, including minor, cumulative, and delayed complications that are often under-represented in traditional operative logs. Structured complication data support reflective practice, objective assessment of learning curves, and competency-based progression, while also informing appropriate case allocation and supervision within training programmes.

The Clavien-Dindo classification (CDC) is currently the surgical complication grading system most widely used [8]. The CDC categorises complications according to the type of therapeutic intervention required, which ranges from minor deviations from the normal postoperative course (grade I) to death (grade V). The Comprehensive Complication Index (CCI) sought to improve on this framework by aggregating all complications experienced by a patient into a single weighted score. However, both systems are fundamentally clinician-centred and intervention-focused, and frequently neglect complications that do not require active medical or surgical treatment such as fatigue, chronic pain, and sexual dysfunction. Furthermore, intraoperative complications are not captured by the CDC.

In addition, these systems do not adequately account for procedure-specific contexts or the clinical relevance of complications relative to the operation performed. A given intervention may have markedly different implications depending on the procedure, anatomic site, and patient expectations. This limitation was a primary motivation for the CAMUS initiative, which was designed to capture event-level detail, cumulative morbidity, and procedure-specific nuance and thus allow more clinically meaningful interpretation and comparison of outcomes across diverse urological surgeries.

Moreover, the CDC and CCI only allow documentation of the highest-grade complication per patient per surgical episode, and thus obscure the cumulative burden of multiple lesser complications. This has significant implications for patient outcomes and recovery experiences, and the accuracy of institutional and interventional benchmarking. In addition, these systems do not integrate patient-reported outcome measures (PROMs) or patient experience metrics and often fail to capture complications occurring beyond 30 d or 90 d postoperatively [9,10], which are particularly relevant for high-morbidity procedures such as radical cystectomy [5]. The under-representation of late, recurrent, or subjective complications poses challenges for both clinical research and real-world patient care.

Multiple systematic reviews of the literature have identified wide heterogeneity in complication reporting in urology. For example, 30-d and 90-d complication rates following radical cystectomy vary significantly between studies and range from 26% to 86%, and from 30% to 100%, respectively [11–17]. While differences in surgical complexity, patient comorbidity, and institutional expertise partly explain this variation, it is widely assumed that inconsistency in complication documentation and classification

plays a greater role. No current system has reached universal acceptance in the urology community, and few have undergone large-scale prospective validation. Even among validated frameworks such as the CDC, ambiguity remains in how to define, grade, and report complications that are serial or recurrent or require multiple interventions to resolve [18–20].

A key challenge in developing any complication reporting system is balancing sufficient clinical detail with usability and feasibility. Excessive complexity risks poor adoption and incomplete reporting, whereas oversimplification obscures clinically meaningful information. CAMUS addresses this by adopting a modular design, with a simple core data set suitable for routine clinical use and optional advanced layers that facilitate granular documentation when required for research, benchmarking, or education.

In addition, there is no consensus on how to report so-called “complication-intervention events”, which are specific combinations of a clinical complication and the therapeutic action taken in response. While these events are highly relevant to patients and clinicians alike, their reporting remains variable and often poorly defined in the literature. Furthermore, there is growing recognition that traditional classification frameworks overlook the perspectives of nursing staff and patients, both of whom provide critical insight into early complication signs, the subjective burden, and the impact on quality of life (QoL).

To address these longstanding challenges, the CAMUS project (Complications After Major and Minor Urological Surgery) was launched in 2019 by a global, multidisciplinary consortium of urologists, anaesthetists, nurses, behavioural scientists, and patient advocates [21]. The aim of CAMUS is to develop a comprehensive, standardised, and patient-inclusive system for classifying surgical complications [21,22]. This initiative builds on existing evidence and practice but seeks to fill critical gaps via a series of interlinked research arms that include stakeholder consensus development, real-world data analysis, the creation of digital infrastructure, and prospective validation [9,23].

The CAMUS initiative was established via targeted competitive research funding obtained during dedicated research fellowships to support methodological development, consensus processes, and infrastructure design. Since inception, CAMUS has been sustained via investigator-driven academic collaboration to ensure scientific independence. Ongoing and future sustainability will be supported via additional competitive funding, shared institutional ownership, and integration into routine audit and digital workflows.

CAMUS was designed as a multiarm study incorporating both retrospective and prospective data collection, Delphi consensus studies with physicians and nurses, behavioural economics-informed patient surveys, and the development of a novel surgical difficulty and risk index. With contributions from 180 centres across 33 countries, CAMUS encompasses data for more than 130 000 major urological procedures [21,22,24–28]. This unprecedented international scope makes it the largest complication classification development project in surgery to date and ensures that the

framework is grounded in real-world diversity of practice and patient populations.

Although initially developed within urology, CAMUS was conceived from the outset as a specialty-agnostic framework. Its principles of comprehensive event capture, intervention-linked grading, and patient-inclusive reporting are applicable across surgical disciplines. Future phases of CAMUS are explicitly designed to support extension to other procedural specialties, particularly those involving major abdominal and pelvic surgery, to facilitate cross-specialty benchmarking and broader adoption of a unified complication reporting language.

The goals of CAMUS are fourfold:

1. To create a conclusive and reproducible language for complication reporting via international Delphi consensus that incorporates expert opinions from surgeons, anaesthetists, perioperative nurses, and patients themselves;
2. To build and maintain a large multinational database of surgical complications that allows for robust statistical analysis, prediction modelling, and interinstitutional benchmarking;
3. To develop validated intraoperative and perioperative risk and difficulty indices for more accurate surgical planning, patient counselling, and resource allocation; and
4. To prospectively validate the CAMUS classification system and associated digital tools that integrate PROMs and other patient-centred metrics to ensure that reporting reflects real-world complication burdens.

In addition to improving classification, the development of accurate risk prediction models may help to explain variation in complication rates by incorporating differences in patient comorbidity, surgical difficulty, and institutional characteristics [29]. Effective risk stratification allows preoperative identification of high-risk cases and facilitates multidisciplinary decision-making, including the allocation of intensive care resources, surgical planning, and tailored postoperative care pathways [30,31]. It also enhances inter-surgeon and interinstitutional comparisons, which are vital for quality benchmarking and performance review [32]. Moreover, the integration of PROMs and patient perspectives into complication reporting ensures a more holistic evaluation of outcomes that reflects not only clinical events but also functional and QoL consequences that matter most to patients [33].

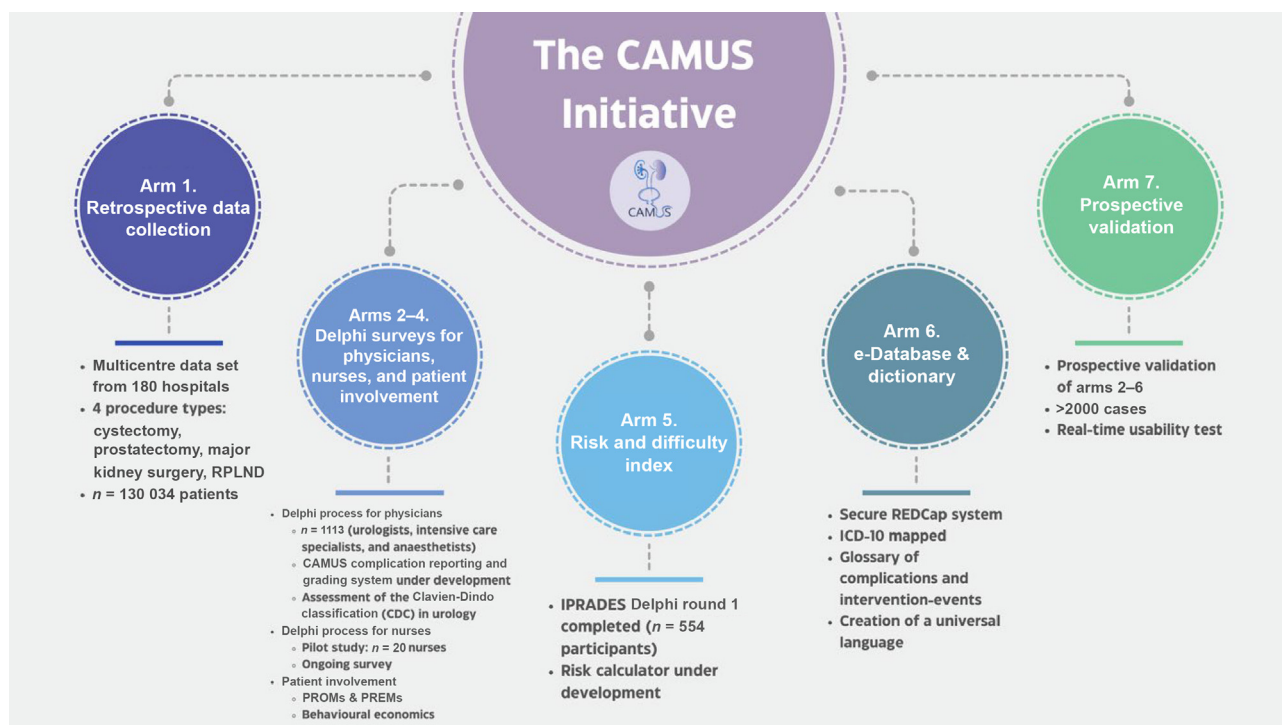
## 2. Study design and framework

The CAMUS initiative is structured as a multiphase, multi-centre international cohort study that includes retrospective and prospective collection of data, the development of stakeholder consensus, the design of digital infrastructure, and validation analysis. The modular design comprises seven coordinated yet distinct study arms, each of which contributes to the overall development and implementation of the CAMUS classification system (Table 1 and Fig. 1).

**Table 1 – Overview of the seven CAMUS study arms: design and progress to date**

| Arm   | Title                         | Objective  | Methods   | Status   |
|-------|-------------------------------|--|---|--|
| Arm 1 | Retrospective data collection | Collect real-world data on major urological procedures and postoperative outcomes          | Retrospective chart review from 180 hospitals; 130 034 cases across 4 procedure types | Data collection complete; analyses and validation ongoing                      |
| Arm 2 | Delphi study: physicians      | Achieve international expert consensus on complication classification and grading          | REDCap-based Delphi survey with 1113 clinicians from 57 countries, ≥75% consensus     | Initial Delphi study complete; framework refinement and validation planned     |
| Arm 3 | Delphi study: nursing staff   | Integrate nursing perspectives into complication reporting and classification              | Pilot Delphi round with 20 nurses assessing feasibility and thematic insights         | Pilot complete; large-scale Delphi planned                                     |
| Arm 4 | Patient involvement           | Assess patient-perceived burden and value of complications using PROMs and economic tools  | Digital survey of PROMs, VAS, and WTP tools to measure subjective complication burden | Planned  |
| Arm 5 | Risk and difficulty index     | Develop a risk and difficulty index for surgical planning based on expert Delphi consensus | Structured Delphi consensus to weight and validate the IPRADES scoring model          | Preliminary Delphi study complete; further Delphi study and validation planned |
| Arm 6 | e-Database and Dictionary     | Design a digital data capture system and dictionary aligned with ICD and CAMUS grading     | Database fields mapped to ICD codes; structured data entry for real-time analysis     | Planned  |
| Arm 7 | Prospective validation        | Pilot real-time implementation and comparison of CAMUS to traditional grading systems      | Real-time entry of >2000 cases; feedback on usability, sensitivity, and acceptability | Planned  |

ICD = International Classification of Diseases; IPRADES = Intraoperative and Postoperative Risk and Difficulty Estimation Index; PROMs = patient reported outcome measures; REDcap = Research Electronic Data capture; VAS = Visual Analogue Scale; WTP = willingness to pay.



**Fig. 1 – Overview of the seven research arms in the CAMUS Initiative, illustrating the multiphase, international framework for complication reporting, consensus development, risk stratification, database creation, and prospective validation. ICD = International Classification of Diseases; IPRADES = Intraoperative and Postoperative Risk and Difficulty Estimation Index; PREMs = patient-reported experience measures; PROMs = patient-reported outcome measures; REDcap = Research Electronic Data capture; RPLND = retroperitoneal lymph node dissection.**

### 2.1. Arm 1: retrospective data collection

To date, discrete data sets have been collated for 130 034 patients who have undergone major urological procedures (radical cystectomy with urinary diversion, radical prostatectomy, major kidney surgery, and retroperitoneal lymph node dissection [RPLND]) at participating centres world-

wide. These data include patient demographics, comorbidities, surgical variables, and postoperative outcomes, with complications graded according to the CDC.

By design, endoscopic procedures such as transurethral resection of bladder tumour and transurethral resection of the prostate were deliberately excluded from the initial validation phase to allow testing of the CAMUS framework in

high-complexity, high-morbidity surgeries for which complication-intervention pathways are more heterogeneous. Inclusion of lower-risk endoscopic procedures is planned in subsequent phases once the system has been fully validated in major surgery.

Moving forward, the objectives of this arm are as follows:

- o To generate robust, clinically relevant insights into post-operative outcomes by analysing the international data set;
- o To externally validate established complication scoring systems, including the CDC and CCI, and assess their consistency, sensitivity, and applicability across diverse health care settings;
- o To conduct patient-level meta-analyses and multivariable regression to identify independent predictors of morbidity as a foundation for predictive models and a validated risk index for preoperative assessment;
- o To facilitate anonymous benchmarking across hospitals, health care systems, and regions worldwide, with identification of structural and procedural factors driving variability in complication rates; and
- o To use the large-scale data set to address a range of clinically relevant research questions, with the ultimate aim of improving surgical risk stratification, outcome prediction, and perioperative care worldwide.

### 2.2. *Arm 2: Delphi study for physicians*

A structured international Delphi survey was conducted in 2022 that involved 1113 clinicians from 57 countries, with consensus achieved on key domains for complication reporting and grading. The survey was performed under the guidance of the CAMUS Steering Committee. Participant experts were contacted via e-mail (with addresses obtained via CAMUS databases and trial coordinators) and word of mouth. Consensus was predefined as  $\geq 75\%$  agreement across rounds.

Moving forward, the Delphi outputs will guide the establishment of a new CAMUS complication grading and reporting system. This will involve refinement and expansion of the CDC, with integration of the new CAMUS domains and supplemental grades, and the creation of a unified framework tailored for urological surgery. The revised system will then be validated against the full CAMUS registry of >130 000 patients, which will allow direct comparison of CAMUS and CDC performance across procedures, centres, and health care systems [24]. This will provide evidence for the sensitivity, reproducibility, and international applicability of the CAMUS framework.

### 2.3. *Arm 3: Delphi study for nursing staff*

A dedicated Delphi survey with specialist urology nurses was conducted in 2022 to capture their perspectives on complication reporting and grading. The pilot phase, performed under guidance by the CAMUS Steering Committee, included 20 participants and revealed strong support (75%) for the CAMUS system and universal recognition of the need for reporting consensus.

Moving forward, the nursing Delphi survey will be expanded to several hundred participants across multiple countries and practice settings. This broader cohort will capture diverse perspectives from perioperative, ward-based, and advanced practice nurses in urology. The goal is to embed nursing expertise into the CAMUS framework by defining how nurses identify, grade, and document complication-intervention events. This will ensure that bedside recognition of morbidity, minor but clinically significant interventions, and QoL-related outcomes are appropriately represented. The expanded survey will also assess training needs, the feasibility of integration into nursing workflows, and barriers to adoption. Findings will directly inform the final CAMUS reporting and grading system, which will thus be inclusive of all professional groups involved in perioperative care [28].

### 2.4. *Arm 4: patient involvement*

Patients undergoing urological surgery will be surveyed to capture PROMs and patient-reported experience measures). Validated tools such as the 36-item Short Form survey on general health (SF-36), International Index of Erectile Function-15 (IIEF), Female Sexual Function Index (FSFI), International Consultation on Incontinence Questionnaire (ICIQ), and Gastrointestinal Quality of Life Index (GIQLI) will be used to assess QoL domains. These will be complemented by behavioural-economics instruments, including willingness to pay (WTP) and perceived value frameworks, which will quantify the subjective burden of complications and identify which outcomes matter most to patients.

Data will be analysed to construct a Patient-Centred Burden Index, which will integrate with clinician-derived CAMUS grading and ensure that classification reflects both objective morbidity and patient-valued outcomes.

### 2.5. *Arm 5: surgical risk and difficulty index*

A Delphi survey process, guided by the CAMUS Steering Committee and involving surgeons, anaesthetists, and methodologists, was conducted in 2025 to develop the CAMUS Intraoperative and Postoperative Risk and Difficulty Estimation Index (IPRADES) tool, which is a comprehensive scoring system for predicting surgical difficulty and perioperative risk in urology. The index incorporates preoperative, intraoperative, and immediate postoperative factors and takes into account for organ-specific variables, surgeon experience, and surgical complexity [26].

Moving forward, the IPRADES Delphi process will be expanded to several hundred international participants to achieve broad consensus and ensure applicability across diverse practice environments. Responses will be analysed to refine item weighting, with multivariable regression modelling used to validate discriminatory accuracy against outcomes such as high-grade complications, intensive care unit (ICU) admission, transfusion, and length of stay. Once calibrated using the CAMUS data set, the final IPRADES score will be categorised into low-risk, moderate-risk, and high-risk strata. It will be implemented as a web-based calculator to guide case selection, patient counselling, benchmarking

of surgical difficulty, and allocation of perioperative resources [27].

### 2.6. Arm 6: CAMUS e-database and dictionary

A secure, user-friendly electronic database will be built to standardise complication reporting across centres. This database will be structured around a CAMUS data dictionary that will incorporate both urology-specific and general complications mapped to International Classification of Diseases v10 (ICD-10) codes where possible. The database will allow time-stamped entry of multiple complications per patient, will link complications to interventions, and will accommodate supplemental grades and PROMs.

Automated export to statistical software and real-time dashboards will support clinical audits, benchmarking, and research. The platform will also include audit trails, role-based access, and encryption to ensure compliance with international data governance standards.

### 2.7. Arm 7: prospective validation

The CAMUS classification and database will undergo large-scale prospective validation following pilot testing. Participating centres will enter data in real time for >2000 new surgical patients for assessment of usability, inter-rater reliability, and completeness of reporting. Outcomes from the CAMUS system will be compared directly to the CDC and CCI to evaluate sensitivity, reproducibility, and alignment with PROMs.

Stakeholder feedback will guide iterative refinement of the dictionary and interface to ensure the feasibility of integration into routine surgical audits and education. This phase is intended to confirm that CAMUS is scalable, reliable, and internationally applicable.

Each arm was independently designed and conducted, with harmonisation overseen by a global steering committee. While the CAMUS methodology is comprehensive, its modular design allows centres to adopt the framework at a level appropriate to their resources. A simplified core data set supports routine clinical use, with advanced components activated selectively. This scalability ensures applicability across diverse health care environments while preserving methodological rigour.

## 3. Protocol overview: data collection and management

### 3.1. Retrospective arm (arm 1)

The CAMUS initiative involved 180 hospitals across 136 cities in 33 countries spanning six continents. The largest number of contributing centres was in Europe ( $n = 96$ ), followed by North America ( $n = 23$ ), Oceania ( $n = 23$ ), Asia ( $n = 21$ ), South America ( $n = 12$ ), and Africa ( $n = 5$ ). This mix of academic, private, and regional centres provides a diverse representation of surgical practice, infrastructure, and patient populations (Table 2). Adult patients (aged  $\geq 18$  yr) undergoing major urological surgeries were included via both retrospective chart review and prospective enrolment.

**Table 2 – Geographic distribution of centres contributing to the CAMUS multicentre database by continent and country**

| Parameter                              | Centres (n) |
|--|-------------|
| Centres contributing data by continent |             |
| Europe                                 | 96          |
| North America                          | 23          |
| Oceania                                | 23          |
| Asia                                   | 21          |
| South America                          | 12          |
| Africa                                 | 5           |
| Centres contributing data by country   |             |
| Germany                                | 28          |
| Australia                              | 22          |
| UK                                     | 18          |
| US                                     | 18          |
| Italy                                  | 13          |
| France                                 | 9           |
| Brazil                                 | 8           |
| Switzerland                            | 7           |
| India                                  | 6           |
| Canada                                 | 5           |
| Belgium                                | 6           |
| Spain                                  | 4           |
| Netherlands                            | 4           |
| South Africa                           | 3           |
| Japan                                  | 3           |
| Argentina                              | 3           |
| Republic of Singapore                  | 3           |
| Turkey                                 | 3           |
| Czechia                                | 2           |
| Austria                                | 2           |
| Taiwan                                 | 1           |
| New Zealand                            | 1           |
| China                                  | 1           |
| Ghana                                  | 1           |
| Chile                                  | 1           |
| Indonesia                              | 1           |
| Greece                                 | 1           |
| Slovakia                               | 1           |
| Malaysia                               | 1           |
| Israel                                 | 1           |
| Sweden                                 | 1           |
| Egypt                                  | 1           |
| Thailand                               | 1           |
| Number of cities/towns                 | 136         |
| Number of hospitals                    | 180         |

In total, 130 034 major urological procedures were captured (Table 3):

- Radical cystectomy with urinary diversion: 29 098 cases from 126 centres.
- Radical prostatectomy: 75 001 cases from 111 centres.
- Major kidney surgery (partial nephrectomy, radical nephrectomy, nephroureterectomy): 24 476 cases from 107 centres.
- RPLND: 1459 cases from 30 centres.

These procedures, performed between 1978 and 2025, represent the largest international data set of its kind in urological surgery. This will provide a uniquely rich platform for benchmarking outcomes across healthcare systems and inform the development and validation of the CAMUS classification.

Participating sites represented diverse geographic and institutional settings, including academic centres, private hospitals, and regional surgical units. Exclusion criteria were patients aged <18 yr, those unable to provide informed consent, and individuals with unreliable data because of advanced illness or cognitive impairment.

**Table 3 – Baseline procedural data for 130 034 patients in the CAMUS multicentre database: number of contributing hospitals and patient numbers for cystectomy, prostatectomy, major kidney surgery, and retroperitoneal lymph node dissection**

| Procedure   | Number |
|---|--------|
| <b>Cystectomy</b>   |        |
| Hospitals contributing cystectomy data                            | 126    |
| Patients who underwent cystectomy                                 | 29 098 |
| <b>Prostatectomy</b>  |        |
| Hospitals contributing prostatectomy data                         | 111    |
| Patients who underwent prostatectomy                              | 75 001 |
| <b>Major kidney surgery</b>                                       |        |
| Hospitals contributing major kidney surgery data                  | 107    |
| Patients who underwent major kidney surgery                       | 24 476 |
| Radical nephrectomy   | 8832   |
| Partial nephrectomy   | 13 670 |
| Nephroureterectomy  | 1974   |
| <b>RPLND</b>  |        |
| Hospitals contributing retroperitoneal lymph node dissection data | 30     |
| Patients who underwent retroperitoneal lymph node dissection      | 1459   |

Data elements captured patient demographics, comorbidities, operative characteristics, and postoperative outcomes, with complications initially graded using the CDC, CCI, and Bern CCI before being mapped to the CAMUS system. Surgeon experience and centre-level procedural volume metrics were also captured in anonymised form for analysis of volume-outcome relationships and training-stage effects in later CAMUS study arms.

Data were collected for the following variables:

- Preoperative: age, sex, body mass index, American Society of Anesthesiologists (ASA) score, Charlson Comorbidity Index, diabetes status, smoking status, renal function, anaemia, prior abdominal surgery, and perioperative therapies (eg, neoadjuvant chemotherapy or radiotherapy).
- Intraoperative: procedure type, surgical approach (open, laparoscopic, robotic), operative time, estimated blood loss, transfusion requirements, and intraoperative complications.
- Postoperative: pathology, nodal staging, hospital length of stay, readmissions, death, complication type and timing, intervention, and CDC grade.

Non-identifiable data were encrypted and stored on secure servers at the Royal Melbourne Hospital in compliance with international data governance standards. Data were managed in Research Electronic Data capture (REDCap), which allows structured field entry with logic checks, dropdown menus, and enforced definitions to minimise errors. Each record was time stamped and version-controlled with a full audit trail. Batch import functionality allowed large-scale institutional uploads, while custom scripts supported export to R, SPSS, and Stata for downstream analysis [34,35].

Future directions for arm 1 include external validation of existing classification systems (CDC, CCI) and the CAMUS classification system across diverse populations, identifying predictors of morbidity through patient-level meta-analysis and regression modelling, and enabling benchmarking

across hospitals and continents, revealing structural and procedural factors associated with variation in outcomes. These analyses will provide the empirical foundation for the CAMUS framework, inform the development of predictive indices, and highlight opportunities to improve perioperative outcomes globally.

Participation in CAMUS is voluntary, and early adopters may be more likely to be academically engaged or quality-focused, which may introduce potential selection bias. However, this is a pragmatic and necessary feature of early framework development to ensure data quality and feasibility. The inclusion of centres from 33 countries across diverse health care systems mitigates, but does not eliminate, this effect. As automation and integration improve, broader participation is anticipated.

### 3.2. Delphi survey for physicians (arm 2)

Between 2020 and 2023, a multiround Delphi survey was conducted to establish international consensus on complication classification and reporting, with the specific aim of refining the CAMUS system. A total of 1113 clinicians from 57 countries, including consultant urologists, trainees, anaesthetists, and intensive care specialists, participated. Surveys were administered via REDCap, structured into 12 modules with Likert scales, multiple-choice questions, and free-text responses. Consensus was predefined as agreement of  $\geq 75\%$ .

Round 1 achieved broad engagement. Participants expressed strong agreement on the need for serial and multistage complication tracking, integration of intraoperative and extended grading, minor and long-term outcomes, disability-adjusted severity modifiers, and patient-reported metrics. Free-text responses were coded independently, synthesised, and ranked before being iteratively presented again in later rounds to achieve convergence.

To build on these findings, CAMUS will formalise a new complication grading and reporting system by refining and extending the CDC via supplemental CAMUS domains (intraoperative, postoperative, extended, and disability-adjunct grades). In parallel, a 0–100 continuous scale will be developed to underpin the CAMUS CCI to allow quantification of cumulative morbidity at the individual patient level.

The revised framework will be validated against the >130 000-patient CAMUS registry to facilitate comparative analyses with the CDC and CCI across procedures, institutions, and continents. These evaluations will test the reproducibility, inter-rater reliability, and sensitivity to patient-centred outcomes. Ultimately, outputs will be synthesised into consensus-driven recommendations and published as international guidelines to provide a foundation for standardised surgical audits, research, and perioperative counselling worldwide.

### 3.3. Delphi survey for nursing staff (arm 3)

A pilot Delphi round was completed with 20 experienced inpatient and outpatient nurses specialised in urology, perioperative nurses, and urology-specific advanced practice nurses/nurse practitioners. The survey addressed complication recognition, intervention documentation, training

needs, and the feasibility of structured nurse participation. The results demonstrated universal support for the development of a standardised classification system. All participants recognised its necessity, and 75% agreed on adoption of the proposed CAMUS framework. Nurses emphasised the importance of their inclusion in classification development, particularly for early bedside detection of morbidity, documentation of interventions that may not require physician input, and management of complications with significant QoL impact such as wound issues, stoma care, and continence. Barriers were also identified, including inconsistent training, under-recognition of nurse-relevant complications, and the lack of structured reporting tools.

To build on these insights, the nursing Delphi process will now be expanded to several hundred participants across multiple continents. Recruitment will deliberately encompass perioperative nurses, ward-based staff, nurse practitioners, and advanced practice nurses to ensure broad representation of roles and practice settings. The survey will test refined definitions, complication-intervention pairings, and reporting tools tailored to the unique contributions of nursing staff to the recognition and management of complications. Specific domains will include early identification of clinical deterioration, documentation practices, the feasibility of integration into daily workflows, and assessment of training needs and barriers to adoption. Findings will be embedded into the CAMUS dictionary and grading schema to ensure that nursing expertise is incorporated into the final framework. This will guarantee that arm 3 of CAMUS reflects the multidisciplinary reality of perioperative care and captures a more complete picture of patient morbidity.

### 3.4. Patient input (arm 4)

Patients from CAMUS collaborative centres will be invited to participate via digital survey platforms. Eligible participants will include adults (aged  $\geq 18$  yr) who have undergone major urological surgery within the previous 12 mo. To capture health-related QoL, validated PROMs will be used, including the SF-36 for general health, IIEF-15, FSFI, ICIQ for urinary continence, and GIQLI for gastrointestinal QoL.

These validated tools will be supplemented by custom-designed behavioural economics modules, such as WTP to avoid specific complications and reverse-WTP or refund preference models related to adverse outcomes. Patients will also complete Visual Analogue Scale (VAS) questionnaires to rate the perceived burden of complications and participate in scenario-based assessments (eg, upgrade and refund simulations) to quantify subjective outcome preferences and complication severity. For instance, postprostatectomy patients may be asked how much they would pay for guaranteed restoration of continence or erectile function, or what refund they would expect if long-term complications occurred.

Findings will be synthesised into a patient-centred subjective burden index designed to complement clinician-derived grading within the CAMUS classification. By incorporating patient valuations, this index will help in redefining what constitutes a “major” or “bothersome” com-

plication, particularly in cases that providers might otherwise categorise as “minor”.

### 3.5. Development of a risk and difficulty index (arm 5)

Underpinned by the published protocol paper, IPRADES is being developed as a CAMUS organ- and procedure-specific tool to anticipate surgical difficulty and estimate perioperative risk in major urological operations. Its purpose is to facilitate standardised assessment of case complexity, training value, and perioperative triage.

Phase 1 was completed using a structured Delphi methodology with 60 high-volume urologists, anaesthetists, and perioperative methodologists. Participants rated 40 candidate variables across four domains: (1) preoperative factors, such as tumour size and stage, organ-specific anatomic complexity (eg, RENAL nephrometry score, prostate volume), prior surgery or radiotherapy, neoadjuvant treatment, comorbidities (ASA score, Charlson Comorbidity Index, body mass index); (2) general intraoperative complexity, including surgical approach (open vs minimally invasive), adhesions or fibrosis, anatomic variants, blood loss, transfusion, operative duration, and local invasion; (3) organ-specific intraoperative findings; and (4) immediate postoperative course indicators, such as ICU admission, early reintervention within 72 h, transfusion, and early complications (optional extension, not required for prospective predictive modelling). Each parameter was rated for clinical relevance and procedural impact using a 10-point Likert scale, with  $\geq 75\%$  agreement required for consensus. Median and interquartile range statistics were used to test stability, with Kruskal-Wallis subgroup analyses performed by discipline and region. Delphi outputs confirmed alignment between surgical and anaesthetic perspectives.

In phase 2, retrospective multicentre data sets will be analysed: >1500 cystectomy cases from the Bern database first, followed by validation in the >130 000-patient CAMUS data set. Associations with predefined outcomes (CDC grade  $\geq III$ , CCI  $\geq 33.7$ , ICU admission) will be examined to define thresholds and calibrate risk weightings.

Phase 3 will involve multivariate logistic regression modelling, with predictive performance assessed via receiver operating characteristic (ROC) curves, calibration plots, c-index metrics, and analysis of the area under the ROC curve (AUC). Stepwise model selection will be based on minimisation of the Akaike information criterion (AIC), while bootstrapping and k-fold cross-validation will mitigate overfitting and test robustness. The final model will be visualised using nomograms (*rms* package in R) and generate a cumulative difficulty score (scale 0–100) stratified into low, moderate, and high tiers, with adjustments for surgeon experience.

Pilot testing will assess construct validity and feasibility, followed by prospective validation across CAMUS centres. Anticipated applications include preoperative communication of risk to patients, surgical planning, benchmarking of procedural difficulty, triaging of teaching cases, and forecasting of resource allocation for ICU and high-dependency units.

### 3.6. *e-Database and dictionary (arm 6)*

The CAMUS e-database will be implemented as a secure, web-based platform using REDCap infrastructure with structured and encrypted data-entry fields. A dynamic data dictionary mapped to ICD-10 codes and urological terminology will guide standardised entry of complications, interventions, and PROMs. The dictionary will encompass both common urological complications (eg, anastomotic leak, haematuria, infection) and general postoperative issues (eg, pneumonia, myocardial infarction).

Governance of the CAMUS dictionary will be overseen by the CAMUS Steering Committee. New complication-intervention events submitted by participating centres will undergo expert review before integration to ensure version control, consistency, and transparency. This structure enables arm 6 to function as a living, continuously updated resource.

The system will support entry of multiple complications per patient, with automatic time-stamping of events and linkage to interventions. Severity will be graded in parallel using CDC, CCI, Bern CCI, and the new CAMUS scale. Complication timelines, readmissions, and patient-reported burden data will be mapped for integrated analysis.

Planned features include a dynamic interface for real-time auditing, automated export to statistical software, and interactive dashboards for morbidity and mortality review, benchmarking, and educational purposes. The e-database will undergo pilot testing to evaluate usability, data integrity, and workflow integration, with iterative refinement based on feedback from end-users and participating institutions.

### 3.7. *Prospective validation (arm 7)*

In future implementation phases, the CAMUS classification and digital infrastructure will be prospectively applied across participating centres. The project aims to capture data from more than 2000 new patients entered in real time for formal validation of the system against traditional classification frameworks. Validation will assess inter-rater reliability, predictive accuracy, alignment with PROMs, and the ability to capture nuanced, multistage complications.

Centres will be invited to provide structured feedback on usability, the data burden, and integration into routine surgical audit workflows. It is anticipated that CAMUS will offer better resolution of complication tracking, greater granularity, enhanced recognition of complications often under-reported in legacy systems, and high acceptability among both clinicians and patients.

### 3.8. *Ethics and regulatory approvals*

Recruitment of centres to process institutional data bases and collect data to characterise complication incidence was undertaken between August 2019 and February 2025. Ethics approval was granted by Melbourne Health (QA2020046) and Epworth HealthCare (EH2021-708). The study was registered on ClinicalTrials.gov (NCT04976946) on August 12, 2021. Additional methodological support

was sought from relevant international bodies, including the European Association of Urology.

## 4. **Statistical analysis**

### 4.1. *Statistical inference and risk factor screening*

To identify independent risk factors for postoperative complications, statistical analyses will be selected according to the data distribution and study design. Continuous variables will be reported as the median and interquartile range, and compared using nonparametric tests (eg, Mann-Whitney U or Kruskal-Wallis test) unless normality assumptions are met. Categorical data will be expressed as the frequency and percentage, and compared using  $\chi^2$  or Fisher's exact tests, as appropriate. Correlations will be assessed using Spearman's rank coefficient. Where relevant, multiple comparisons will be adjusted using standard correction methods (eg, Bonferroni or false discovery rate).

### 4.2. *Systematic meta-analysis of individual patient data*

In the first study arm (retrospective cohort data) we will use a meta-analysis of individual patient data (IPD) to investigate clinical outcomes and predictive factors across a large cohort of patients undergoing urological procedures. By pooling raw, patient-level data from multiple studies and centres, we aim to overcome limitations inherent to traditional meta-analyses of aggregate data, such as inconsistent variable definitions and lack of adjustment for individual-level covariates.

Our objectives are to (1) derive more precise estimates of key outcomes, (2) identify and validate predictors of perioperative and long-term complications, and (3) explore potential interactions or subgroup effects that could inform personalised risk stratification and clinical decision-making. This comprehensive analysis will use the strengths of IPD to provide robust, generalisable evidence that could improve patient counselling, risk estimation, and perioperative planning in urological practice.

#### 4.2.1. *Methodological description and statistical analysis*

We will harmonise variables by reconciling definitions of exposures, outcomes, and covariates across data sets using a standardised data dictionary. When necessary, we recoded or imputed variables to ensure consistency.

The primary outcomes (eg, major postoperative complications within 30 d and 90 d, long-term functional outcomes, survival) and secondary outcomes (eg, length of stay, readmission, minor complications) included and candidate predictors (eg, demographic factors, comorbidities, procedural variables, and preoperative laboratory parameters) will be described.

We will use a one-stage IPD meta-analysis framework that fits generalised linear mixed-effects models with study or centre as a random effect to account for clustering. This approach allows simultaneous estimation of overall effects and exploration of patient-level interactions. Missing data will be handled via multiple imputation under the assump-

tion of missing at random. We will assess heterogeneity by estimating variance components across studies and tested for effect modification by key covariates. Sensitivity analyses will include two-stage approaches and complete-case analyses to evaluate the robustness of the findings.

#### 4.3. Machine learning

Machine learning (ML) algorithms will be used to identify generalisable complication-intervention event patterns and enhance prediction accuracy beyond traditional statistical models. The objective is to identify nonlinear relationships and complex interactions that may be overlooked in conventional analyses. The intention is to use an ensemble approach that leverages a suite of ML algorithms. This suite consists of standard techniques, including logistic regression (for binary outcomes only), support vector machines, naïve Bayes classifiers, k-nearest neighbours, discriminant analysis, random forests, and neural networks. If the sample size and data richness permit, more advanced deep learning techniques may also be investigated, including recurrent neural networks or long short-term memory models for sequential or time-dependent data, autoencoders for unsupervised dimensionality reduction and anomaly detection, and Bayesian neural networks for quantification of uncertainty. Model training will use repeated tenfold cross-validation within the development data set (80%). An external validation set (20%) will be used to test generalisability. A grid of tuning parameters will be established on the basis of initial analysis, and optimal configurations will be selected by minimising the cross-validation error. The performance of models will be assessed using a comprehensive set of metrics, including discrimination measures (ROC, AUC, precision, recall, F1 score, and balanced accuracy), calibration metrics (Brier score, calibration plots, and the Hosmer-Lemeshow test, where applicable), and interpretability tools such as variable importance metrics (eg, Gini index in random forests).

#### 4.4. Development of prediction models for diverse outcome parameters

Multivariate parametric prediction models will be used to assess the simultaneous effects of independent variables on a range of outcome measures. Depending on the type of outcome, we will apply multivariate linear regression for continuous variables, multivariate logistic regression for binary outcomes, and generalised linear (mixed) models for data with a non-normal distribution or hierarchical structure. Outcome measures will include mortality and morbidity-related parameters (eg, overall complication burden at defined time points, and specific complications such as ureteroileal anastomotic stricture).

When necessary, outcome transformations (eg, Box-Cox, inverse-logit) will be used to meet model assumptions such as normality of residuals or homogeneity of variance. If sufficient data are available, we will split the data set into a training set (80%) and an independent testing/validation set (20%) to allow internal validation and prevent model overfitting. Model selection will be guided by stepwise procedures (eg, backward elimination) that minimise the AIC.

Model diagnostics may include the Shapiro-Wilk test for the normality of residuals, Bartlett's test for the homogeneity of variance, standardised residuals to detect outliers, and the Hosmer-Lemeshow test for generalised linear (mixed) models. Model performance will be evaluated using standard techniques such as ROC curves and the AUC for classification models and  $R^2$  values for continuous outcome models.

We will conduct sensitivity analyses by applying different link functions, excluding outliers and influential observations, or developing comparable prediction models using modern ML methods such as support vector machines, naïve Bayes, or decision trees (Section 4.5). Results will be visually presented with confidence intervals and/or summarised in tables.

#### 4.5. Prediction modelling of complications

In the first phase, prediction models for complications will be developed using data from a tertiary referral centre for cystectomy and urinary diversion (Department of Urology, Inselspital Bern) that were prospectively collected between 1999 and 2021, including 1557 patients undergoing cystectomy and urinary diversion at the Department of Urology, Inselspital Bern.

In the second phase, these models will be externally validated using data from the CAMUS collaborative cohort described above.

For the Bern cystectomy cohort, each complication (with a maximum of 54) was recorded with respect to the postoperative day (POD), type of complication (eg, pulmonary, cardiac), and type of intervention required, and was graded according to the CDC as determined by two senior clinicians. Using the CDC, we calculated the CCI score for POD 1 to POD 30 for each patient. To calculate the CCI score, each CDC grade was multiplied by a specific weight as described in the original publication. These weights were derived from patients and physicians to accurately reflect the severity of complications from a clinical perspective. Multiple complication scores were then summarised for each patient. The square root of the sum divided by two yields the CCI score. The maximum value of the CCI score was set to 100, which reflects death of the patient.

To proceed with prediction modelling, all preoperative available variables will be included. Laboratory values will be used if the proportion of missing values is  $\sim$ 25% and the assessment date is within 30 d before surgery as part of the clinical routine. In cases of multiple values, the mean will be calculated and used for further computations. For the number of patients and predictor variables, no sample size calculation will be performed. All the predictors included are assessed preoperatively and will be grouped into categories according to the clinical context (eg, baseline data, laboratory findings, cancer data). Categorical predictors will then be summarised using the count and proportion, while numerical predictors will be described using the mean and median, depending on the data distribution.

The primary model outcome will be CCI-defined (and therefore cumulative) morbidity between POD 1 and POD 30, and between POD 31 and POD 90. Owing to the nature

of the data assessment, blinding of the assessors is not feasible. On the basis of clinical relevance, we have defined four CCI thresholds for our analyses:  $\geq 20.9$  = mild,  $\geq 26.2$  = moderate,  $\geq 33.7$  = moderate-severe, and  $\geq 42.4$  = severe. These thresholds reflect CCI scores for CDC grade II, IIIa, IIIb, and IVa, respectively.

Prediction models will be reported according to the guidelines for reporting clinical prediction models that use regression or ML methods (TRIPOD+AI; <https://www.tri-pod-statement.org/>). The model-building and evaluation approach used has been described in previous studies on the development of clinical prediction models. To assess the predictive performance for the primary outcome, we will train random forest models owing to their ability to deal with nonlinear relationships between dependent and independent variables. This is an important feature when predicting complication risk, as nonlinearity must be expected. For each predictor category, a model will be trained for both POD and CCI thresholds.

Missing data will be imputed using a single imputation method, assuming missing at random. For continuous variables, we will use median imputation. Categorical variables will be imputed by the mode.

For each model, the data set will be randomly split into a training set (70%) and a test set (30%), with splitting performed with respect to the outcome variable. Predictor variables will not be rescaled, standardised, or transformed and no hyperparameter tuning will be performed. All models will be calculated using the *caret* package.

ROC curves and the corresponding AUC will be calculated using predicted probabilities with the *pROC* package. Confidence intervals for the AUC values will be computed via bootstrapping. Calibration belts with associated 95% confidence intervals will be created for POD 3, 5, 10, 20, and 30 using the *givitiR* package. As recommended, the clinical utility of the trained models will be assessed using decision curve analysis for selected PODs (POD 5 and 30) with different CCI thresholds for the best-performing model domain using the *dcurves* package. Decision curve analysis involves the concept of net benefit (NB). NB weights benefit from true-positive classifications, with potential harm from false-positive classifications. Specific NB values depend on the risk aversion of clinicians and/or patients, which puts model performance in a realistic clinical context. Owing to differences in the prevalence of complications according to severity and POD, the standardised NB will be calculated by dividing the NB values by the highest attainable NB in each model to allow better and more intuitive comparison between models.

#### 4.6. Software and statistical power

Throughout, we will analyse data using SPSS v20.0 statistical software (SPSS, Chicago, IL, USA) and R v4.1.0 (R Foundation for Statistical Computing, Vienna, Austria). Owing to the exploratory and retrospective nature of the studies, no formal a priori power calculation will be conducted. However, post hoc power estimates may be provided for key findings where appropriate. Missing data will be assessed, and if >5% of data are missing for key variables, a multiple imputation

method (eg, multiple imputation by chained equations) will be applied. Sensitivity analyses will be conducted to compare the results from imputed and complete-case analyses. Statistical significance will be defined as  $p < 0.05$  (two-tailed), unless otherwise stated.

## 5. Discussion

The CAMUS initiative addresses long-standing gaps in surgical outcome reporting by introducing a patient-inclusive, multidisciplinary, and internationally validated classification system for urological complications. Historically, complication reporting has suffered from inconsistency and under-reporting that hinder effective benchmarking, research, and informed consent. Complication rates reported after major urological procedures such as cystectomy vary widely—for instance, 30-d and 90-d morbidity rates range from 26% to 86%, and from 30% to 100%, respectively—which underscores the urgent need for a standardised methodology.

The global representation of academic centres, private hospitals, and regional surgical units within CAMUS facilitated the development of a data set that reflects real-world diversity in patient populations, surgical complexity, and health care systems. This multicentre, multinational architecture strengthens the generalisability and clinical relevance of the CAMUS classification, and provides clarity on the true burden of surgical complications across various settings and levels of care.

Drawing on data from more than 130 000 major urological procedures contributed by 180 centres across 33 countries, CAMUS represents one of the largest and most comprehensive complication data sets assembled in the field. The breadth of this registry supports robust multivariable modelling to evaluate how baseline characteristics such as comorbidities, tumour burden, and prior interventions impact postoperative outcomes. With this scale, CAMUS provides the statistical power required to develop validated prediction models and risk-adjusted benchmarks, which thus addresses the longstanding opacity in surgical morbidity and will strengthen the evidence base for shared decision-making.

Crucially, CAMUS moves beyond physician-centred grading systems such as the CDC and CCI, which either fail to capture multiple complications per patient or reduce complex trajectories to single summary scores. CAMUS has a granular, event-level reporting format that accommodates cumulative, sequential, and multimodal complications, and thus more accurately reflects the full arc of patient morbidity and will facilitate both clinical audit and research.

A defining innovation of CAMUS is the integration of nursing and patient perspectives. Nurses contribute valuable insights into early deterioration and recovery trajectories, and their participation in the Delphi consensus improved the credibility and inclusivity of the reporting system. Equally significant is the incorporation of patient-reported outcomes and behavioural economic methods such as WTP and burden scaling, which highlight the high subjective impact of complications often considered “low-grade” in clinical terms (eg, urinary incontinence or sexual dysfunc-

tion). This alignment with patient priorities enhances the utility of the system for shared decision-making and counselling.

Another major advance is the IPRADES instrument. Developed via expert consensus and validated against CAMUS data sets, this organ-specific scoring system stratifies surgical complexity and perioperative risk. Its modular design incorporates preoperative and intraoperative factors to support multidisciplinary planning, patient selection, and trainee allocation. Later phases will expand validation across additional procedures and institutions.

Beyond expert-derived indices, ML approaches may further enhance the estimation of surgical difficulty by integrating patient factors, intraoperative metrics, and outcome data at scale. Artificial intelligence-based models can identify nonlinear relationships and dynamically refine risk estimates over time. These approaches are envisioned as complementary decision-support tools that augment, rather than replace, clinically interpretable indices such as IPRADES.

### 5.1. Strengths

The CAMUS initiative is unique in both scale and scope. Its principal strength lies in its multinational, multidisciplinary, and multistakeholder design to capture perspectives from surgeons, anaesthetists, nurses, patients, and health economists. Unlike prior frameworks, CAMUS integrates both objective clinical parameters and subjective patient-reported burdens, and thus bridges a longstanding gap between clinician-centred and patient-centred outcome measures. The combination of Delphi consensus studies, behavioural economics methods, and large-scale registry validation ensures both methodological robustness and practical feasibility.

Another strength is the prospective orientation: unlike retrospective systems that suffer from heterogeneity and under-reporting, CAMUS is built on encrypted REDCap-based infrastructure, which allows structured, real-time complication capture and cross-centre benchmarking. The initiative anticipates future integration with electronic health records (EHRs), mobile applications, and ML-driven predictive tools, ensuring adaptability to evolving healthcare technologies. Collectively, CAMUS functions not only as a classification system but also as a template for global standardisation in surgical quality assurance.

Standardised definitions and intervention-based logic make CAMUS particularly amenable to automated data extraction. Rule-based algorithms, natural language processing, and ML tools can identify complication-intervention events from structured and unstructured clinical data, with prepopulation of CAMUS fields for clinician validation. This human-in-the-loop approach has the potential to substantially reduce manual data entry while improving completeness and accuracy.

### 5.2. Impact on research

CAMUS can reshape surgical outcomes research by overcoming the lack of standardisation that has historically limited cross-study comparisons. By generating the world's

largest harmonised data set of urological complications, CAMUS will allow predictive modelling, big-data analytics, and ML to explore trajectories of multimodal or recurrent complications rather than collapsing them into a single grade.

Because CAMUS incorporates nursing and patient perspectives, it can also facilitate mixed-methods studies examining how bedside recognition and subjective burden correlate with objective morbidity. Its structured methodology and dynamic data dictionary make it reproducible and scalable, which represents a prototype for complication reporting across other surgical specialties.

### 5.3. Impact on clinical practice

In clinical practice, CAMUS is poised to improve patient safety, perioperative planning, and transparency in surgical audits. The patient-centred burden index redefines what constitutes a “major” complication, which will ensure that outcomes traditionally regarded as “minor” (eg, incontinence, sexual dysfunction) are recognised for their QoL impact. This will directly strengthen informed consent and support shared decision-making.

The CAMUS IPRADES risk and difficulty score will allow structured case stratification, trainee allocation, and targeted perioperative resource planning such as ICU triage. Institutions will benefit from CAMUS-enabled dashboards that can enhance transparency in morbidity and mortality reviews, support benchmarking, and align with value-based health care frameworks. At a system level, CAMUS will provide robust, standardised metrics that can inform policy-making, reimbursement models, and surgical quality indicators.

The REDCap-based e-database, which is mapped to a dynamic ICD-10-linked dictionary, allows multilayered complication recording, PROM integration, and automated reporting. Pilot evaluations have shown high user satisfaction, and future developments will include mobile entry, EHR integration, and predictive analytics.

### 5.4. Limitations

Despite its strengths, CAMUS is not without limitations. Retrospective data collection carries risks of selection and documentation bias, and institutional variability in reporting thresholds persists. While prospective validation and structured training will be applied to mitigate these issues, full integration will require sustained cultural and operational change across institutions.

The use of behavioural economics tools in clinical contexts also introduces challenges, including cross-cultural variability in how patients interpret economic trade-offs and potential response bias. These differences highlight the importance of ongoing calibration and localisation of PROMs to ensure sensitivity, cultural appropriateness, and interpretability across diverse health care settings.

Finally, logistic and regulatory barriers to global data-sharing remain. Variations in governance frameworks, ethics approval processes, and digital infrastructure may delay widespread adoption. Nevertheless, the phased design of CAMUS—spanning retrospective analysis, Delphi consensus,

e-database development, and prospective validation—ensures that these limitations are systematically addressed.

CAMUS establishes a foundation for global standardisation in complication reporting, with potential for cross-specialty expansion. Its tools support surgical planning, quality assurance, education, and longitudinal outcome monitoring. By shifting the paradigm from single-event reporting to patient-centred, multistakeholder classification, CAMUS offers a more transparent, inclusive, and clinically useful model of surgical quality. Future directions include broader procedure coverage (endoscopic and ambulatory urology), ML-enhanced risk prediction, and embedding of CAMUS within surgical training and international guidelines to ensure that its benefits extend to both clinicians and patients.

## 6. Conclusions

The CAMUS initiative has established a global, multidimensional framework for surgical complication reporting that overcomes the limitations of existing classification systems. By integrating surgeon, nurse, and patient perspectives with rigorous methodological design, CAMUS advances the accuracy, transparency, and clinical utility of postoperative morbidity documentation. Its ability to capture cumulative, sequential, and subjective complication data allows more meaningful reflection of surgical quality and patient-centred outcomes. By combining clinical, nursing, and patient-reported data within a single structured framework, CAMUS aims to standardise classification across diverse health care systems while advancing global surgical transparency.

With more than 130 000 procedures analysed and tools under development for risk stratification and assessment of intraoperative difficulty, CAMUS provides not only an advanced reporting structure but also an analytical foundation for predictive modelling, institutional benchmarking, and policy development. It can support improvements in surgical training, informed consent, and shared decision-making. The forthcoming expansion of CAMUS into prospective data capture, real-time registry platforms, and ML applications will enhance clinical decision support, audit systems, and health-service planning.

CAMUS is poised to redefine global standards in surgical reporting by promoting harmonised terminology, improving preoperative counselling, and allowing robust comparisons across centres, systems, and procedures. It represents a transformative step in the measurement of surgical outcomes that places equal weight on the perspectives of providers and patients, and that aligns surgical care with the evolving demands of transparency, accountability, and excellence in health care.

**Author contributions:** Marc A. Furrer had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

*Study concept and design:* Furrer.

*Acquisition of the data:* Soliman, Furrer.

*Analysis and interpretation of the data:* Soliman, Furrer.

*Drafting of the manuscript:* Soliman, Furrer.

*Critical revision of the manuscript of important intellectual content:* All authors.

*Statistical analysis:* Soliman.

*Obtaining funding:* Furrer, Wuethrich.

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*Supervision:* Furrer.

*Other:* None.

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## Appendix A. Supplementary material

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