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3D printing adoption in NHS trusts within the United Kingdom

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ABSTRACT

Additive manufacturing and 3D printing is being widely adopted by the medical industry. This study provides a comprehensive overview of the current state of 3D printing technology in NHS trusts across the UK. Data was collected through a survey using the freedom of information act. The survey revealed that 53 NHS trusts (∼25 %) across the UK are utilising the technology, with a diverse range of strategies and applications. The most common application was the creation of guides and models, used for pre-operative planning, intraoperative guidance, and educational purposes. The study also highlights the regulatory and ethical considerations involved in 3D printing in healthcare. The findings indicate that there are no 3D printing specific standards or guidelines being followed for medical devices and therefore underscores the need for clear and consistent regulatory guidelines to be established. As the 3D printing technology continues to advance, its applications in healthcare are expected to expand rapidly, warranting further research into its impact on patient outcomes and healthcare costs.

1. Introduction

3D printing also known as additive manufacturing (AM), is the process of creating a three-dimensional object where material is added layer by layer and built up to create a 3D part [1]. This is in contrast to the traditional subtractive manufacturing processes where the final design of a part is realised by removing material from a stock through a series of subtractive operations which in turn produces waste.

In recent times 3D printing is being widely used in different industries around the world. The fields of agriculture, healthcare, automotive and aerospace industries are increasingly using 3D printing technology to print functional components that can be used in a variety of applications with mass customisation due to their computer-aided design [2].

Healthcare industry in particular has embraced 3D printing technology more enthusiastically than any other sector [3]. During the COVID-19 pandemic, 3D printing was at the forefront in the fight against the virus. It served as a critical resource, enabling the fast production of essential tools such as personal protective equipment, medical devices and isolation wards to help combat the virus [4].

Surgeons are increasingly using 3D models to understand complex structures in their patients and using the models to perform rehearsals to determine the most optimal surgical plan and procedure. Evidence suggests that utilising 3D printing technology reduces surgical time and helps minimise the likelihood of errors occurring during the procedure [5]. The presence imaging data for surgical models are therefore often accessible and derived from MRI, CT scans, and, in some cases, ultrasounds serves as an initial foundation for 3D printing [6].

In other biomedical and healthcare settings, 3D printing has also evolved as an innovative platform, leading to remarkable progress in the production of biomaterials and their deployment in tissue engineering and regenerative medicine [7]. Bone scaffolds, 3D printed from a blend of biomaterials designed to mimic the constituents of natural bone, have shown promise in aiding the repair of bone defects [8].

In dentistry, 3D oral scans of the mouth are taken which are then transformed into a 3D model. This 3D model is then used to produce variety of orthodontic appliances such as retainers, aligners, dentures, surgical guides etc [9].

Adopters aiming to leverage 3D printing in the pharmaceutical industry have embraced the utilisation of fused or sintered powders as a foundational material. In a broader context, 3D printing technology introduces a novel, cost-effective, and innovative approach to fabricating oral dosage medications or pills. Early technology trials involved researchers examining the potential to employ 3D printing for creating medications with more adaptable delivery schedules [10].

Patients in need of prosthetics now have new options thanks to the

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simplicity of 3D printing for one-of-a-kind objects. In fact, a lot of hospitals are investing in their own 3D printers, and in the upcoming years, it's anticipated that this trend will continue [11].

This study investigates the trend and the current landscape of 3D printing within the National Health Service (NHS) trusts across the United Kingdom. Through a Freedom of Information (FOI) request, the research aims to determine the extent of 3D printing utilisation, its established applications, and the existing regulatory framework governing this technology within the NHS. The ultimate goal is to leverage these insights to identify the necessary regulations and requirements for the safe and sustainable incorporation of 3D printed parts and materials into the medical industry. This analysis does not only assess the potential of 3D printing to improve medical care, but also review the specific requirements that ensure the quality and efficacy of these printed components, while simultaneously promoting environmentally friendly practices within the healthcare sector.

2. Methods

From the Department of Health, 221 NHS Trusts were identified in the United Kingdom which excluded those with mental health or ambulance services within their names. A freedom of information request was sent to these trusts via email on the March 13, 2023 under the freedom of information act 2000. The following questions were asked in the request.

1. a) Is 3D printing technology being used at your facilities? Yes/No. b) If No for (a) do you plan on utilising 3D printing technology in the near future? Yes/No. c) If Yes to (b) What part(s) do you intent to 3D print (e.g. Prosthetic limbs, hearing aids etc.)?
2. What 3D Printers are being used for producing the parts (Brand name & model)?
3. What type of parts/products are being printed (e.g. Prosthetic hand, prosthetic leg, splint, hip joint etc.) Please be specific.
4. What materials are being commonly used for 3D printing at your facilities?
5. What ISO standards and/or other ASTM/BS standards are being followed when producing the parts/products?
6. Please briefly describe the ethics process that is required for using 3D printing parts in patients?

Two follow up questions were sent to the NHS trusts that responded yes to question 1a.

i) Is the 3D printing being conducted on-site, outsourced to an external company or a combination of both?
ii) If the 3D printing is outsourced, please provide the name(s) of the company/companies or external vendor(s) with whom the NHS trust has engaged for these services.

The Freedom of Information Act 2000 grants individuals the ability to request and obtain information held by most public authorities. This request can be made through written correspondence, such as a letter or email, and the public body must respond within 20 working days. To address potential limitations arising from missing data and non-responses, attempts were made to contact non-responding trusts to understand the reasons for non-response. This is crucial, as missing information on specific applications or regulations could hinder the ability to assess the current state of 3D printing in the NHS. For this research, responses collected until September 13, 2023 were included.

3. Results

3.1. Trend of 3D printing technology at NHS trusts in UK

From the 221 FOI requests that were sent out, 214 (96.8 %) responses were obtained between March 13, 2023 and September 13, 2023, the number of responses are summarised in Fig. 1. Of those 214 responses, only 53 (24.8 %) of the trusts currently utilise 3D printing technology within their facilities and their NHS codes listed in Table 1. These results include those that outsource their 3D printing to different companies as well as those that 3D print on their own premises. 158 (73.8 %) do not utilise the technology with 140 out of the 158 having no such plans of using it in the near future. 13 trusts are considering it as a possibility while the remaining 5 did not have the information on record. 3 trusts withheld information due to cybersecurity concerns.

The map in Fig. 2 shows locations of NHS trusts that utilise 3D printing within UK, whilst the associate hospital codes can be seen in the Table 1, the comprehensive hospital list with their names can be found in the supplementary information. Out of the 53 NHS trusts that use 3D printing, 48 of them reside within England. Only 2 trusts in Scotland and 3 trusts in Wales utilise the technology. None of the trusts in Northern Ireland currently utilise 3D printing.

3.2. In house and outsourced 3D printing

42 out of the 53 NHS trusts responded to the follow up question regarding the 3D printing location, whether it was being conducted on-site or outsourced to external companies. 26 NHS trusts conducted all their 3D printing on-site. This allows them to create patient-specific models and surgical guides etc right within their premises. On the other hand, 5 trusts have chosen to outsource their 3D printing needs, leveraging the expertise of specialised companies. Interestingly, 11 NHS trusts have opted for a hybrid approach, utilising both in-house and outsourced services for their 3D printing requirements. This diverse range of strategies highlights the flexibility of 3D printing technology in catering to the unique needs of each NHS trust. Table 2 shows the companies that were contracted or utilised by the NHS trusts for their 3D printing requirements.

3.3. Utilities of 3D printers and printing materials

48 out of the 53 trusts that use 3D printing provided information regarding the printers that they use. From the remaining 5, 2 withheld information due to cybersecurity concerns and 3 did not have the information as the printing was being done by a third party (outsourced).

There were 33 different printers that were reportedly being used by the NHS trusts (Fig. 3). Formlabs, Ultimaker, and Stratasys 3D printers were the most prevalent with 37, 21, and 18 printers respectively. Majority of the NHS trusts had at least one of the three printers, with Formlabs printers being owned by 77 %, Ultimaker printers by 44 %, and Stratasys printers by 38 % of NHS trusts.

The Formlabs Form 3(+) and Form 3B(+) were the most commonly used printers with 13 different NHS trusts utilising the 3D printers each. This was followed by the Formlabs Form 2 and Ultimaker 3/S3, being utilised by 11 NHS trusts each. Stratasys did not have a 3D printer within the top 5 most used printer but due to their sheer variety of 3D printers, their total numbers tally up high enough to make them one of the top 3 manufacturers within the list with 8 different 3D printers being utilised by 18 different NHS trusts.

Table 3 summarises the printing technologies, feedstock and prices of the different 3D printers being used by the NHS trusts. The most common printing technologies of these 3D printers were Fused Filament Fabrication (FFF), Fused Deposition Modelling (FDM), PolyJet and Stereolithography (SLA), being used by 10, 9, 6 and 4 printers out of 33 respectively. The most common 3D printers, the Form 3(+) and Form 3B (+) both utilised SLA printing technology. SLA is one of the most precise and adaptable printing technology, offering excellent accuracy and spatial resolution, along with beneficial processing results and biocompatibility [12]. A drawback is that multi-material printing with traditional SLA resin baths is difficult/not viable.

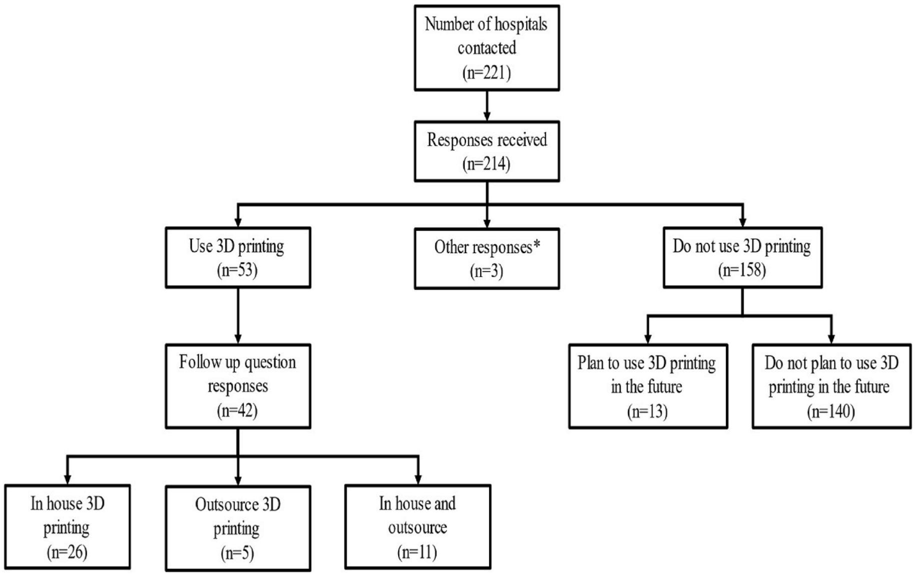

Fig. 1. Flow Chart with Freedom of Information questionnaire responses. * = *Information not held/Information withheld due to cybersecurity concerns.*

Table 1
NHS trusts codes (The comprehensive hospital names are listed in Table S1 and is available in the supplementary information).

#	CODE	#	CODE	#	CODE	#	CODE
1	ALDERHEY	2	BCHC	3	BHT	4	CHESTERFIELD
5	HYP	6	KGH	7	KCH	8	LIVERPOOLFT
9	MSE	10	MKUH	11	NGH	12	NCA
13	OXFORD	14	RDUH	15	RSC	16	RUH
17	STEES	18	STGEORGES	19	STHK	20	SC
21	THE-CHRISTIE	22	NUTH	23	RJAH	24	RGH
25	RWH	26	SATH	27	TSDFT	28	UHB
29	UHD	30	UHL	31	WWL	32	BCU
33	CTM	34	PLH	35	UCLH	36	LOTHIAN
37	BWC	38	STH	39	LTHTR	40	UHCW
41	WHT	42	SBUHB	43	BARTS	44	GOSH
45	YORK	46	DCHFT	47	CUH	48	UHNM
49	GGC	50	MFT	51	LEEDSTH	52	QVH
53	GSTT						

3.4. Medical and healthcare applications of 3D printing

A range of different responses were received in regard to the parts and the purpose of the 3D printing that was being undertaken. These responses were divided into 5 separated categories.

- **Guides/Models** - This category involved any part that was created to be used as a guide either for pre-surgical, intraoperative or training/educational purposes. These also included models of patients' body parts for analysis and also for testing other medical devices and technology such as medical imaging.
- **Protoypes/Research** – This group included any parts that were created for the purposes of prototyping for research and design.
- **Implant** - This classification involved any part or medical device that was going to have direct contact with the patient's internal body for long durations. These could be permanent implants or temporary implants but with the risk of rejection from the body due to biocompatibility.
- **Device** - This grouping involved all the remaining medical devices that did not fall into the other categories. This could be anything such as a cast for broken bones or prosthetics or inlet filters.
- **Non-medical parts** – This category included parts which do not serve a medical function such as a card holder or replacement parts of broken items.

As shown in Fig. 4 the most common application of 3D printing currently being utilised was of Guide/Model by 68 % (36) in the NHS trusts. These consisted of surgical guides, anatomical models for diagnosis, radiotherapy phantoms, bone structures, dental impressions etc. These were being used for pre-operative planning, intra operative and for educational purposes. The models were also being used as a guide to create other patient specific devices such as orthodontic retainers and prosthetics.

The second most common application was of devices. Common devices that were being printed include, wheelchair joysticks, non-invasive surgical instruments, splints, radiotherapy bolus, insoles, prosthetics etc. These were produced by 42 % (22) of the trusts.

Printing for prototype/research purposes and printing of non-medical parts were the third and fourth most common applications with 34 % (18) and 30 % (16) of trusts utilising it for these purposes respectively. Prototyping/research responses included 3D printing of prototypes for general engineering projects, innovation projects, reverse engineering, specialist measurement instrumentation in connection with research and development projects. Prototypes for postural management systems, rapid prototyping, naval valves, septal button, prototype objects for quality assurance of medical imaging etc. 3D Printing of non-medical parts included handles, knobs, clips, spare parts, clamps, adapters, equipment holders etc.

Lastly only 8 % (4) of NHS trust currently were implanting 3D printed parts into patients and they were stents made of biocompatible

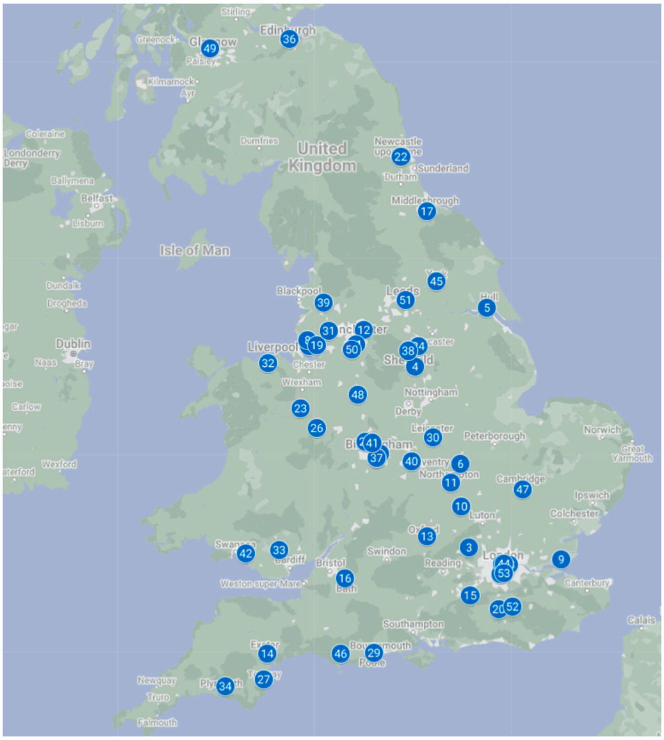

Fig. 2. Locations of NHS trusts that utilise 3D printing within UK. *(Full version of the map is available and can be accessed via this hyperlink -* https://bit.ly/NHS3DPrintingMap*)*.

resins and 3D printed plates made of titanium which is biocompatible and inert and also the material of choice for conventional manufacturing methods.

3.5. Materials being used for 3D printing

There were 19 different 3D printing materials that were mentioned in the responses (Fig. 5). This variety of materials was due to the number of different printers being used, each requiring feedstock/material depending upon the method of 3D printing and because each application required different properties of materials.

Photopolymer resins category emerged as the most prevalent with 34 (64 %) different NHS trusts employing these materials. The popularity of resins can be attributed to their ability to offer a range of properties tailored to specific printing requirements. Notably, resins are renowned for their capacity to produce prints of high resolution and strength at a rapid pace, rendering them ideal for the creation of detailed and robust models. This also coincides with the data from Table 3 which indicated that Formlabs printers, utilising resin material, are the most commonly used 3D printers at NHS trusts.

Stratasys Vero resins were the most popular form of resin being used by (21 %) of all trusts. These included Vero Clear, Vero White, Vero Glaze etc as they are an extremely versatile material used with PolyJet printing which can combine multiple materials into a single object for various colours and textures.

In the category of polymers, a diverse array of materials was observed, with 29 (55 %) of the different NHS trusts employing them. This prevalence can be largely attributed to the widespread use of Polylactic Acid (PLA), a polymer that was utilised by 28 (53 %) of the NHS trusts. The factors contributing to PLA's popularity include its cost-effectiveness, superior performance, biocompatibility, and biodegradability. As a result of these factors, there was a notable degree of overlap within the polymer category, particularly when compared to the resin category.

Table 2
List of companies utilised by the NHS trusts for their 3D printing needs. Further service details and product regulatory management by each provider can be found via the company's web sites which are listed in Table S2 in the supplementary information.

Company	Service description	NHS Trust
Insight Surgery	Supply a range of surgical guides and models	ALDERHEY, WWL
Shapeways	Offer patient specific prosthetics, models and medical devices	BARTS
Aston University	3D print images of hearts for education and training	BWC
Orthoscape	3D printed patient specific treatments for the knee and cranial maxillo-facial implants	CUH, SBUHB
Renishaw plc	Additive manufacturing, product design and metal 3D printing	CUH
3DPRINTUK	Specialise in low volume production of plastic 3D printed parts	CUH
Design&Smile	Dental lab that also 3D prints diagnostic waxups and impression trays	KCH
KLS Martin Group (IPS®Implant)	Additive fabricated implant and stereolithographic anatomical models	KCH, UHD, GGC, SBUHB
Materialise	2D and 3D planning tools, personalised instrumentation, and implants	KCH, STH, UDH
De Puy Synthes	Specialise in orthopaedic procedures including titanium 3D printed implants	KCH
Stryker	Offer a range of medical devices and equipment including models, guides and implants.	NCA, STH
Cavendish Implants	Provide customised patient specific implants	RUH
OsteoPlus	Orthopaedic supplies and patient specific devices using 3D printing	RUH
Newcastle University	3D printing facilities for research collaborations	NUTH
Northumbria University	3D printing facilities for research collaborations	NUTH
MAG Orthotics Limited	3D printed insoles for shoes	RGH
3D Creation Labs	Provide rapid prototyping for over 100 materials	PLH
Cobnut 3D	Offers model design and Fusion Deposition Modelling 3D printing	PLH
3D People Limited UK	3D printing service including prototyping, sampling or manufacturing	PLH
MakeItQuick Manufacturing	Online express service. Offer low volume manufacturing and one-off prototypes (FDM & SLA 3D printing)	PLH
Straumann	3D printer supplier. Specialists in dental implants.	GGC

Regarding metal 3D printing, only 2 (4 %) trusts were using metal 3D printing. The 3D printing of these metals was being outsourced to specialist companies on an ad hoc basis.

3.6. Regulations for utilising 3D printed products

Information related to the regulations that were being followed when 3D printing medical devices were reported by the NHS trusts as shown in Table 4 below. Some trusts provided detailed descriptions of their regulatory compliance while others provided the name of the regulatory agency they follow.

The most common response was N/A or none from 18 (34 %) trusts, as they did not follow any standards or regulations when 3D printing. The next three common responses were very similar and related to each other. ISO 13485 from 17 (32 %), Medical Devices Regulation (MDR) from 12 (23 %) and ISO 9001 from 8 (15 %) NHS trusts. In order to comply with the MDR set out by the Medicines and Healthcare products Regulatory Agency (MHRA), NHS trusts must have a quality management system in place along with a risk assessment process when producing medical devices. ISO 13485 is a Quality Management Systems standard specifically for medical devices. This standard is based off ISO

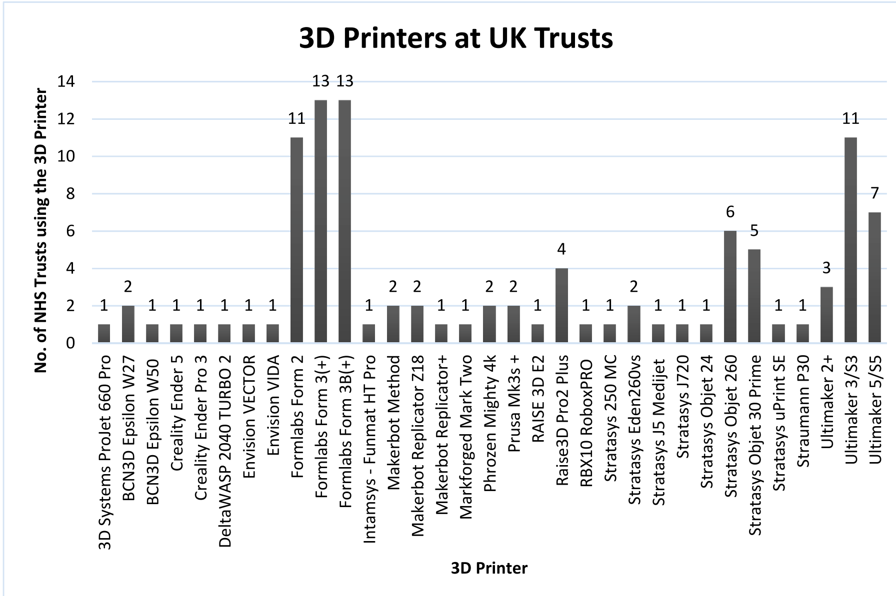

Fig. 3. Graph of all the 3D printers being used within the NHS Trusts.

9001 Quality Management System but removes some of the requirements as they do not relate to medical devices. Therefore, organisations that meet one standard do not automatically comply with the other and vice versa.

The quality management system contains risk assessment as well which is necessary for 3D printed parts to determine how the manufacturing process has affected the physical properties of the part for its intended use. ISO 14971 which is a standalone risk assessment standard for medical devices was also being used by 4 trusts.

In house quality control and local quality management systems were used by 8 (15 %) trusts. This is also an option as the MHRA do not require an organisation to follow any official internationally recognised standards specifically.

3.7. *Ethical process when using 3D printed products on patients*

The NHS trusts were also asked for any ethical processes they follow in regard to usage of 3D printed parts in patients. 35 (66 %) of the 53 responses for this question were either none or N/A as shown in Table 5. This was due to various reasons such as.

- They did not implant 3D printed parts into patients
- The 3D printed parts were external devices
- They only 3D printed diagnostic models and did not use it in patients
- They only 3D printed non-medical parts
- They were using 3D printing to replace an existing manufacturing technique and therefore required no additional ethical considerations

The most common response from the remaining NHS trusts was MHRA and MDR compliance by 8 (15 %) of trusts. All parts they made were MDR compliant and sometimes they required MHRA approval. The next most common responses were research approval with 6 (11 %), informed consent process with 5 (9 %) and biocompatible materials with 5 (9 %) trusts each using these ethical processes.

3D printing for research purposes and proposals required its own ethics approval processes. Hospitals had to contact the Health Research Authority (HRA) and MHRA or other organisations such as General Dental Council (GDC) and Institute of Maxillofacial Prosthetists and Technologists (IMPT) depending upon their research field, to obtain an ethics approval.

For the informed consent process, the patients had to approve the usage of the 3D printed part within their treatment. The patient's confidentiality and outcomes were very strongly aligned with this ethical process. Biocompatible material usage was mentioned in the ethics process when 3D printing medical parts which allowed the part to be in contact with the cells and tissues of a patient without causing an immunological response.

The remaining responses included external audits by 3 (6 %), internal meetings by 3 (6 %) and prescriptions from clinician by 2 (4 %) NHS trusts respectively.

4. Discussion

4.1. *Current state and adoption trends*

The results of this study provide a comprehensive overview of the current state of 3D printing technology in NHS trusts across the UK. The data reveals that a significant number of these trusts have already adopted this technology, with a small number indicating an intention to adopt it in the near future. This suggests a growing trend towards the integration of 3D printing in healthcare, which aligns with global trends in the medical field [13].

A few NHS trusts withheld information regarding their 3D printing usage due to cybersecurity concerns. Cybersecurity is a major concern for hospitals due to the sensitive nature of the data they handle, including patient records and other confidential information. In the context of 3D printing, cybersecurity concerns may arise due to the potential risks associated with the digital files used in the printing process. These files could be intercepted, altered, or stolen if not properly secured, leading to potential patient safety issues or breaches of privacy. Furthermore, the 3D printers themselves could be targeted by cyberattacks, potentially disrupting hospital operations. Therefore, some hospitals chose to withhold certain information about their 3D printing operations to mitigate these risks.

The diversity in the adoption strategies of 3D printing technology, with most trusts opting for solely in-house operations, some outsourcing, and the rest employing a hybrid approach combining both, underscores the flexibility of this technology. It suggests that 3D printing can be tailored to meet the unique needs and resources of each NHS trust. However, it also raises questions about the factors influencing these strategic decisions, such as cost-effectiveness, quality control, and

Table 3
Summary of the different 3D printers being used by their respective NHS trusts, their product specification and price. (*Price ranges shown below are based on current market price)* The list of the abbreviations for each material is available in Table S3 in the supplementary information.

Printer Name	Printing Technology	Materials	Price GBP (Incl. VAT)	NHS Trusts Code
3D Systems ProJet 660 Pro	ColorJet Printing (CJP)/ Binder Jetting	Sand, Powder	£52,590	CUH
BCN3D Epsilon W27/W50	Fused Filament Fabrication (FFF)	PLA, PET-G, TPU 98A, PVA, ABS, PP, PA, GF30, PAHT, CF15	£6533 - £8211	SC, SATH, NCA
Creality Ender 5/ Pro 3	Fused Deposition Modeling (FDM)	PLA, ABS, TPU, WOOD, COPPER	Discontinued Pro 3 £190.80	CTM
DeltaWASP 2040 TURBO 2	Fused Deposition Modeling (FDM)	ASA, PLA, ABS, Flex, HIPS, PETG, TPU, PP, ABS + PC, PA carbon	Discontinued	LOTHIAN
Envision VECTOR/ VIDA	Digital Light Processing (DLP)	Resin, WaterClear Resin, ABS-like Resin, Dental SG Resin	£16,125	STGEORGES
Formlabs Form 2/3 (+)/3B(+)	Stereolithography (SLA)	Resins	£3066 - £5950	ALDERHEY, HYP, CUH, GSTT, KCH, KGH, MFT, MKUH, QVH, STH, LTHTR, STEES, NUTH, TSDFT, UHCW, UCLH, UHB, UHD, UHNM, YORK, GGC, LOTHIAN CTM, SBUHB
Intamsys - Funmat HT Pro	Fused Filament Fabrication (FFF)	PEEK, PEEK + CF, PEEK + GF, PEKK, PC, PA, ABS, ASA, PETG, HIPS, TPU, PLA, PVA	£105,180 - £131,475	BARTS
Makerbot Method/ Replicator Z18/ Replicator+	Fused Deposition Modeling (FDM)	PLA, ABS, PET-G, PLA Tough	£2340- £4,460, Z18 Discontinued	BWC, STEES, RWH, OXFORD
Markforged Mark Two	Fused Filament Fabrication (FFF)/Continuous Fiber Reinforcement (CFR)	Onyx (Nylon with micro carbon-fibres), Nylon, Precise PLA, Smooth TPU 95A, Fibreglass, Carbon Fibre, Kevlar, High temperature Fibreglass	£19,620	LEEDSTH
Phrozen Mighty 4k	Stereolithography (SLA)	Resins	£500	CHESTERFIELD, SATH
Prusa Mk3s+	Fused Deposition Modeling (FDM)	PLA, ABS, PETG	£875	CUH, WHT
RAISE 3D E2/Pro2 Plus	Fused Filament Fabrication (FFF)	PLA, ABS, PC, PVA, NYLON, PETG, PP, HIPS, TPU, Carbon Fibre	£3299 - £5399	CTM, RSC, LOTHIAN, BCU, SBUHB
RBX10 RoboxPRO	Fused Filament Fabrication (FFF)	ABS, PETG, PC, Nylon	Discontinued	STGEORGES
Stratasys 250 MC	Fused Deposition Modeling (FDM)	ABS, PC-ABS, PPSF/PPSU	Discontinued	UHB
Stratasys Eden260vs	PolyJet	Vero, Resin, Tango, MED610, RGD525, Durus, Rigur	Discontinued	LTHTR, STHK
Stratasys J5 Medijet/J720	Polyjet	Vero, DraftWhite, MED837, MED610, MED615RGD™ IV	£52,590 - £122,710	UHB, UHNM
Stratasys Objet 24/ 260/30 Prime	PolyJet	Vero, Agilus30, Tango, RGD720, Digital ABS	24 & 260 Discontinued, 30 Prime - £31,553	LEEDSTH, ALDERHEY, BARTS, KCH, WWL, CTM, MFT, NGH, RUH, GGC
Stratasys Print SE	Fused Deposition Modeling (FDM)	ABS	Discontinued	ALDERHEY
Straumann P30	Digital Light Processing (DLP)	Resins	£18,000	SOMERSETFT
Ultimaker 2+/3/ S3/5/s5	Fused filament fabrication (FFF)	PLA, ABS, CPE, CPE+, PC, Nylon, TPU 95A, PP, PETG, PVA	£2148 - £6234	CUH, STEES, NUTH, BHT, EKH, MSE, TSDFT, GSTT, LEEDSTH, ALDERHEY, BCHC, DCHFT, SC, WWL, GGC, UHB, CTM

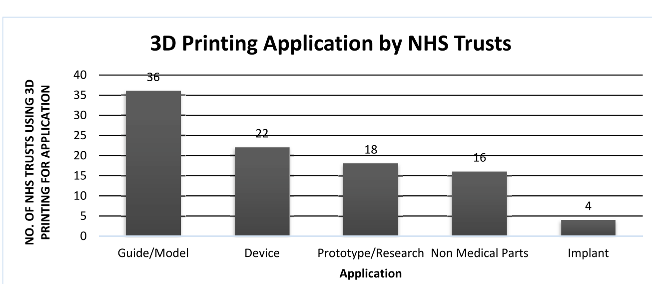

Fig. 4. Graph showing the number of NHS Trusts utilising 3D printing for the different applications.

technical expertise, which could be explored in future research.

The results shed light on the various applications of 3D printing in healthcare, from the creation of guides and models to the production of implants and devices. The most common application was the creation of guides and models, which are used for pre-operative planning, intra-operative guidance, and educational purposes. This underscores the value of 3D printing in enhancing surgical precision and patient outcomes.

The wide range of 3D printers being used by the trusts further highlights the versatility of this technology. However, the prevalence of certain brands, such as Formlabs, Ultimaker, and Stratasys, suggests that these brands may offer specific advantages in terms of performance, material compatibility, ease of use, or cost-effectiveness. Further research could explore the reasons behind these preferences.

The use of a wide variety of materials in 3D printing, from photo-polymer resins to metals, reflects the diverse needs of different applications. The choice of material can significantly impact the performance and safety of the printed part, making this an important area for further research and regulation.

4.2. *Innovation and future in healthcare*

The field of 3D printing is constantly evolving, with new innovations emerging that hold immense potential for the future of healthcare. Bioprinting, a rapidly developing technology that utilises 3D printing techniques to create living functional tissues and organs suitable for transplantation by combining living cells, scaffolds with 3D inter-connected structures, and bioactive agents, represents a particularly exciting future direction [14]. This technology has the potential to

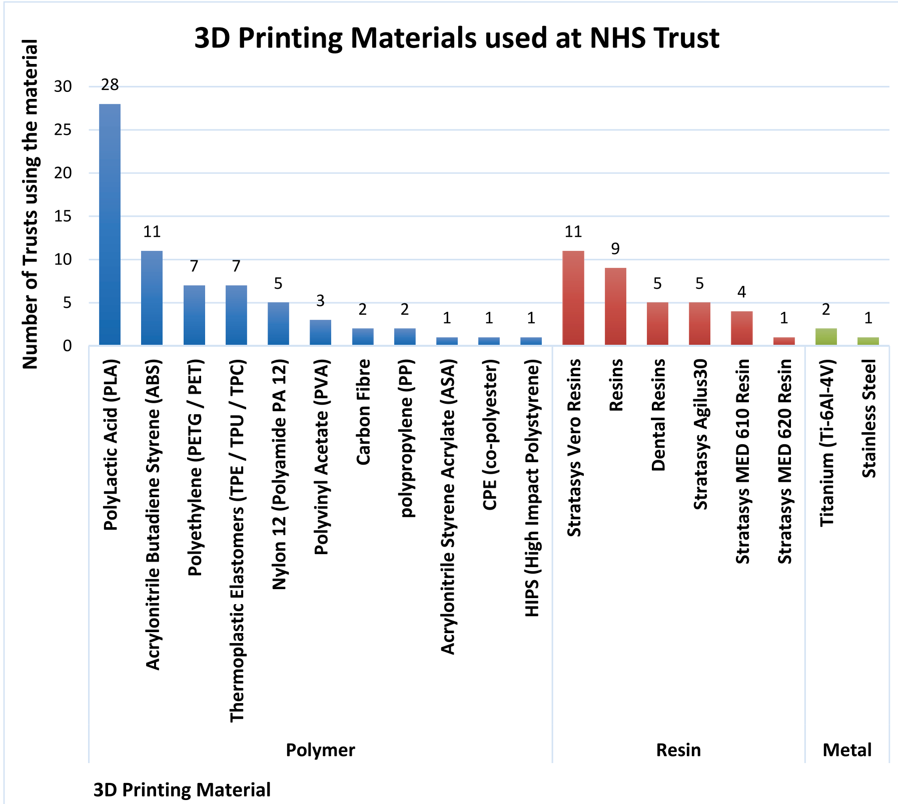

Fig. 5. Materials being used for 3D printing in NHS Hospitals.

revolutionise organ transplantation, a field currently limited by a shortage of donor organs and the risk of rejection. Bioprinting could offer patients personalised, biocompatible organs, significantly improving transplant outcomes.

Beyond transplantation, 3D bioprinting offers exciting possibilities for personalised medicine. For example, bio printed patient-specific tissues could be used for drug testing and development, allowing for more accurate predictions of drug efficacy and reduced side effects. Additionally, bio printed "organ-on-a-chip" devices could be used to model complex biological systems, potentially accelerating medical research within the NHS [15]. Further research and development in bioprinting materials and techniques are crucial to bringing this technology to fruition within the NHS.

4.3. Barriers to entry and regulatory considerations

Timely and widespread adoption of 3D printing technology in healthcare can significantly improve patient care and outcomes. However, several obstacles are currently impeding this progress. These barriers include.

- **Cost** - 3D printing equipment and materials specifically designed for healthcare applications can be expensive (Table 3), which may limit accessibility for some NHS trusts.
- **Regulations** - The regulatory landscape for 3D-printed medical devices is still evolving and standardised protocols for design, testing, and quality control specific to 3D-printed medical devices are still under development. This lack of standardisation can hinder wider adoption due to concerns about the safety, efficacy, and consistency of 3D-printed devices compared to traditionally manufactured medical products.
- **Cybersecurity** - As mentioned earlier, cybersecurity concerns regarding the digital files and printers used in 3D printing need to be addressed to ensure patient safety and data privacy.

The study reveals that the majority of NHS trusts do not follow any specific standards or regulations when 3D printing. This is concerning, given the potential risks associated with the use of 3D printed parts in healthcare. The trusts that do follow regulations primarily comply with ISO 13485, MDR, and ISO 9001, which are standards related to quality management systems and regulatory requirements for medical devices. These existing regulations could potentially serve as a foundation for developing more specific guidelines for 3D printed medical devices.

The lack of regulatory compliance by some NHS trusts can be attributed to the classification of 3D-printed medical devices as custom-made devices (CMDs) under the MDR [16]. Meeting specific criteria defined by the MDR exempts CMDs from certain regulations. These criteria typically involve being designed and produced for a single patient based on a written prescription from a qualified healthcare professional, addressing the patient's specific needs, and not being mass-produced.

The exemption for CMDs can vary across countries and regulatory bodies. What qualifies as exempt in one region might not be exempt in another. This lack of consistency underscores the need for clear and consistent regulatory guidelines for 3D printing in healthcare. Regulatory bodies could play a positive role in the widespread adoption of 3D printing technology within the healthcare sector by.

- Establishing clear guidelines for the design, development, and use of 3D printed medical devices.
- Facilitating the development of standardised testing and certification procedures for these devices.
- Providing resources and guidance to NHS trusts on the safe and effective implementation of 3D printing technologies.

Table 4
Responses of NHS Trusts regarding regulations and standards being used for 3D printing of medical devices.

Responses regarding Regulations	No. of Trusts Responded	%	Description	NHS Trusts Code
N/A or None	18	34 %	Not Applicable or do not use any	BWC, BHT, CHESTERFIELD, GSTT, HYP, LTHTR, NGH, OXFORD, RDUH, RSC, SOMERSETFT, STHK, RGH, RWH, UHCW, PLH, WHT, CTM
ISO 13485	17	32 %	Medical devices — Quality management systems — Requirements for regulatory purposes	ALDERHEY, BCHC, CUH, GSTT, LEEDSTH, QVH, RUH, STH, STGEORGES, NUTH, RJAH, UHB, UHL, WWL, GGC, BCU, SBUHB
MDR	12	23 %	Medical Devices Regulations (EU)	KCH, MFT, MSE, RUH, SC, SATH, TSDFT, UHD, UHL, UHNM, GGC, LOTHIAN
ISO 9001	8	15 %	Quality management system – requirements for regulatory purposes (certifiable)	BARTS, EKH, GSTT, LEEDSTH, NCA, SC, NUTH, UCLH
In house quality control Local QMS	8	15 %	Local quality management systems	DCHFT, MFT, MKUH, STEES, STHK, UHD, LOTHIAN, CTM
ISO 14971	4	8 %	Application and process of risk management of medical devices	NCA, SC, NUTH, UHL
MDD	4	8 %	Medical Devices Directive	CUH, UHD, UHL, YORK
MHRA	5	9 %	Medicines and Healthcare products Regulatory Agency (UK)	MFT, MKUH, QVH, RUH, STEES
ISO 10993	2	4 %	Biological evaluation of medical devices	RUH, NUTH
FDA	2	4 %	The United States Food and Drug Administration	NUTH, LOTHIAN
CE	2	4 %	Marking on products sold in the European Economic Area that have been assessed to meet high safety, health, and environmental protection requirements	LOTHIAN, RUH
BS EN 12182	1	2 %	General requirements and test methods for technical aids (medical devices) for disabled persons	SC
ISO 27001	1	2 %	Requirements for information security management systems (ISMS)	NUTH
ISO 60601	1	2 %	Basic safety and essential performance of medical electrical equipment and systems for use in the home healthcare environment	UHL
ISO/ASTM 52900	1	2 %	Establishes and defines terms used in additive manufacturing (AM) technology	UHL
ISO 15223	1	2 %	Symbols used to express information supplied for a medical device	NUTH
BS EN 556	1	2 %	Sterilisation of medical devices. Requirements for medical devices to be designated "STERILE"	NUTH
BS EN 1041	1	2 %	Medical device manufacturers comply with the information requirements of the European medical device directives.	NUTH

Table 5
Responses regarding ethical process of using 3D printed parts in the hospitals. N/A = Not applicable.

Ethical Process	No. of Trusts	%	NHS Trusts Code
None or N/A	35	66 %	BARTS, BCHC, BWC, BHT, CUH, CHESTERFIELD, DCHFT, EKH, HYP, LTHTR, MFT, MSE, MKUH, NGH, OXFORD, QVH, RDUH, RSC, STH, SOMERSETFT, STHK, SC, NUTH, RGH, RWH, TSDFT, UCLH, UHCW, UHL, WHT, YORK, GGC, BCU, CTM, SBUHB
MHRA and MDR	8	15 %	CUH, NCA, STEES, SATH, UHB, UHL, LOTHIAN, BCU
Research Approval	6	11 %	GOSH, GSTT, NCA, NUTH, UHCW, UHL
Informed consent process	5	9 %	LEEDSTH, RUH, UHD, UHL, BCU
Biocompatible material	5	9 %	CUH, KCH, RUH, UHL, UHNM
External Audits	3	6 %	KCH, UHB, UHD
Internal meetings	3	6 %	RUH, KCH, MFT
Prescriptions from clinician	2	4 %	RUH, STGEORGES

5. Conclusions

In conclusion, this study provides valuable insights into the current state of 3D printing in NHS trusts across the UK. It highlights the diverse strategies and applications of this technology, as well as the regulatory and ethical considerations involved. As 3D printing continues to evolve and its applications in healthcare continue to expand, it will be interesting to see how these trends and practices develop in the future.

Further efforts are needed to establish standardised protocols, clear and consistent regulations, testing procedures, and guidelines specific to 3D-printed medical devices to ensure patient safety.

The freedom of information act provides a great method for researchers to gather key data. Further research could explore the factors influencing the strategic decisions of NHS trusts regarding 3D printing, as well as the impact of this technology on patient outcomes and healthcare costs.

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CRediT authorship contribution statement

Rafay Ul Azeem: Writing – original draft, Investigation, Formal analysis, Data curation. **Shokraneh K. Moghaddam:** Writing – review & editing, Validation. **Richard Kaye:** Writing – review & editing, Validation. **Malcolm MacKenzie:** Writing – review & editing, Validation, Methodology, Conceptualization. **Vincenzo Di Ilio:** Writing – review & editing, Visualization, Funding acquisition. **Yusuf Umar:** Writing – review & editing, Visualization, Validation. **Yuen-Ki Cheong:** Writing – review & editing, Visualization, Validation, Supervision, Project administration, Methodology, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Vincenzo Di Ilio reports financial support was provided by UK Research and Innovation. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bprint.2024.e00346.

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