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An International Consensus Panel on the Value Proposition of Digital Surgery

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Abstract

Objectives: The use of digital technology in surgery is increasing rapidly, with a wide array of new applications from pre-surgical planning to post-surgical performance assessment. Understanding the clinical and economic value of these technologies is vital for making appropriate health policy and purchasing decisions. We explore the potential value of digital technologies in surgery and produce expert consensus on how to assess this value.

Design: A modified Delphi and consensus conference approach was adopted. Delphi rounds were used to generate priority topics and consensus statements for discussion.

Setting and participants: An international panel of 14 experts was assembled, representing relevant stakeholder groups: clinicians, health economists, HTA practitioners, policy makers and industry.

Primary and secondary outcome measures: A scoping questionnaire was used to generate research questions to be answered. Two further rounds of questionnaires were used to rate the importance of these research questions. A final questionnaire was used to generate statements for discussion during three consensus conferences. After discussion, the panel voted on their level of agreement from 1-9; where 1 = strongly disagree and 9 = strongly agree. Consensus was defined as a mean level of agreement of >7.

Results: Four priority topics were identified: (1) how data are used in digital surgery, (2) the existing evidence base for digital surgical technologies, (3) how digital technologies may assist surgical training and education, and (4) methods for the assessment of these technologies. Seven consensus statements were generated and refined, with the final level of consensus ranging from 7.1 – 8.0.

Conclusion: Potential benefits of digital technologies in surgery include reducing unwarranted variation in surgical practice, increasing access to surgery, and reducing health inequalities. Assessments to consider the value of the entire surgical ecosystem holistically are critical, especially as many digital technologies are likely to interact simultaneously in the operating theatre.

Article Summary

Strengths and limitations of this study

- Using a combination of a modified Delphi process and a series of consensus conferences, this study generates expert consensus on the value of digital surgical technologies.
- This study identifies specific considerations for Health Technology Assessments (HTAs) of digital surgical technologies.
- Although the expert panel assembled for this study represents a range of stakeholders and geographies, the results are subjective and may not represent all relevant viewpoints.

- The study did not have a designated patient representative; however, it did include consumer health informatics expertise and members who have been surgical patients.
- This study's aim is not to provide methodological guidance for completing assessments of DSTs, but rather to advise HTA bodies who may be developing frameworks for digital technology to consider the specific nuances and complexities of digital technologies in surgery.

Introduction

Digital technologies are being used increasingly in healthcare systems globally, accelerated by the COVID-19 pandemic [1]. These technologies, known as Digital Health Technologies (DHTs), are extremely diverse. The Food and Drug Administration (FDA) includes mobile health (mHealth), health information technologies, wearable devices, telehealth, telemedicine, and personalised medicine in its definition of digital health [2], while the National Institute of Health and Care Excellence (NICE) simply notes that DHTs "comprise a wide range of products used in the health and care system including apps, software and online platforms" [3]. Given that DHTs have such a broad range of functionalities, use cases, and benefits, understanding and evaluating them are highly complex tasks.

DHTs differ from other health technologies in several ways. Firstly, many digital technologies are frequently updated. Artificial intelligence (AI) based technologies are changing perpetually as algorithms learn from new data. This rapid pace of development makes evaluating the clinical and economic benefits of these technologies challenging. Further, the evidence supporting these technologies may not be as robust as other health technologies such as medical devices or pharmaceuticals. DHTs are often highly context dependent, particularly within surgery or other hospital settings, making standard randomized trial designs less applicable compared to other forms of evidence [4]. Like medical devices, there may also be an operator learning curve related to digital technologies. However, in some cases, there is a learning curve both on the side of the physician and the patient. To further add to the complexity, DHTs are often used simultaneously or integrated with another technology such as a medical device. These complexities, in addition to the huge range of use cases, level of autonomy and potential risk, make assessing digital technologies for safety, efficacy and cost effectiveness a uniquely difficult proposition [4].

In surgery, digital technologies are rapidly being developed and adopted, from pre-operative planning and intra-operative guidance to post-operative performance assessment [5]. Advancements in training and education [6], virtual reality (VR) [7], machine learning [5], and telehealth [8] are being implemented in surgical practice, either as standalone solutions or alongside other DHTs and devices.

This is increasingly true in Robot-Assisted Surgery (RAS), as advancements in digital capabilities are developing in tandem with various robotic platforms.

Lam et al., [9] in a Delphi exercise, aimed to define “Digital Surgery”, agreeing upon “the use of technology for the enhancement of preoperative planning, surgical performance, therapeutic support, or training, to improve outcomes and reduce harm”. Lam et al. [9] also reported that there were no clearly defined reimbursement or business models for these technologies. Furthermore, adoption barriers may arise due to difficulties in demonstrating safety and clinical benefits. Future research was recommended into developing a framework for the introduction and evaluation of surgical AI and establishing a business model with industry [9].

There have been several frameworks for evaluating digital technologies published by various Health Technology Assessment (HTA) bodies in recent years, many of which are still evolving and being refined. A review by San Miguel et al. [10] at the Belgian Health Care Knowledge Centre (KCE) reviewed six existing European frameworks (table 1) for evaluating digital technologies as part of the further development of their own procedures.

Table 1 - Existing Frameworks developed by HTA agencies for Assessing Digital Health Technologies in Europe, adapted from San Miguel et al. 2022 [10].

Country	Framework for DTs	Author	Year
Germany	Fast track procedure for DiGAs	(BfArM)	2020

UK	Evidence Standards Framework for DMTs	National Institute for Health and Care Excellence (NICE)	2019
France	Loi de financement de la sécurité sociale pour 2022 Guide on specific features of clinical evaluation of a connected medical device (CMD)	Haute Autorité de Santé (HAS)	2022
Finland	Digi-HTA framework	Centre for Health and Technology, FinCCHTA and the University of Oulu's MIPT research group	2019
Netherlands	Guidance for assessment of digital care	Knowledge Centre Digital Care (Health Insurers)	2021
Austria	Framework for reimbursement decisions of digital health technologies	Austrian Institute for HTA (AIHTA)	2021

The frameworks listed vary in scope considerably. The DiGA procedure in Germany, for example, was designed specifically for health apps [11]. The NICE Evidence Standards Framework (ESF) [3] was initially deployed with 3 evidence tiers focusing largely on standalone apps and software packages, with recent updates including considerations for AI and Data-Driven technologies with adaptive algorithms. The Finnish Digi-HTA framework is slightly broader, including specific considerations for robotics and AI [12], although no assessments have been completed on such technologies used in surgery to date [13]. Outside of Europe, guidelines have also been developed in countries like South Korea; however, these guidelines only cover AI for medical imaging and 3D printing and so are limited in scope [14]. The World Bank Group (WBG) has developed a framework for the economic evaluation of digital health interventions [15]. The WBG developed the World Health Organisation's (WHO) user-focused classification to group DHTs into 3 categories, excluding "digital health systems" that consist of "information systems and digital health architecture". Most recently, the Institute for Clinical and Economic Review (ICER) collaborated with the Peterson Health Technology Institute (PHTI) to produce their assessment framework for DHTs [16], which covers digital therapeutics, chronic care management apps, remote patient monitoring, and administrative technologies.

Further HTA work is ongoing in countries such as Spain, where the Agency for Health Quality and Assessment of Catalonia (AQuAS) has developed a methodological framework to carry out a comprehensive DHT assessment, which is currently being reviewed by the Ministry of Health [17]. A group of six HTA bodies from England, Scotland, Wales, Australia and Canada agreed to collaborate on 5 key topics in 2022, one of which is digital and artificial intelligence [18]. Further, NICE is piloting Early Value Assessments (EVAs), which aim to foster greater collaboration between regulatory, HTA and research organisations [19], with a particular focus on digital technologies. These assessments are completed earlier than a standard HTA and include an evidence review to highlight evidence gaps that can be addressed, often through a Real-World Evidence (RWE) study. NICE has also developed a RWE framework, that defines real-world data as "data relating to patient health or experience or care delivery collected outside the context of a highly controlled clinical trial" [20].

Despite the range of efforts to develop assessment frameworks for DHTs, no consistent standards have yet been agreed upon, partially due to the diversity in technologies, in the setting of use, and in reimbursement models [15]. Many frameworks, including the NICE ESF [3] and ICER-PHTI [16] framework use a risk-based model for evidence standards. Surgery is a uniquely high-risk environment. This requires a high bar for regulatory approval, in terms of safety and efficacy. However, payers and policymakers are still challenged when quantifying the clinical and economic utility of these technologies. Unlike health apps, DHTs used in surgery may be high-cost technologies or are used in conjunction with other high-cost surgical devices, such as robotic platforms. Payment and reimbursement models are likely to differ significantly. Applications for example may use a subscription model or a population-based payment model. Advanced visualization systems are more likely to be purchased as a separate product in the operating theatre or may be integrated into a robotic platform. Calculating the economic impact of such technologies is potentially very complex. Existing frameworks, such as the WBG framework, may provide a good starting point for DHTs used in surgery. For instance, the framework recommends that any evaluation needs to determine the context for how the technology is used, the complexity of the evaluation, and then set the analytic principles. These recommendations should help decision makers to account for the unique context in which some technologies are used, as well as be representative of the technologies' value propositions [15].

In this article, we focus on Digital Surgical Technologies, referred to from here onwards as DSTs. Elsewhere, we have developed guidance for the assessment of RAS platforms [21]. Existing frameworks for evaluating digital technologies in healthcare, have so far inadequately included specific considerations for digital technologies used in surgery [13]. While Lam et al. 2022 include robotics as part of their definition of digital surgery [9], we consider that DSTs are a broader category of technologies that may be integral to robotic platforms, used alongside these platforms or used standalone. Notwithstanding, they offer distinctive additional potentials, besides the clinical utility of the platforms themselves. We argue that this additional digital capacity in robotic surgery merits specific attention for developing frameworks for value assessment of DSTs. In this article, we therefore aim to highlight specific value potentials of digital technologies in surgery and call for more systematic considerations of these value perspectives in the evaluations made by healthcare decision makers.

Methods

A modified Delphi approach was used in conjunction with a consensus conference approach [22]. An international expert panel was assembled, including 14 panellists from nine countries and four continents. The panel included 11 of the members of a previous international expert panel put together to discuss HTAs of RAS [21] but also included other members recommended by the existing panel. A total of four new members were chosen for their knowledge and expertise on digital technologies in surgery (table 2). The panel members represent a wide range of relevant stakeholders, including surgeons, health economists, HTA practitioners and methodologists, policy makers and industry representatives.

Table 2 - Panellists' Details, listed in alphabetical order.

Panel Member	Country	Clinician	HTA	Methodologist	Economist	Policymaker	Digital
CHAIR: Dr. Anastasia Chalkidou	UK		x	x	x	x	x
Dr. Payam Abrishami	Netherlands		x			x	x
Prof. Jean-Christophe Bernhard	France	x					x

Prof. Richard Culbertson	USA		x			x	
Dr. Jo Carol Hiatt	USA	x				x	
Prof. Ataru Igarashi	Japan				x	x	x
Dr Gretchen Purcell Jackson	USA	x					x
Prof. Guy Maddern	Australia	x	x			x	
Dr. Joseph Soon Yau Ng	Singapore	x					x
Prof. Anita Patel	UK		x		x		
Dr. Koon Ho Rha	South Korea	x					x
Prof. Prasanna Sooriakumaran	UK	x					x
Scott Tackett	USA	Industry					
Prof. Giuseppe Turchetti	Italy		x	x	x	x	

Four Delphi questionnaires were used to develop priority topics for discussion (Figure 1).

Figure 1 - Structure of Delphi Questionnaires

An initial scoping questionnaire invited panellists to rate the importance of questions identified as potential research priorities during the previous panel discussions [21] and to suggest any other questions or issues that the group should address. The second questionnaire asked panellists to rate the importance of four questions from 1 – 9, where 1 indicated "not important" and 9 indicated "critical." The group was also asked to rate the same questions from 1 – 9 based on their perceived ability to contribute to the discussion of these questions, where 1 indicated "no knowledge/expertise" and 9 indicated "very high knowledge and expertise." The suggested priority topics are summarized in table 3:

Table 3 - Proposed Priority Topics and their Perceived Importance and Panel Ability to Answer

Priority Topics	Mean Level of Importance	Mean level of Panel Knowledge

How does Digital Technology affect operational efficiency and performance and how does this translate into clinical and economic benefit?	7.9	7.7
What are the benefits of utilising digital technology in Training and Education, and can we assess how this affects the overall clinical utility of the technology?	7.2	6.5
How can data capture feed into research/real world evidence generation and how can this help HTAs?	7.8	7.5
How can digital technologies help in remote monitoring, prediction of adverse events and identifying high-risk patients?	7.3	7.4

Following the generation of research questions, the panel members were asked to provide the three most important issues to tackle when considering the value of Digital Surgery.

These issues were discussed during the first of three consensus conferences, in which eight initial consensus statements were drafted. The consensus statements were further refined during the second consensus conference and finalized during the 3rd conference.

Results

The key issues to tackle, as proposed by the panel, were categorized into four topics for discussion: (1) how data are used in surgery, (2) the existing evidence base for DSTs, (3) how digital technologies may be used in surgical training and education, and (4) methods for the assessment of these technologies. Given and the often-tandem development and integration of DSTs with robotic platforms, many of the topics discussed were in the context of DSTs used in RAS; however, the panel felt the consensus statements would still be broadly applicable to all DSTs.

Eight consensus statements, two per topic, were developed during the first consensus conference. These statements were discussed during the second interactive consensus conference. The panel convened three times (between March and June 2023) for in-depth discussion of the topics. Seven consensus statements were formulated and agreed upon, then refined to form the conclusion of the final consensus conference (table 4).

Table 4 - Final Consensus Statements

1	Adopting a horizon scanning protocol is critical as future use cases for digital surgical technologies will continually emerge.
2	Digital technologies can provide the ability to train, retrain and retain surgeons' proficiency/skills more effectively than traditional methods and this is of high value to healthcare systems and wider society.
3	Data interoperability needs to be advocated by all stakeholders because it is a pre-requisite for realising the full potential of digital surgery and indeed many digital health interventions.
4	Digital Surgical Technologies link clinician and patient-related outcomes with objective performance indicators. These links should be considered by both national and hospital-level HTAs.
5	Given the current evidence base into the effects of digital technologies is still in its infancy, comparative studies assessing robotic surgery with and without the digital component should be considered whenever relevant and feasible.
6	Increasing automation is likely to be a particular driver for the re-evaluation of any recommendations made by this panel.
7	Digital surgical technologies allow diverse potential benefits, including reducing unwarranted variation in surgical practice, increasing access and reducing inequalities (e.g., through 5G remote surgery). It is important for assessments to consider the value holistically within the entire surgical ecosystem.

Discussion

Traditional evaluation frameworks for drugs, devices, and even new digital technologies may not be applicable for certain types of DSTs used as part of surgical practice. While many DSTs employ applications and software, they are often not used as standalone technologies. Rather, they exist as part of an array of technologies used in the operating theatre and wider hospital setting. This rich interaction is particularly true for RAS systems, in which the robotic platform includes a rapidly developing portfolio of digital solutions. Advanced computer imaging for pre-operative planning, intra-operative virtual reality assistance, simulation-based surgical training, real-time decision support, data recording, post-operative analytics, performance assessments, and AI-based clinical decision support are examples of DSTs integrated with robotic platforms [23, 24].

DSTs aim to provide improved surgical outcomes or processes, notably when integrated into robotic surgery platforms [25, 26]. Additionally, many share complexities such as learning curve issues and multi-indication applications [21]. DSTs also have additional value and intricacies that are unique to specific stakeholders or processes, particularly in terms of training and education, workflow, and efficiency, and in generating RWE. Given that DSTs are often part of a large ecosystem of technologies in the surgical setting, this highlights the need to consider their value holistically according to the specificities of the setting of use and specific perspectives of the stakeholder the evaluation is addressed to. The WBG framework suggested a value aggregation function as one such method [15]. Despite the range of potential values that DSTs may bring, the evidence is still in its infancy, and is often not growing at the same rapid pace as the technologies. It should be noted that this lack of evidence represents an opportunity for HTAs and other healthcare decision makers to provide guidance for evidence generation. This guidance may ensure that appropriate study designs are recommended according to the type of DST, studies are performed efficiently, and that they capture relevant outcomes.

The emerging evidence for DSTs has highlighted a wide range of potential use cases and value propositions. The organizational and social benefits of digitizing surgery are of particular interest due to their novelty from the perspective of policy makers and HTA bodies. Tele-operated surgery is one example where DSTs may allow for increased access to surgery due to advancements in 5G and telepresence technology, particularly for patients in rural areas [27-29]. Such remote care, along with virtual consultations and patient apps or wearables, may have far reaching sustainability benefits by avoiding the need for travel [30]. Additionally, reduction in unwarranted variation through improved training and performance assessments may address equity of care issues and provide further social benefits [31]. Digital aspects of RAS technology have the capability of delivering greater implementation of minimally invasive surgery than prior known minimally invasive surgical approaches. These enhancements include, but are not limited to advanced imaging, simulation, remote proctoring, telepresence, intraoperative guidance, decision support, data analytics, improved standardization of procedures, and reduced variation of care. As such, digital RAS ecosystems have the potential to allow surgeons and care teams to more effectively treat, by providing greater quality, accessibility, and availability of minimally invasive surgery to a greater number of patients. RAS coupled with a digital ecosystem has shown to reduce barriers to patient access of minimally invasive surgery from improved generalized adoptability and implementation practice. These barriers include factors weighing on the patient's quality of life over the course of their illness through diagnosis, treatment, and recuperation. The restoration of the patient to full activities of daily living is best viewed not as an episode of illness but rather as a patient journey through the care continuum over time until healing is complete. From this perspective, a RAS digital ecosystem may enable more minimally invasive surgery to be performed on more patients, experiencing a journey of considerable humanistic value with quicker recovery, less pain, earlier hospital discharge and with fewer ensuing complications.

RAS platforms have already caused a shift in surgical training and education, and digital technologies assessing performance may revolutionize surgical learning models. Virtual reality [7], simulation [32] and objective performance indicators (OPIs) [33] are increasingly being utilized in surgical training. Telepresence further enables access to surgical expertise and knowledge irrespective of geographic location. Real-time advice and intervention from expert surgeons can be facilitated remotely [34]. Sustainability benefits include not least minimization of training-related travel and wet lab exercises. Our panel agreed that emerging technologies would not only reduce the time to proficiency for novice surgeons but would also allow for career-long continuous improvement for practicing surgeons. The panel agreed emerging digital surgery technologies may also reduce total time and cost needed to train novice surgeons, which is often a cost borne by institutions. HTAs should look to describe the utility of these DSTs according to their specific perspectives and context, for example, as part of robotic platforms. They can then look to develop methods to quantify this cost impact to their institution or jurisdiction. As is stated in consensus point 2, new DSTs are likely to increase healthcare provider's ability to train, retrain and retain surgeons. This may be particularly relevant for national health systems facing pressures related to ageing populations and surgeon shortages [21]. Not uncommon, panel members reported difficulties in their own practices in recruiting surgeons if robotic platforms were not available. Furthermore, a 2021 study found that 73.8% of surgical trainees would value greater access to robotic surgery training, 73.4% believed that robotic surgery was important for the future of their desired specialty, and 77.2% believed it should be incorporated into formal surgical training [35]. A topic of particular interest to the panel was the use of objective performance indicators (OPIs) to evaluate surgeon performance [36]. OPIs are quantitative measurements, derived from kinematic and system events data that are automatically captured by (some robot-assisted) surgical systems [36]. Automatically capturing objective measures of surgeon performance may allow for a scalable evaluation of a certain surgical technique that has not been possible in the past. This may represent an opportunity to improve or accelerate surgical training and allow for continuous improvement, even among intermediate and expert surgeons [37]. OPIs may also provide insights related to operational workflow and efficiency, as well as be linked to post-operative outcomes [38]. Early evidence has shown that these metrics may predict outcomes, such as early urinary continence recovery [38] and length of stay, particularly when considering confounding patient factors, such as age and BMI. Surgical platforms equipped to capture OPIs may improve outcomes by a measurable and predictable amount. Whether related to skill assessment and learning, workflow and efficiency, or post-operative outcomes, insights generated by OPIs can have a measurable impact clinically and economically. As DSTs related to OPIs continue to be developed, HTAs at a national and local level need to consider them as proxy of value and try to quantify them in a harmonised way. The evidence base for these measures is growing and if strong links can be established, this may represent a paradigm shift in surgical training and practice. Healthcare decision makers need to determine how and to what extent these technologies fit within their value assessments and what their implications are for future use and adoption. Lastly, these technologies may also represent a risk for privacy. As Lam et al. 2022 noted, large scale recording of operating room data may increase the threat of litigation for surgical teams, many of whom may be reluctant to consent to data collection [9] and patients may also have objections to their data being collected.

Increasing automation of data collection may have far reaching consequences, not least in terms of the ability to generate RWE for measuring surgical outcome and for healthcare decision making. RWE is consistently listed as a vital part of how we evaluate technologies [20]. Traditionally used for post-market surveillance, it is increasingly being recognised in regulatory approvals and HTA evaluations. A major barrier to RWE generation is the hands-on time required, often by clinical staff, to collect data. Automating and standardising this process may be of great value to the healthcare system by saving staff time and increasing the depth and quality of data available for decision-making and policy development. It is vital, however, that all stakeholders in the surgical space advocate for interoperability of data between different technologies and systems. This may be a barrier to the generation of good quality RWE. If substantial time and resources are required to ensure that one dataset is compatible with another, this defeats the purpose of automated collection.

Here, we advocate for the development of surgery-specific considerations in evaluation frameworks for digital technologies; however, this requires flexibility and adaptability to new innovations coming at a rapid pace. Existing frameworks provide a starting place, but continued methodological work may be needed to define appropriate processes for specific technologies. A strong horizon scanning protocol would go some way to ensuring that we are ready to evaluate incoming technologies.

Limitations

This work aimed to gather expert insights into the evaluation of DSTs. A wide range of expertise from across the globe was gathered; however, the modified Delphi exercise only included the 14 panellists and could have been expanded to include a greater sample size. However, given the novelty of the topic and requirement for specific expertise, a smaller group of 14 was considered sufficient, similar to the panel described in Erskine et al. 2023 [21]. To make up for the reduced number of responses for the Delphi exercise, the panel met 3 times to discuss the topics at length, as opposed to a single meeting in many standard Delphi approaches.

A further limitation is the lack of patient representation. While the panel did not have a designated patient representative, it did include consumer health informatics expertise and members who have been surgical patients. In the future, the group may look to convene such a panel to specifically discuss the results of this work and the prior results of Erskine et al. 2023 [21]. In particular, patients' opinions on the patient-related and social benefits of digital technologies would be valuable.

The previous work of this panel aimed to provide guidance for HTA bodies completing assessments of RAS platforms and concluded that digital technologies were an increasingly important consideration in surgery. Here, given that there are no prior assessments to our knowledge, and that the evidence base for these technologies is still limited as this time, the panel's aim is not to provide methodological guidance for completing assessments of DSTs, but rather to advise HTA bodies who may be developing frameworks for digital technology to consider the specific nuances and complexities of digital technologies in surgery. While this is an initial step, it is recommended that HTA bodies consider the conclusions of this work when developing evaluation frameworks for DSTs. Most likely, such considerations may be made as an add-on to wider frameworks for DHTs.

Conclusions

Evaluating DSTs requires taking into account specific considerations of use within the surgical context that differ from other DHTs. Frameworks and methodologies developed for assessing DHTs should therefore consider the unique complexities of the high-stakes surgical environment and increasingly digitally enabled surgical ecosystem. It is unlikely that digital surgery is the only specialty with particular difficulties in assessing value. Digital ecosystems are arising in many areas of healthcare, such as in home-care [22] and personalised medicine, where digital technologies are radically changing the care models. New capacities are being built into the assessment frameworks to consider the benefits of DHTs in decreasing healthcare inequalities, and lowering carbon emissions. As these ecosystems are established, it is vital to ensure that the individual technologies that the systems are comprised of are evaluated holistically. In surgery, there are additional value propositions that need to be considered by HTAs, including the value of reducing unwarranted variations in performing surgical procedures, accelerating proficiency-based surgical training, and making complex surgical care more accessible to patients in need. Further, OPIs may have substantial impacts on surgical education and training. Lastly, the enormous potential for automated data collection and evidence generation should not be underestimated. All stakeholders should advocate for data inter-operability to fully recognise this value.

Author Statement:

Jamie Erskine supported the design of the research, supported the background research for the panel discussions, supported the facilitation of the panel meetings and drafted the first version of the manuscript.

Richard Charter supported the facilitation of the panel meetings and reviewed the manuscript.

Matthew Lien supported the background research for the panel discussions and reviewed the manuscript.

Anastasia Chalkidou provided oversight for the design of the research, chaired the expert panel and reviewed the manuscript.

The remaining authors were members of the panel, attended the panel meetings and reviewed the manuscript.

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Conflicts of Interest Statement

Scott Tackett is an employee of Intuitive Surgical and as such he receives compensation and benefits as part of his employment agreement, as well as stock from Intuitive Surgical.

Gretchen Purcell Jackson is employee of Intuitive Surgical and as such she receives compensation and benefits as part of her employment agreement, as well as stock from Intuitive Surgical. She also owns stock or stock options from IBM and Kyndryl and is President and Chair, of the Board of Directors for the American Medical Informatics Association.

Matthew Lien is an employee of Intuitive Surgical and as such he receives compensation and benefits as part of his employment agreement.

Jamie Erskine and Richard Charter are employees of Alira Health. Alira Health received consulting fees from Intuitive Surgical for the coordination of the panel.

Richard Charter and Anastasia Chalkidou are the co-chairs of the HTAi Medical Device Interest Group.

Americo Cicchetti has received consulting fees for Novartis, Astra Zeneca, Lilly, Sanofi, Roche, and Gilead.

Richard Culbertson has received payment from the American College of Healthcare Executives for past publications.

Koon Ho Rha is an execute of NAVER.

Joseph Soon Yau Ng is a board member of the Asian Society for Gyn Robotic Surgery and the Robotic Surgery Society of Singapore.

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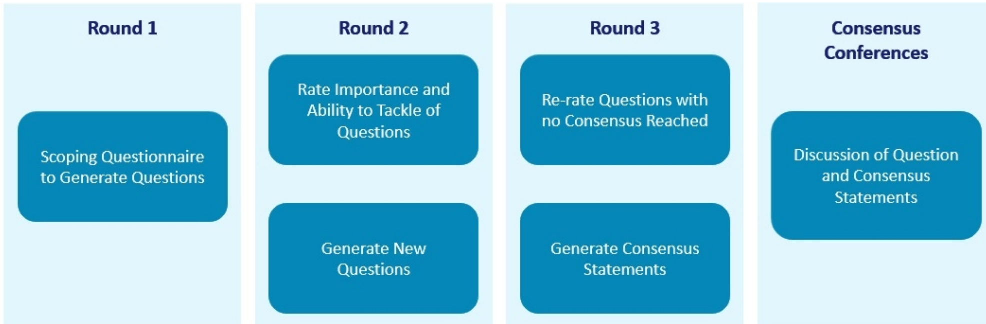

Figure 1 - Structure of Delphi Questionnaires

186x61mm (144 x 144 DPI)

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Title			
	#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1
Abstract			
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Introduction			
Problem	#3	Nature and significance of the local problem	3-7

description			
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	3-7
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	3-7
Specific aims	#6	Purpose of the project and of this report	6-7
Methods			
Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	3-7
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	7-9
Intervention(s)	#08b	Specifics of the team involved in the work	7-9
Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	7-9
Study of the Intervention(s)	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	N/A
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	N/A
Measures	#10b	Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	N/A
Measures	#10c	Methods employed for assessing completeness and accuracy of data	N/A
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	N/A
Analysis	#11b	Methods for understanding variation within the data, including the effects of time as a variable	N/A
Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	N/A

Results

	#13a	Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	N/A
	#13b	Details of the process measures and outcome	9
	#13c	Contextual elements that interacted with the intervention(s)	N/A
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	N/A
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	N/A
	#13f	Details about missing data	N/A
Discussion			
Summary	#14a	Key findings, including relevance to the rationale and specific aims	10-13
Summary	#14b	Particular strengths of the project	2-3
Interpretation	#15a	Nature of the association between the intervention(s) and the outcomes	N/A
Interpretation	#15b	Comparison of results with findings from other publications	N/A
Interpretation	#15c	Impact of the project on people and systems	10-13
Interpretation	#15d	Reasons for any differences between observed and anticipated outcomes, including the influence of context	N/A
Interpretation	#15e	Costs and strategic trade-offs, including opportunity costs	N/A
Limitations	#16a	Limits to the generalizability of the work	14
Limitations	#16b	Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	14
Limitations	#16c	Efforts made to minimize and adjust for limitations	14
Conclusion	#17a	Usefulness of the work	14-15
Conclusion	#17b	Sustainability	N/A
Conclusion	#17c	Potential for spread to other contexts	12, 14

Conclusion	#17d	Implications for practice and for further study in the field	12, 14
Conclusion	#17e	Suggested next steps	12, 14
Other information			
Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	16

 This checklist was completed on 23. November 2023 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

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An International Consensus Panel on the Value Proposition of Digital Surgery

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An International Consensus Panel on the Value Proposition of Digital Surgery

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Abstract

Objectives: The use of digital technology in surgery is increasing rapidly, with a wide array of new applications from pre-surgical planning to post-surgical performance assessment. Understanding the clinical and economic value of these technologies is vital for making appropriate health policy and purchasing decisions. We explore the potential value of digital technologies in surgery and produce expert consensus on how to assess this value.

Design: A modified Delphi and consensus conference approach was adopted. Delphi rounds were used to generate priority topics and consensus statements for discussion.

Setting and participants: An international panel of 14 experts was assembled, representing relevant stakeholder groups: clinicians, health economists, Health Technology Assessment experts, policy makers and industry.

Primary and secondary outcome measures: A scoping questionnaire was used to generate research questions to be answered. A second questionnaire was used to rate the importance of these research questions. A final questionnaire was used to generate statements for discussion during three consensus conferences. After discussion, the panel voted on their level of agreement from 1-9; where 1 = strongly disagree and 9 = strongly agree. Consensus was defined as a mean level of agreement of >7.

Results: Four priority topics were identified: (1) how data are used in digital surgery, (2) the existing evidence base for digital surgical technologies, (3) how digital technologies may assist surgical training and education, and (4) methods for the assessment of these technologies. Seven consensus statements were generated and refined, with the final level of consensus ranging from 7.1 – 8.6.

Conclusion: Potential benefits of digital technologies in surgery include reducing unwarranted variation in surgical practice, increasing access to surgery, and reducing health inequalities. Assessments to consider the value of the entire surgical ecosystem holistically are critical, especially as many digital technologies are likely to interact simultaneously in the operating theatre.

Article Summary

Strengths and limitations of this study

- Using a combination of a modified Delphi process and a series of consensus conferences, this study generates expert consensus on the value of digital surgical technologies.
- This study identifies specific considerations for Health Technology Assessments (HTAs) of Digital Surgical Technologies (DSTs).
- Although the expert panel assembled for this study represents a range of stakeholders and geographies, the results are subjective and may not represent all relevant viewpoints.

- The study did not have a designated patient representative; however, it did include consumer health informatics expertise and members who have been surgical patients.
- This study's aim is not to provide methodological guidance for completing assessments of DSTs, but rather to advise HTA bodies who may be developing frameworks for digital technology to consider the specific nuances and complexities of digital technologies in surgery.

Introduction

Digital technologies are being used increasingly in healthcare systems globally, accelerated by the COVID-19 pandemic with the global telehealth market reaching more than $80 billion USD in 2021 and expected to reach over $200 billion USD in 2025 [1]. These technologies, known as Digital Health Technologies (DHTs), are extremely diverse. The Food and Drug Administration (FDA) includes mobile health (mHealth), health information technologies, wearable devices, telehealth, telemedicine, and personalised medicine in its definition of digital health [2], while the National Institute of Health and Care Excellence (NICE) simply notes that DHTs "comprise a wide range of products used in the health and care system including apps, software and online platforms" [3]. Given that DHTs have such a broad range of functionalities, use cases, and benefits, understanding and evaluating them are highly complex tasks.

DHTs differ from other health technologies in several ways. Firstly, many DHTs are frequently updated. Artificial intelligence (AI) based technologies are changing perpetually as algorithms learn from new data. This rapid pace of development makes evaluating the clinical and economic benefits of these technologies challenging. Further, the evidence supporting DHTs may not be as robust as other health technologies such as medical devices or pharmaceuticals [4, 5]. DHTs are often highly context dependent, particularly within surgery or other hospital settings, making standard randomized trial designs less applicable compared to other forms of evidence, such as Real World Evidence (RWE) [6]. Large scale RCTs, for example, are often performed by clinical trial networks or contract research organizations (CROs) that operate outside of normal clinical practice. This may be less applicable for some digital health technologies (particularly those that implement AI) as data collected from routine clinical practice are often required for the operation of these technologies. Further, like medical devices [7], there may also be an operator learning curve related to digital technologies [8]. To further add to the complexity, DHTs are often used simultaneously or integrated with another technology such as a medical device. These complexities, in addition to the huge range of use cases, level of autonomy and potential risk, make assessing digital technologies for safety, efficacy and cost effectiveness a uniquely difficult proposition [6].

In surgery, digital technologies are rapidly being developed and adopted, from pre-operative planning and intra-operative guidance to post-operative performance assessment [9]. Advancements in training and education [10], virtual reality (VR) [11], machine learning [9], and telehealth [12] are being implemented in surgical practice, either as standalone solutions or alongside other DHTs and devices. This is increasingly true in Robot-Assisted Surgery (RAS), as advancements in digital capabilities are developing in tandem with various robotic platforms [13, 14].

Lam et al., [15] in a Delphi exercise, aimed to define “Digital Surgery”, agreeing upon “the use of technology for the enhancement of preoperative planning, surgical performance, therapeutic support, or training, to improve outcomes and reduce harm”. The study also reported that there were no clearly defined reimbursement or business models for these technologies. Furthermore, adoption barriers may arise due to difficulties in demonstrating safety and clinical benefits. The authors recommended future research into developing a framework for the introduction and evaluation of surgical AI and establishing a business model with industry .

There have been several frameworks for evaluating digital technologies published by various Health Technology Assessment (HTA) bodies in recent years, many of which are still evolving and being refined. A review by San Miguel et al. [16] at the Belgian Health Care Knowledge Centre (KCE) reviewed six existing European frameworks (table 1) for evaluating digital technologies as part of the further development of their own procedures.

Table 1 - Existing Frameworks developed by HTA agencies for Assessing Digital Health Technologies in Europe, adapted from San Miguel et al. 2022 [16].

Country	Framework for DTs	Author	Year
Germany	Fast track procedure for DiGAs	The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM)	2020
UK	Evidence Standards Framework for DMTs	National Institute for Health and Care Excellence (NICE)	2019
France	Loi de financement de la sécurité sociale pour 2022 Guide on specific features of clinical evaluation of a connected medical device (CMD)	Haute Autorité de Santé (HAS)	2022
Finland	Digi-HTA framework	Centre for Health and Technology, FinCCHTA and the University of Oulu's MIPT research group	2019
Netherlands	Guidance for assessment of digital care	Knowledge Centre Digital Care (Health Insurers)	2021
Austria	Framework for reimbursement decisions of digital health technologies	Austrian Institute for HTA (AIHTA)	2021

The frameworks listed vary in scope considerably. The DiGA procedure in Germany, for example, was designed specifically for health apps [17].. The Finnish Digi-HTA framework is slightly broader, including specific considerations for robotics and AI [18], although no assessments have been completed on such technologies used in surgery to date [19]. Outside of Europe, guidelines have also been developed in countries like South Korea; however, these guidelines only cover AI for medical imaging and 3D printing and so are limited in scope [20].

Despite the range of efforts to develop assessment frameworks for DHTs, no consistent standards have yet been agreed upon, partially due to the diversity in technologies, in the setting of use, and in reimbursement models [21]. Payers and policymakers are still challenged when quantifying the clinical and economic utility of these technologies. Unlike health apps, DHTs used in surgery may be high-cost technologies or are used in conjunction with other high-cost surgical devices, such as robotic platforms. Payment and reimbursement models are likely to differ significantly. Applications for example may use a subscription model or a population-based payment model. Some digital technologies in surgery are more likely to be purchased as a separate product in the operating theatre but many are integrated into a robotic platform or even into a digital operating theatre [14]. Calculating the economic impact of such technologies is potentially very complex.

In this article, we focus on Digital Surgical Technologies, referred to from here onwards as DSTs. Elsewhere, we have developed guidance for the assessment of RAS platforms [22]. Existing frameworks for evaluating digital technologies in healthcare, have so far inadequately included specific considerations for digital technologies used in surgery [19]. While Lam et al. 2022 include robotics as part of their definition of digital surgery [15], we consider that DSTs are a broader category of technologies that may be integral to robotic platforms, used alongside these platforms or used standalone. Notwithstanding, they offer distinctive additional potentials, besides the clinical utility of the platforms themselves. We argue that this additional digital capacity in robotic surgery merits specific attention for developing frameworks for value assessment of DSTs.

In this article, we describe a Modified Delphi study that aims to develop consensus on the value potentials of digital technologies in surgery and highlight important considerations and challenges in assessing these value perspectives.

Methods

A modified Delphi approach was used in conjunction with a consensus conference approach [23]. An international expert panel was assembled, including 14 panellists from nine countries and four continents. The panel included 11 of the members of a previous international expert panel put together to discuss HTAs of RAS [22] but also included other members recommended by the existing panel. A total of four new members were chosen for their knowledge and expertise on digital technologies in surgery (table 2). The panel members represent a wide range of relevant stakeholders, including surgeons, health economists, HTA practitioners and methodologists, policy makers and industry representatives.

Table 2 - Panellists' Details, listed in alphabetical order.

Panel Member	Country	Clinician	HTA*	Methodologist	Economist	Policymaker	Digital**
CHAIR: Dr. Anastasia Chalkidou	UK		x	x	x	x	x
Dr. Payam Abrishami	Netherlands		x			x	x
Prof. Jean-Christophe Bernhard	France	x					x
Prof. Richard Culbertson	USA		x			x	
Dr. Jo Carol Hiatt	USA	x				x	
Prof. Ataru Igarashi	Japan				x	x	x
Dr Gretchen Purcell Jackson	USA	x					x
Prof. Guy Maddern	Australia	x	x			x	
Dr. Joseph Soon Yau Ng	Singapore	x					x
Prof. Anita Patel	UK		x		x		
Dr. Koon Ho Rha	South Korea	x					x
Prof. Prasanna Sooriakumaran	UK	x					x
Scott Tackett	USA	Industry					
Prof. Giuseppe Turchetti	Italy		x	x	x	x	

*Health Technology Assessment. These panel members have experience of performing health technology assessment at the national or local level.

** These panel members have experience of utilizing digital technologies in surgery or performing health technology assessments of digital technologies.

Three questionnaires were used to develop priority topics for discussion between January and March 2023 (Figure 1).

Figure 1 - Structure of Modified Delphi Process

An initial scoping questionnaire, developed in Google Forms (Google, CA, USA) and sent as a link by email, invited panellists to rate the importance of two questions (see topics 1 and 2 in table 3) identified as potential research priorities during the previous panel discussions [22] and to suggest any other questions or issues that the group should address. A further two questions were added at this stage (see topics 3 and 4 in table 3), totalling four. The second questionnaire, also created and distributed in the same format, asked panellists to rate the importance of these four questions from 1 – 9, where 1 indicated "not important" and 9 indicated "critical." The group was also asked to rate the same questions from 1 – 9 based on their perceived ability to contribute to the discussion of these questions, where 1 indicated "no knowledge/expertise" and 9 indicated "very high knowledge and expertise." These rankings are subjective and merely descriptive. The suggested questions were considered priority topics and are summarized in table 3, ranked by their perceived level of importance:

Table 3 - Proposed Priority Topics and their Perceived Importance and Panel Ability to Answer

	Priority Topics	Mean Level of Importance	Mean level of Panel Knowledge
1	How does Digital Technology affect operational efficiency and performance and how does this translate into clinical and economic benefit?	7.9	7.7
2	How can data capture feed into research/real world evidence generation and how can this help HTAs?	7.8	7.5
3	How can digital technologies help in remote monitoring, prediction of adverse events and identifying high-risk patients?	7.3	7.4
4	What are the benefits of utilising digital technology in Training and Education, and can we assess how this affects the overall clinical utility of the technology?	7.2	6.5

It is notable that the panel voted the topic of training and education (topic 4 in table 3) as the topic with the lowest mean level of panel knowledge. To ensure that the panel were well informed during the discussions, the members that were more familiar with this topic provided details of their experiences with using digital technologies in surgical training and education.

Following the generation of the priority topics shown above, the panel members were asked to provide the three most important issues to tackle within these topics when considering the value of Digital Surgery.

These issues were discussed during the first of three consensus conferences, in which eight initial consensus statements were drafted. The consensus statements were further refined during the second consensus conference and finalized during the 3rd conference, with a total of seven being finalised.

Patient and Public Involvement

Although patients were not directly involved in the design of the research, the impetus for the research project was informed by the previous work of the panel, which considered how robotic surgery can affect patient outcomes including quality of life and patient satisfaction.

Results

The key issues to tackle, as proposed by the panel, were categorized into four topics for discussion: (1) how data are used in surgery, (2) the existing evidence base for DSTs, (3) how digital technologies may be used in surgical training and education, and (4) methods for the assessment of these technologies. Given the often-tandem development and integration of DSTs with robotic platforms, many of the topics discussed were in the context of DSTs used in RAS; however, the panel felt the consensus statements would still be broadly applicable to all DSTs.

Eight consensus statements, two per topic, were developed during the first consensus conference (see table 4). These statements were discussed during the second interactive consensus conference. The panel convened three times (between March and June 2023) for in-depth discussion of the topics. Each of these meetings was 'hybrid', with some panel members meeting in person where feasible and others joining through teleconferencing software (Zoom, CA, USA). The original list of eight consensus statements was reduced to seven final statements that were agreed upon, and refined to form the conclusion of the final consensus conference (table 4).

Table 4 – Priority Topics for Discussion and Draft Consensus Statements

Topic	Draft Consensus Statement
1. Data used in Surgery	Interoperability is vital for making the best use of data collected by digital surgical technologies.

	Data captured by digital surgical systems can provide real time insights and decision support to improve operational efficiency and performance. These benefits may be better suited to assessment at the hospital level.
2. The evidence base for DSTs	Digital technologies may allow for linkage between clinician (and patient-related) outcomes and system capabilities. This could allow for more detailed evidence generation.
	There is a current lack of evidence into the effects of digital technologies. Comparative studies between robotic surgery with and without digital technology are recommended for most digital technologies.
3. Surgical Training & Education	Future improvements to simulators/VR/immersive surgery will need to be taken into account by an HTA and any recommendations made here will require to consider these changes.
	Data captured can drive technical proficiency and continuous improvement for surgeons. The ability to retain, and train surgeons remotely, including support from 'super specialists' may be a benefit that hospital-based HTAs should consider.
4. Methods for Assessment	Different digital surgical platforms have very different Infrastructure capabilities. This needs to be captured by HTAs.
	There are various ways in which digital technologies allow for the assessment and reduction of variation in clinical practice and may also increase access (i.e, through 5g remote surgery). This ability to reduce health inequalities/inequities should be considered by HTAs.

Table 5 - Final Consensus Statements

	Consensus Statement	Mean Level of Agreement*
1	Adopting a horizon scanning protocol is critical as future use cases for digital surgical technologies will continually emerge.	7.6
2	Digital technologies can provide the ability to train, retrain and retain surgeons' proficiency/skills more effectively than traditional methods and this is of high value to healthcare systems and wider society.	8.6
3	Data interoperability needs to be advocated by all stakeholders because it is a pre-requisite for realising the full potential of digital surgery and indeed many digital health interventions.	8

4	Digital Surgical Technologies link clinician and patient-related outcomes with objective performance indicators. These links should be considered by both national and hospital-level HTAs.	7.1
5	Given the current evidence base into the effects of digital technologies is still in its infancy, comparative studies assessing robotic surgery with and without the digital component should be considered whenever relevant and feasible.	7.6
6	Increasing automation is likely to be a particular driver for the re-evaluation of any recommendations made by this panel.	7.3
7	Digital surgical technologies allow diverse potential benefits, including reducing unwarranted variation in surgical practice, increasing access and reducing inequalities (e.g., through 5G remote surgery). It is important for assessments to consider the value holistically within the entire surgical ecosystem.	7.5

***From 1-9, where 9 is the highest level of agreement**

Discussion

This modified Delphi consensus study utilised a series of questionnaires to identify potential value perspectives of DSTs and potential challenges in assessing this value. An expert panel discussed these challenges and developed a series of consensus statements. The panel agreed that traditional evaluation frameworks for drugs, devices, and even new digital technologies may not be applicable for certain types of DSTs used as part of surgical practice. While many DSTs employ applications and software, they are often not used as standalone technologies. Rather, they exist as part of an array of technologies used in the operating theatre and wider hospital setting. This rich interaction is particularly true for RAS systems, in which the robotic platform includes a rapidly developing portfolio of digital solutions. Advanced computer imaging for pre-operative planning, intra-operative virtual reality assistance, simulation-based surgical training, real-time decision support, data recording, post-operative analytics, performance assessments, and AI-based clinical decision support are examples of DSTs integrated with robotic platforms [14, 24].

DSTs aim to provide improved surgical outcomes or processes, notably when integrated into robotic surgery platforms [25, 26]. Additionally, many share complexities such as learning curve issues and multi-indication applications [22]. Our panel considered that DSTs also have additional value and intricacies that are unique to specific stakeholders or processes, particularly in terms of training and education, workflow, and efficiency, and in generating RWE (see consensus statements 2 and 7 in table 5). Given that DSTs are often part of a large ecosystem of technologies in the surgical setting, this highlights the need to consider their value holistically according to the specificities of the setting of use and specific perspectives of the stakeholder the evaluation is addressed to. The World Bank Group framework for the economic assessment of digital health technologies suggested a value aggregation function – where multiple value attributes are weighted based on the preferences of chosen stakeholder groups - as one such method [21]. Despite the range of potential values that DSTs may bring, the evidence is still in its infancy, and is often not growing at the same rapid pace as the technologies (see consensus statement 5). The panel noted that this lack of evidence represents an opportunity for HTAs and other healthcare decision makers to provide guidance for evidence generation. This guidance may ensure that appropriate study designs are recommended according to the type of DST, studies are performed efficiently, and that they capture relevant outcomes.

The emerging evidence for DSTs has highlighted a wide range of potential use cases and value propositions. Our panel agreed that the organizational and social benefits of digitizing surgery are of particular interest due to their novelty from the perspective of policy makers and HTA bodies. Tele-operated surgery is one example where DSTs may allow for increased access to surgery due to advancements in 5G and telepresence technology, particularly for patients in rural areas [27-29]. Such remote care, along with virtual consultations and patient apps or wearables, may have far reaching sustainability benefits by avoiding the need for travel [30]. Additionally, reduction in unwarranted variation through improved training and performance assessments may address equity of care issues and provide further social benefits [31].

Digital aspects of RAS technology have the capability of delivering greater implementation of minimally invasive surgery than prior known minimally invasive surgical approaches. These enhancements include, but are not limited to advanced imaging, simulation, remote proctoring, telepresence, intraoperative guidance, decision support, data analytics, improved standardization of procedures, and reduced variation of care. As such, digital RAS ecosystems have the potential to allow surgeons and care teams to more effectively treat, by providing greater quality, accessibility, and availability of minimally invasive surgery to a greater number of patients. The panel discussed that this may have particular importance in regions or countries with less well-developed surgical programmes, such as in Low and Middle-Income

Countries (LMICs). Telepresence further enables access to surgical expertise and knowledge irrespective of geographic location. .

Despite being the topic on which our panel perceived as having the least knowledge, RAS platforms have already caused a shift in surgical training and education, and digital technologies assessing performance may revolutionize surgical learning models. Virtual reality [11], simulation [32] and objective performance indicators (OPIs) [33] are increasingly being utilized in surgical training. Real-time advice and intervention from expert surgeons can be facilitated remotely [34]. Our panel agreed that emerging technologies would not only reduce the time to proficiency for novice surgeons but would also allow for career-long continuous improvement for practicing surgeons. The panel agreed emerging digital surgery technologies may also reduce total time and cost needed to train novice surgeons, which is often a cost borne by institutions. HTAs should look to describe the utility of these DSTs according to their specific perspectives and context, for example, as part of robotic platforms. They can then look to develop methods to quantify this cost impact to their institution or jurisdiction. As is stated in consensus point 2, new DSTs are likely to increase healthcare provider's ability to train, retrain and retain surgeons. This may be particularly relevant for national health systems facing pressures related to ageing populations and surgeon shortages [22]. Panel members reported difficulties in their own practices in recruiting surgeons if robotic platforms were not available. Furthermore, a 2021 study found that 73.8% of surgical trainees would value greater access to robotic surgery training, 73.4% believed that robotic surgery was important for the future of their desired specialty, and 77.2% believed it should be incorporated into formal surgical training [35].

A topic of particular interest to the panel was the use of OPIs to evaluate surgeon performance [36]. OPIs are quantitative measurements, derived from kinematic and system events data that are automatically captured by (some robot-assisted) surgical systems [36]. Automatically capturing objective measures of surgeon performance may allow for a scalable evaluation of certain surgical techniques that have not been possible in the past. This may represent an opportunity to improve or accelerate surgical training and allow for continuous improvement, even among intermediate and expert surgeons [37]. OPIs may also provide insights related to operational workflow and efficiency, as well as be linked to post-operative outcomes [38]. Early evidence has shown that these metrics may predict outcomes, such as early urinary continence recovery [38] and length of stay, particularly when considering confounding patient factors, such as age and BMI. Surgical platforms equipped to capture OPIs may improve outcomes by a measurable and predictable amount. The panel concurred that whether related to skill assessment and learning, workflow and efficiency, or post-operative outcomes, insights generated by OPIs can have a measurable impact clinically and economically (see consensus statement 4). As DSTs related to OPIs continue to be developed, the panel recommended that HTAs at a national and local level may consider them as proxy of value, or as surrogate outcomes, and try to quantify them in a harmonised way. The evidence base for these measures is growing and if strong links can be established, this may represent a paradigm shift in surgical training and practice. The panel would urge healthcare decision makers to determine how, and to what extent, these technologies fit within their value assessments and what their implications are for future use and adoption. On the other hand, the panel also discussed how these technologies may also represent a risk for privacy. As Lam et al. 2022 noted, large scale recording of operating room data may increase the threat of litigation for surgical teams, many of whom may be reluctant to consent to data collection [9] and patients may also have objections to their data being collected.

The panel felt that increasing automation of data collection may have far reaching consequences, not least in terms of the ability to generate RWE for measuring surgical outcome and for healthcare decision making (see consensus statement 6). RWE is consistently listed as a vital part of how we evaluate technologies [39]. Traditionally used for post-market surveillance, it is increasingly being recognised in regulatory approvals and HTA evaluations [39]. A major barrier to RWE generation is the hands-on time required, often by clinical staff, to collect data. Automating and standardising this process may be of great value to the healthcare system by saving staff time and increasing the depth and quality of data available for decision-making and policy development. The panel also considered that all stakeholders in the surgical space must advocate for interoperability of data between different technologies and systems (see consensus statement 3). This may be a barrier to the generation of good quality RWE. If substantial time and resources are required to ensure that one dataset is compatible with another, this defeats the purpose of automated collection. The panel also noted that it is vital to ensure that studies of DSTs (and particularly early phase studies of AI technologies which involve the training of algorithms) are conducted to high standards, following guidance from SPIRIT and CONSORT-AI on conducting and reporting trials [4, 6, 40]. Patient safety and equity are paramount, and avoiding unexpected consequences that arise due to utilising unrepresentative populations should be prioritised [6].

Here, we advocate for the development of surgery-specific considerations in evaluation frameworks for digital technologies; however, this requires flexibility and adaptability to new innovations coming at a rapid pace. Existing frameworks provide a starting place, but continued methodological work may be needed to define appropriate processes for specific technologies. A strong horizon scanning protocol would go some way to ensuring that we are ready to evaluate incoming technologies (see consensus statement 1).

Limitations

This work aimed to gather expert insights into the evaluation of DSTs. A wide range of expertise from across the globe was gathered; however, the modified Delphi exercise only included the 14 panellists and could have been expanded to include a greater sample size. However, given the novelty of the topic and requirement for specific expertise, a smaller group of 14 was considered sufficient, similar to the panel described in Erskine et al. 2023 [22]. To make up for the reduced number of responses for the Delphi exercise, the panel met 3 times to discuss the topics at length, as opposed to a single meeting in many standard Delphi approaches.

The panel did not have representation from LMICs for this piece of work. This may bias the results towards high-income countries and it should be noted that there are specific benefits of DSTs in their potential to increase access to minimally invasive surgery in lower-income settings [41].A further limitation is the lack of patient representation. While the panel did not have a designated patient representative, it did include consumer health informatics expertise and members who have been surgical patients. In the future, the group may look to convene such a panel to specifically discuss the results of this work and the prior results of Erskine et al. 2023 [22]. In particular, patients' opinions on the patient-related and social benefits of digital technologies would be valuable. The panel discussed topics that may be potential future considerations for further work, including surgical technologies' ability to reduce health inequities and increasing patient access in rural areas and LMIC's, their effect on environmental sustainability, and the patient and public perspective. These value types may be considered broadly 'societal value' and could be a future research project for this panel.

The previous work of this panel aimed to provide guidance for HTA bodies completing assessments of RAS platforms and concluded that digital technologies were an increasingly important consideration in surgery. Here, given that there are no prior assessments to our knowledge, and that the evidence base for these technologies is still limited as this time, the panel's aim is not to provide methodological guidance for completing assessments of DSTs, but rather to advise HTA bodies who may be developing frameworks for digital technology to consider the specific nuances and complexities of digital technologies in surgery. While this is an initial step, it is recommended that HTA bodies consider the conclusions of this work when developing evaluation frameworks for DSTs. Most likely, such considerations may be made as an add-on to wider frameworks for DHTs.

Conclusions

Evaluating DSTs requires taking into account specific considerations of use within the surgical context that differ from other DHTs. Frameworks and methodologies developed for assessing DHTs should therefore consider the unique complexities of the high-stakes surgical environment and increasingly digitally enabled surgical ecosystem. It is unlikely that digital surgery is the only specialty with particular difficulties in assessing value. Digital ecosystems are arising in many areas of healthcare, such as in home-care [22] and personalised medicine, where digital technologies are radically changing the care models. New capacities are being built into the assessment frameworks to consider the benefits of DHTs in decreasing healthcare inequalities, and lowering carbon emissions. As these ecosystems are established, it is vital to ensure that the individual technologies that the systems are comprised of are evaluated holistically. In surgery, there are additional value propositions that need to be considered by HTAs, including the value of reducing unwarranted variations in performing surgical procedures, accelerating proficiency-based surgical training, and making complex surgical care more accessible to patients in need. Further, OPIs may have substantial impacts on surgical education and training. Lastly, the enormous potential for automated data collection and evidence generation should not be underestimated. All stakeholders should advocate for data inter-operability to fully recognise this value.

Author Statement:

Jamie Erskine supported the design of the research, supported the background research for the panel discussions, supported the facilitation of the panel meetings and drafted the first version of the manuscript.

Richard Charter supported the facilitation of the panel meetings and reviewed the manuscript.

Matthew Lien supported the background research for the panel discussions and reviewed the manuscript.

Anastasia Chalkidou provided oversight for the design of the research, chaired the expert panel and reviewed the manuscript.

The remaining authors were members of the panel, attended the panel meetings and reviewed the manuscript.

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Conflicts of Interest Statement

Scott Tackett is an employee of Intuitive Surgical and as such he receives compensation and benefits as part of his employment agreement, as well as stock from Intuitive Surgical.

Matthew Lien is an employee of Intuitive Surgical and as such he receives compensation and benefits as part of his employment agreement.

Jamie Erskine and Richard Charter are employees of Alira Health. Alira Health received consulting fees from Intuitive Surgical for the coordination of the panel.

Richard Charter and Anastasia Chalkidou are the co-chairs of the HTAi Medical Device Interest Group.

Americo Cicchetti has received consulting fees for Novartis, Astra Zeneca, Lilly, Sanofi, Roche, and Gilead.

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Data Availability Statement

All data relevant to the study are included in the article or available as supplementary information.

Ethical Approval Statement

No ethics approval was sought as this research did not include either human or animal subjects.

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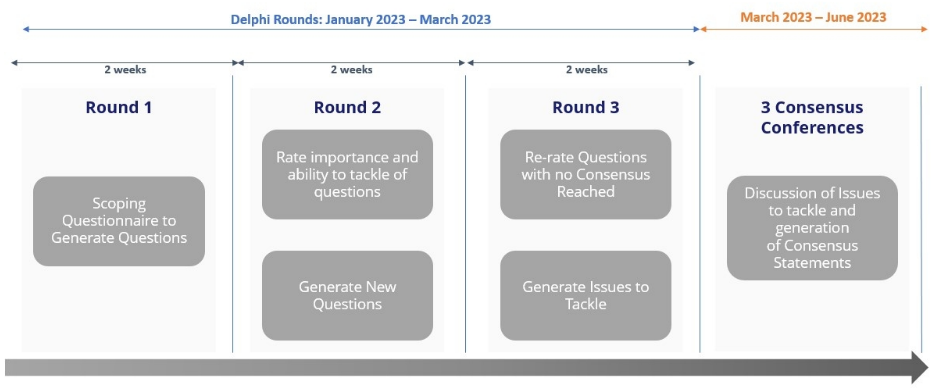

Figure 1 - Structure of Modified Delphi Process

338x190mm (96 x 96 DPI)

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Title			
	#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1
Abstract			
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Introduction			
Problem	#3	Nature and significance of the local problem	3-7

description			
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	3-7
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	3-7
Specific aims	#6	Purpose of the project and of this report	6-7
Methods			
Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	3-7
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	7-9
Intervention(s)	#08b	Specifics of the team involved in the work	7-9
Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	7-9
Study of the Intervention(s)	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	N/A
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	N/A
Measures	#10b	Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	N/A
Measures	#10c	Methods employed for assessing completeness and accuracy of data	N/A
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	N/A
Analysis	#11b	Methods for understanding variation within the data, including the effects of time as a variable	N/A
Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	N/A

Results

	#13a	Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	N/A
	#13b	Details of the process measures and outcome	9
	#13c	Contextual elements that interacted with the intervention(s)	N/A
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	N/A
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	N/A
	#13f	Details about missing data	N/A

Discussion

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Summary	#14b	Particular strengths of the project	2-3
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Interpretation	#15b	Comparison of results with findings from other publications	N/A
Interpretation	#15c	Impact of the project on people and systems	10-13
Interpretation	#15d	Reasons for any differences between observed and anticipated outcomes, including the influence of context	N/A
Interpretation	#15e	Costs and strategic trade-offs, including opportunity costs	N/A
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 This checklist was completed on 23. November 2023 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

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An International Consensus Panel on the Potential Value of Digital Surgery

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An International Consensus Panel on the Potential Value of Digital Surgery

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Abstract

Objectives: The use of digital technology in surgery is increasing rapidly, with a wide array of new applications from pre-surgical planning to post-surgical performance assessment. Understanding the clinical and economic value of these technologies is vital for making appropriate health policy and purchasing decisions. We explore the potential value of digital technologies in surgery and produce expert consensus on how to assess this value.

Design: A modified Delphi and consensus conference approach was adopted. Delphi rounds were used to generate priority topics and consensus statements for discussion.

Setting and participants: An international panel of 14 experts was assembled, representing relevant stakeholder groups: clinicians, health economists, Health Technology Assessment experts, policy makers and industry.

Primary and secondary outcome measures: A scoping questionnaire was used to generate research questions to be answered. A second questionnaire was used to rate the importance of these research questions. A final questionnaire was used to generate statements for discussion during three consensus conferences. After discussion, the panel voted on their level of agreement from 1-9; where 1 = strongly disagree and 9 = strongly agree. Consensus was defined as a mean level of agreement of >7.

Results: Four priority topics were identified: (1) how data are used in digital surgery, (2) the existing evidence base for digital surgical technologies, (3) how digital technologies may assist surgical training and education, and (4) methods for the assessment of these technologies. Seven consensus statements were generated and refined, with the final level of consensus ranging from 7.1 – 8.6.

Conclusion: Potential benefits of digital technologies in surgery include reducing unwarranted variation in surgical practice, increasing access to surgery, and reducing health inequalities. Assessments to consider the value of the entire surgical ecosystem holistically are critical, especially as many digital technologies are likely to interact simultaneously in the operating theatre.

Article Summary

Strengths and limitations of this study

- Using a combination of a modified Delphi process and a series of consensus conferences, this study generates expert consensus on the value of digital surgical technologies.
- This study identifies specific considerations for Health Technology Assessments (HTAs) of Digital Surgical Technologies (DSTs).
- Although the expert panel assembled for this study represents a range of stakeholders and geographies, the results are subjective and may not represent all relevant viewpoints.

- The study did not have a designated patient representative; however, it did include consumer health informatics expertise and members who have been surgical patients.
- This study's aim is not to provide methodological guidance for completing assessments of DSTs, but rather to advise HTA bodies who may be developing frameworks for digital technology to consider the specific nuances and complexities of digital technologies in surgery.

Introduction

Digital technologies are being used increasingly in healthcare systems globally, accelerated by the COVID-19 pandemic with the global telehealth market reaching more than $80 billion USD in 2021 and expected to reach over $200 billion USD in 2025 [1]. These technologies, known as Digital Health Technologies (DHTs), are extremely diverse. The Food and Drug Administration (FDA) includes mobile health (mHealth), health information technologies, wearable devices, telehealth, telemedicine, and personalised medicine in its definition of digital health [2], while the National Institute of Health and Care Excellence (NICE) simply notes that DHTs "comprise a wide range of products used in the health and care system including apps, software and online platforms" [3]. Given that DHTs have such a broad range of functionalities, use cases, and benefits, understanding and evaluating them are highly complex tasks.

DHTs differ from other health technologies in several ways. Firstly, many DHTs are frequently updated. Artificial intelligence (AI) based technologies are changing perpetually as algorithms learn from new data. This rapid pace of development makes evaluating the clinical and economic benefits of these technologies challenging. Further, the evidence supporting DHTs may not be as robust as other health technologies such as medical devices or pharmaceuticals [4, 5]. DHTs are often highly context dependent, particularly within surgery or other hospital settings, which could mean that standard randomized trial designs are less applicable in some cases compared to other forms of evidence, such as Real World Evidence (RWE) [6]. Large scale RCTs, for example, are often performed by clinical trial networks or contract research organizations (CROs) that operate outside of normal clinical practice. This may be less applicable for some digital health technologies (particularly those that implement AI) as data collected from routine clinical practice are often required for the operation of these technologies. Further, like medical devices [7], there may also be an operator learning curve related to digital technologies [8]. To further add to the complexity, DHTs are often used simultaneously or integrated with another technology such as a medical device and can be used across a variety of different indications. These complexities, in addition to the huge range of use cases, level of autonomy and potential risk, make assessing digital technologies for safety, efficacy and cost effectiveness a uniquely difficult proposition [6].

In surgery, digital technologies are rapidly being developed and adopted, from pre-operative planning and intra-operative guidance to post-operative performance assessment [9]. Advancements in training and education [10], virtual reality (VR) [11], machine learning [9], and telehealth [12] are being implemented in surgical practice, either as standalone solutions or alongside other DHTs and devices. This is increasingly true in Robot-Assisted Surgery (RAS), as advancements in digital capabilities are developing in tandem with various robotic platforms [13, 14].

Lam et al., [15] in a Delphi exercise, aimed to define “Digital Surgery”, agreeing upon “the use of technology for the enhancement of preoperative planning, surgical performance, therapeutic support, or training, to improve outcomes and reduce harm”. The study also reported that there were no clearly defined reimbursement or business models for these technologies. Furthermore, adoption barriers may arise due to difficulties in demonstrating safety and clinical benefits. The authors recommended future research into developing a framework for the introduction and evaluation of surgical AI and establishing a business model with industry .

There have been several frameworks for evaluating digital technologies published by various Health Technology Assessment (HTA) bodies in recent years, many of which are still evolving and being refined. A review by San Miguel et al. [16] at the Belgian Health Care Knowledge Centre (KCE) reviewed six existing European frameworks (table 1) for evaluating digital technologies as part of the further development of their own procedures.

Table 1 - Existing Frameworks developed by HTA agencies for Assessing Digital Health Technologies in Europe, adapted from San Miguel et al. 2022 [16].

Country	Framework for DTs	Author	Year
Germany	Fast track procedure for DiGAs	The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM)	2020
UK	Evidence Standards Framework for DMTs	National Institute for Health and Care Excellence (NICE)	2019
France	Loi de financement de la sécurité sociale pour 2022 Guide on specific features of clinical evaluation of a connected medical device (CMD)	Haute Autorité de Santé (HAS)	2022
Finland	Digi-HTA framework	Centre for Health and Technology, FinCCHTA and the University of Oulu's MIPT research group	2019
Netherlands	Guidance for assessment of digital care	Knowledge Centre Digital Care (Health Insurers)	2021
Austria	Framework for reimbursement decisions of digital health technologies	Austrian Institute for HTA (AIHTA)	2021

The frameworks listed vary in scope considerably. The DiGA procedure in Germany, for example, was designed specifically for health apps [17].. The Finnish Digi-HTA framework is slightly broader, including specific considerations for robotics and AI [18], although no assessments have been completed on such technologies used in surgery to date [19]. Outside of Europe, guidelines have also been developed in countries like South Korea; however, these guidelines only cover AI for medical imaging and 3D printing and so are limited in scope [20].

Despite the range of efforts to develop assessment frameworks for DHTs, no consistent standards have yet been agreed upon, partially due to the diversity in technologies, in the setting of use, and in reimbursement models [21]. Payers and policymakers are still challenged when quantifying the clinical and economic utility of these technologies. Unlike health apps, DHTs used in surgery may be high-cost technologies or are used in conjunction with other high-cost surgical devices, such as robotic platforms. Payment and reimbursement models are likely to differ significantly. Applications for example may use a subscription model or a population-based payment model. Some digital technologies in surgery are more likely to be purchased as a separate product in the operating theatre but many are integrated into a robotic platform or even into a digital operating theatre [14]. Calculating the economic impact of such technologies is potentially very complex.

In this article, we focus on Digital Surgical Technologies, referred to from here onwards as DSTs. Elsewhere, we have developed guidance for the assessment of RAS platforms [22]. Existing frameworks for evaluating digital technologies in healthcare, have so far inadequately included specific considerations for digital technologies used in surgery [19]. While Lam et al. 2022 include robotics as part of their definition of digital surgery [15], we consider that DSTs are a broader category of technologies that may be integral to robotic platforms, used alongside these platforms or used standalone. Notwithstanding, they offer distinctive additional potentials, besides the clinical utility of the platforms themselves. We argue that this additional digital capacity in robotic surgery merits specific attention for developing frameworks for value assessment of DSTs.

In this article, we describe a Modified Delphi study that aims to develop consensus on the

value potentials of digital technologies in surgery and highlight important considerations and challenges in assessing these value perspectives.

Methods

A modified Delphi approach was used in conjunction with a consensus conference approach [23]. An international expert panel was assembled, including 14 panellists from nine countries and four continents. The panel included 11 of the members of a previous international expert panel put together to discuss HTAs of RAS [22] but also included other members recommended by the existing panel. A total of four new members were chosen for their knowledge and expertise on digital technologies in surgery (table 2). The panel members represent a wide range of relevant stakeholders, including surgeons, health economists, HTA practitioners and methodologists, policy makers and industry representatives. The surgeons on the panel all had significant experience in a range of soft-tissue surgeries completed both with and without robotic assistance. The health economists on the panel had significant experience in modelling complex health interventions, including robotic surgery platforms. HTA practitioners on the panel had experience of assessing health technologies including medical devices and robotic surgery platforms at national and regional HTA bodies. Methodologists had previous experience of developing research and assessment methods for health technologies. Policymakers had experience of making national and regional level decisions about the implementation of health policy and adoption of health technologies including medical devices. Many of the panel also had specific experience in utilizing digital technologies in surgery or performing health technology assessments of digital technologies.

Table 2 - Panellists' Details, listed in alphabetical order.

Panel Member	Country	Clinician	HTA*	Methodologist	Economist	Policymaker	Digital**
CHAIR: Dr. Anastasia Chalkidou	UK		x	x	x	x	x
Dr. Payam Abrishami	Netherlands		x			x	x
Prof. Jean-Christophe Bernhard	France	x					x
Prof. Richard Culbertson	USA		x			x	
Dr. Jo Carol Hiatt	USA	x				x	
Prof. Ataru Igarashi	Japan				x	x	x
Dr Gretchen Purcell Jackson	USA	x					x
Prof. Guy Maddern	Australia	x	x			x	
Dr. Joseph Soon Yau Ng	Singapore	x					x
Prof. Anita Patel	UK		x		x		

Dr. Koon Ho Rha	**South Korea**	x					x
Prof. Prasanna Sooriakumaran	**UK**	x					x
Scott Tackett	**USA**	Industry					
Prof. Giuseppe Turchetti	**Italy**		x	x	x	x	

***Health Technology Assessment. These panel members have experience of performing health technology assessment at the national or local level.**

** These panel members have experience of utilizing digital technologies in surgery or performing health technology assessments of digital technologies.

Three questionnaires were used to develop priority topics for discussion between January and March 2023 (Figure 1).

Figure 1 - Structure of Modified Delphi Process

An initial scoping questionnaire, developed in Google Forms (Google, CA, USA) and sent as a link by email, invited panellists to rate the importance of two questions (see topics 1 and 2 in table 3) identified as potential research priorities during the previous panel discussions [22] and to suggest any other questions or issues that the group should address. A further two questions were added at this stage (see topics 3 and 4 in table 3), totalling four. The second questionnaire, also created and distributed in the same format, asked panellists to rate the importance of these four questions from 1 – 9, where 1 indicated "not important" and 9 indicated "critical." The group was also asked to rate the same questions from 1 – 9 based on their perceived ability to contribute to the discussion of these questions, where 1 indicated "no knowledge/expertise" and 9 indicated "very high knowledge and expertise." These rankings are subjective and merely descriptive. The suggested questions were considered priority topics and are summarized in table 3, ranked by their perceived level of importance:

Table 3 - Proposed Priority Topics and their Perceived Importance and Panel Ability to Answer

Priority Topics	Mean Level of Importance	Mean level of Panel Knowledge

1	How does Digital Technology affect operational efficiency and performance and how does this translate into clinical and economic benefit?	7.9	7.7
2	How can data capture feed into research/real world evidence generation and how can this help HTAs?	7.8	7.5
3	How can digital technologies help in remote monitoring, prediction of adverse events and identifying high-risk patients?	7.3	7.4
4	What are the benefits of utilising digital technology in Training and Education, and can we assess how this affects the overall clinical utility of the technology?	7.2	6.5

It is notable that the panel voted the topic of training and education (topic 4 in table 3) as the topic with the lowest mean level of panel knowledge. To ensure that the panel were well informed during the discussions, the members that were more familiar with this topic provided details of their experiences with using digital technologies in surgical training and education.

Following the generation of the priority topics shown above, the panel members were asked to provide the three most important issues to tackle within these topics when considering the value of Digital Surgery.

These issues were discussed during the first of three consensus conferences, in which eight initial consensus statements were drafted. The consensus statements were further refined during the second consensus conference and finalized during the 3rd conference, with a total of seven being finalised.

Patient and Public Involvement

Although patients were not directly involved in the design of the research, the impetus for the research project was informed by the previous work of the panel, which considered how robotic surgery can affect patient outcomes including quality of life and patient satisfaction.

Results

The key issues to tackle, as proposed by the panel, were categorized into four topics for discussion: (1) how data are used in surgery, (2) the existing evidence base for DSTs, (3) how digital technologies may be used in surgical training and education, and (4) methods for the assessment of these technologies. Given the often-tandem development and integration of DSTs with robotic platforms, many of the topics discussed were in the context of DSTs used in RAS; however, the panel felt the consensus statements would still be broadly applicable to all DSTs.

Eight consensus statements, two per topic, were developed during the first consensus conference (see table 4). These statements were discussed during the second interactive consensus conference. The panel convened three times (between March and June 2023) for in-depth discussion of the topics. Each of these meetings was 'hybrid', with some panel members meeting in person where feasible and others joining through teleconferencing software (Zoom, CA, USA). The original list of eight consensus statements was reduced to seven final statements that were agreed upon, and refined to form the conclusion of the final consensus conference (table 4).

Table 4 – Priority Topics for Discussion and Draft Consensus Statements

Topic	Draft Consensus Statement
1. Data used in Surgery	Interoperability is vital for making the best use of data collected by digital surgical technologies.
	Data captured by digital surgical systems can provide real time insights and decision support to improve operational efficiency and performance. These benefits may be better suited to assessment at the hospital level.
2. The evidence base for DSTs	Digital technologies may allow for linkage between clinician (and patient-related) outcomes and system capabilities. This could allow for more detailed evidence generation.
	There is a current lack of evidence into the effects of digital technologies. Comparative studies between robotic surgery with and without digital technology are recommended for most digital technologies.
3. Surgical Training & Education	Future improvements to simulators/VR/immersive surgery will need to be taken into account by an HTA and any recommendations made here will require to consider these changes.
	Data captured can drive technical proficiency and continuous improvement for surgeons. The ability to retain, and train surgeons remotely, including support from 'super specialists' may be a benefit that hospital-based HTAs should consider.
4. Methods for Assessment	Different digital surgical platforms have very different Infrastructure capabilities. This needs to be captured by HTAs.
	There are various ways in which digital technologies allow for the assessment and reduction of variation in clinical practice and may also increase access (i.e, through 5g remote surgery). This ability to reduce health inequalities/inequities should be considered by HTAs.

Table 5 - Final Consensus Statements

	Consensus Statement	Mean Level of Agreement*
1	Adopting a horizon scanning protocol is critical as future use cases for digital surgical technologies will continually emerge.	7.6
2	Digital technologies can provide the ability to train, retrain and retain surgeons' proficiency/skills more effectively than traditional methods and this is of high value to healthcare systems and wider society.	8.6
3	Data interoperability needs to be advocated by all stakeholders because it is a pre-requisite for realising the full potential of digital surgery and indeed many digital health interventions.	8
4	Digital Surgical Technologies link clinician and patient-related outcomes with objective performance indicators. These links should be considered by both national and hospital-level HTAs.	7.1
5	Given the current evidence base into the effects of digital technologies is still in its infancy, comparative studies assessing robotic surgery with and without the digital component should be considered whenever relevant and feasible.	7.6
6	Increasing automation is likely to be a particular driver for the re-evaluation of any recommendations made by this panel.	7.3
7	Digital surgical technologies allow diverse potential benefits, including reducing unwarranted variation in surgical practice, increasing access and reducing inequalities (e.g., through 5G remote surgery). It is important for assessments to consider the value holistically within the entire surgical ecosystem.	7.5

***From 1-9, where 9 is the highest level of agreement**

Discussion

This modified Delphi consensus study utilised a series of questionnaires to identify potential value perspectives of DSTs and potential challenges in assessing this value. An expert panel discussed these challenges and developed a series of consensus statements. The panel agreed that traditional evaluation frameworks for drugs, devices, and even new digital technologies may not be applicable for certain types of DSTs used as part of surgical practice. While many DSTs employ applications and software, they are often not used as standalone technologies. Rather, they exist as part of an array of technologies used in the operating theatre and wider hospital setting. This rich interaction is particularly true for RAS systems, in which the robotic platform includes a rapidly developing portfolio of digital solutions. Advanced computer imaging for pre-operative planning, intra-operative virtual reality assistance, simulation-based surgical training, real-time decision support, data recording, post-operative analytics, performance assessments, and AI-based clinical decision support are examples of DSTs integrated with robotic platforms [14, 24].

DSTs aim to provide improved surgical outcomes or processes, notably when integrated into robotic surgery platforms [25, 26]. Additionally, many share complexities such as learning curve issues and multi-indication applications [22]. Our panel considered that DSTs also have additional value and intricacies that are unique to specific stakeholders or processes, particularly in terms of training and education, workflow, and efficiency, and in generating RWE (see consensus statements 2 and 7 in table 5). Given that DSTs are often part of a large ecosystem of technologies in the surgical setting, this highlights the need to consider their value holistically according to the specificities of the setting of use and specific perspectives of the stakeholder the evaluation is addressed to. The World Bank Group framework for the economic assessment of digital health technologies suggested a value aggregation function – where multiple value attributes are weighted based on the preferences of chosen stakeholder groups - as one such method [21]. Despite the range of potential values that DSTs may bring, the evidence is still in its infancy, and is often not growing at the same rapid pace as the technologies (see consensus statement 5). The panel noted that this lack of evidence represents an opportunity for HTAs and other healthcare decision makers to provide guidance for evidence generation. This guidance may ensure that appropriate study designs are recommended according to the type of DST, studies are performed efficiently, and that they capture relevant outcomes.

The emerging evidence for DSTs has highlighted a wide range of potential use cases and value propositions. Our panel agreed that the organizational and social benefits of digitizing surgery are of particular interest due to their novelty from the perspective of policy makers and HTA bodies. Tele-operated surgery is one example where DSTs may allow for increased access to surgery due to advancements in 5G and telepresence technology, particularly for patients in rural areas [27-29]. Such remote care, along with virtual consultations and patient apps or wearables, may have far reaching sustainability benefits by avoiding the need for travel [30]. Additionally, reduction in unwarranted variation through improved training and performance assessments may address equity of care issues and provide further social benefits [31].

Digital aspects of RAS technology have the capability of delivering greater implementation of minimally invasive surgery than prior known minimally invasive surgical approaches. These enhancements include, but are not limited to advanced imaging, simulation, remote proctoring, telepresence, intraoperative guidance, decision support, data analytics, improved standardization of procedures, and reduced variation of care. As such, digital RAS ecosystems have the potential to allow surgeons and care teams to more effectively treat, by providing greater quality, accessibility, and availability of minimally invasive surgery to a greater number of patients. The panel discussed that this may have particular importance in regions or countries with less well-developed surgical programmes, such as in Low and Middle-Income Countries (LMICs). Telepresence further enables access to surgical expertise and knowledge irrespective of geographic location.

Despite being the topic on which our panel perceived as having the least knowledge, RAS platforms have already caused a shift in surgical training and education, and digital technologies assessing performance may revolutionize surgical learning models. Virtual reality [11], simulation [32] and objective performance indicators (OPIs) [33] are increasingly being utilized in surgical training. Real-time advice and intervention from expert surgeons can be facilitated remotely [34]. Our panel agreed that emerging technologies would not only reduce the time to proficiency for novice surgeons but would also allow for career-long continuous improvement for practicing surgeons. The panel agreed emerging digital surgery technologies may also reduce total time and cost needed to train novice surgeons, which is often a cost borne by institutions. HTAs should look to describe the utility of these DSTs according to their specific perspectives and context, for example, as part of robotic platforms. They can then look to develop methods to quantify this cost impact to their institution or jurisdiction. As is stated in consensus point 2, new DSTs are likely to increase healthcare provider's ability to train, retrain and retain surgeons. This may be particularly relevant for national health systems facing pressures related to ageing populations and surgeon shortages [22]. Panel members reported difficulties in their own practices in recruiting surgeons if robotic platforms were not available. Furthermore, a 2021 study found that 73.8% of surgical trainees would value greater access to robotic surgery training, 73.4% believed that robotic surgery was important for the future of their desired specialty, and 77.2% believed it should be incorporated into formal surgical training [35].

A topic of particular interest to the panel was the use of OPIs to evaluate surgeon performance [36]. OPIs are quantitative measurements, derived from kinematic and system events data that are automatically captured by (some robot-assisted) surgical systems [36]. Automatically capturing objective measures of surgeon performance may allow for a scalable evaluation of certain surgical techniques that have not been possible in the past. This may represent an opportunity to improve or accelerate surgical training and allow for continuous improvement, even among intermediate and expert surgeons [37]. OPIs may also provide insights related to operational workflow and efficiency, as well as be linked to post-operative outcomes [38]. Early evidence has shown that these metrics may predict outcomes, such as early urinary continence recovery [38] and length of stay, particularly when considering confounding patient factors, such as age and BMI. Surgical platforms equipped to capture OPIs may improve outcomes by a measurable and predictable amount. The panel concurred that whether related to skill assessment and learning, workflow and efficiency, or post-operative outcomes, insights generated by OPIs can have a measurable impact clinically and economically (see consensus statement 4). As DSTs related to OPIs continue to be developed, the panel recommended that HTAs at a national and local level may consider them as proxy of value, or as surrogate outcomes, and try to quantify them in a harmonised way. The evidence base for these measures is growing and if strong links can be established, this may represent a paradigm shift in surgical training and practice. The panel would urge healthcare decision makers to determine how, and to what extent, these technologies fit within their value assessments and what their implications are for future use and adoption. On the other hand, the panel also discussed how these technologies may also represent a risk for privacy. As Lam et al. 2022 noted, large scale recording of operating room data may increase the threat of litigation for surgical teams, many of whom may be reluctant to consent to data collection [9] and patients may also have objections to their data being collected.

The panel felt that increasing automation of data collection may have far reaching consequences, not least in terms of the ability to generate RWE for measuring surgical outcome and for healthcare decision making (see consensus statement 6). RWE is consistently listed as a vital part of how we evaluate technologies [39]. Traditionally used for post-market surveillance, it is increasingly being recognised in regulatory approvals and HTA evaluations [39]. A major barrier to RWE generation is the hands-on time required, often by clinical staff, to collect data. Automating and standardising this process may be of great value to the healthcare system by saving staff time and increasing the depth and quality of data available for decision-making and policy development. The panel also considered that all stakeholders in the surgical space must advocate for interoperability of data between different technologies and systems (see consensus statement 3). This may be a barrier to the generation of good quality RWE. If substantial time and resources are required to ensure that one dataset is compatible with another, this defeats the purpose of automated collection. The panel also noted that it is vital to ensure that studies of DSTs (and particularly early phase studies of AI technologies which involve the training of algorithms) are conducted to high standards, following guidance from SPIRIT and CONSORT-AI on conducting and reporting trials [4, 6, 40]. Patient safety and equity are paramount, and avoiding unexpected consequences that arise due to utilising unrepresentative populations should be prioritised [6]. It should be noted that RCTs should still be considered the gold standard where they are feasible, and RWE should be considered as having additional value, rather than replacing traditional methods. In addition, all studies should be conducted to the highest possible standard and reported using the aforementioned transparency standards, as well as noting potential biases and limitations.

Here, we advocate for the development of surgery-specific considerations in evaluation frameworks for digital technologies; however, this requires flexibility and adaptability to new innovations coming at a rapid pace. Existing frameworks provide a starting place, but continued methodological work may be needed to define appropriate processes for specific technologies. A strong horizon scanning protocol would go some way to ensuring that we are ready to evaluate incoming technologies (see consensus statement 1).

Limitations

This work aimed to gather expert insights into the evaluation of DSTs. A wide range of expertise from across the globe was gathered; however, the modified Delphi exercise only included the 14 panellists and could have been expanded to include a greater sample size. However, given the novelty of the topic and requirement for specific expertise, a smaller group of 14 was considered sufficient, similar to the panel described in Erskine et al. 2023 [22]. To make up for the reduced number of responses for the Delphi exercise, the panel met 3 times to discuss the topics at length, as opposed to a single meeting in many standard Delphi approaches.

The panel did not have representation from LMICs for this piece of work. This may bias the results towards high-income countries and it should be noted that there are specific benefits of DSTs in their potential to increase access to minimally invasive surgery in lower-income settings [41].A further limitation is the lack of patient representation. While the panel did not have a designated patient representative, it did include consumer health informatics expertise and members who have been surgical patients. In the future, the group may look to convene such a panel to specifically discuss the results of this work and the prior results of Erskine et al. 2023 [22]. In particular, patients' opinions on the patient-related and social benefits of digital technologies would be valuable. The panel discussed topics that may be potential future considerations for further work, including surgical technologies' ability to reduce health inequities and increasing patient access in rural areas and LMIC's, their effect on environmental sustainability, and the patient and public perspective. These value types may be considered broadly 'societal value' and could be a future research project for this panel.

The previous work of this panel aimed to provide guidance for HTA bodies completing assessments of RAS platforms and concluded that digital technologies were an increasingly important consideration in surgery. Here, given that there are no prior assessments to our knowledge, and that the evidence base for these technologies is still limited as this time, the panel's aim is not to provide methodological guidance for completing assessments of DSTs, but rather to advise HTA bodies who may be developing frameworks for digital technology to consider the specific nuances and complexities of digital technologies in surgery. While this is an initial step, it is recommended that HTA bodies consider the conclusions of this work when developing evaluation frameworks for DSTs. Most likely, such considerations may be made as an add-on to wider frameworks for DHTs.

Conclusions

Evaluating DSTs requires taking into account specific considerations of use within the surgical context that differ from other DHTs. Frameworks and methodologies developed for assessing DHTs should therefore consider the unique complexities of the high-stakes surgical environment and increasingly digitally enabled surgical ecosystem. It is unlikely that digital surgery is the only specialty with particular difficulties in assessing value. Digital ecosystems are arising in many areas of healthcare, such as in home-care [22] and personalised medicine, where digital technologies are radically changing the care models. New capacities are being built into the assessment frameworks to consider the benefits of DHTs in decreasing healthcare inequalities, and lowering carbon emissions. As these ecosystems are established, it is vital to ensure that the individual technologies that the systems are comprised of are evaluated holistically. In surgery, there are additional value propositions that need to be considered by HTAs, including the value of reducing unwarranted variations in performing surgical procedures, accelerating proficiency-based surgical training, and making complex surgical care more accessible to patients in need. Further, OPIs may have substantial impacts on surgical education and training. Lastly, the enormous potential for automated data collection and evidence generation should not be underestimated. All stakeholders should advocate for data inter-operability to fully recognise this value.

Author Contributions Statement:

Jamie Erskine is responsible for the overall content as the guarantor.

Jamie Erskine supported the design of the research, supported the background research for the panel discussions, supported the facilitation of the panel meetings and drafted the first version of the manuscript.

Richard Charter supported the facilitation of the panel meetings and reviewed the manuscript.

Matthew Lien supported the background research for the panel discussions and reviewed the manuscript.

Anastasia Chalkidou provided oversight for the design of the research, chaired the expert panel and reviewed the manuscript.

P Abrishami was a member of the panel, attended the panel meetings and reviewed the manuscript.

J-C Bernhard was a member of the panel, attended the panel meetings and reviewed the manuscript.

R Culbertson was a member of the panel, attended the panel meetings and reviewed the manuscript.

J C Hiatt was a member of the panel, attended the panel meetings and reviewed the manuscript.

A Igarashi was a member of the panel, attended the panel meetings and reviewed the manuscript.

G Purcell Jackson was a member of the panel, attended the panel meetings and reviewed the manuscript.

G Maddern was a member of the panel, attended the panel meetings and reviewed the manuscript.

J S Y Ng was a member of the panel, attended the panel meetings and reviewed the manuscript.

A Patel was a member of the panel, attended the panel meetings and reviewed the manuscript.

K H Rha was a member of the panel, attended the panel meetings and reviewed the manuscript.

P Sooriakumaran was a member of the panel, attended the panel meetings and reviewed the manuscript.

S Tackett was a member of the panel, attended the panel meetings and reviewed the manuscript.

G Turchetti was a member of the panel, attended the panel meetings and reviewed the manuscript.

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Alira Health received consulting fees from Intuitive Surgical for coordinating the consensus panel meetings. The panel members were reimbursed only for their travel and accommodation costs related to the panel meetings.

Conflicts of Interest Statement

Scott Tackett is an employee of Intuitive Surgical and as such he receives compensation and benefits as part of his employment agreement, as well as stock from Intuitive Surgical.

Gretchen Purcell Jackson is employee of Intuitive Surgical and as such she receives compensation and benefits as part of her employment agreement, as well as stock from Intuitive Surgical. She also owns stock or stock options from IBM and Kyndryl and is President and Chair, of the Board of Directors for the American Medical Informatics Association.

Matthew Lien is an employee of Intuitive Surgical and as such he receives compensation and benefits as part of his employment agreement.

Jamie Erskine and Richard Charter are employees of Alira Health. Alira Health received consulting fees from Intuitive Surgical for the coordination of the panel.

Richard Charter and Anastasia Chalkidou are the co-chairs of the HTAi Medical Device Interest Group.

Americo Cicchetti has received consulting fees for Novartis, Astra Zeneca, Lilly, Sanofi, Roche, and Gilead.

Richard Culbertson has received payment from the American College of Healthcare Executives for past publications.

Koon Ho Rha is an execute of NAVER.

Joseph Soon Yau Ng is a board member of the Asian Society for Gyn Robotic Surgery and the Robotic Surgery Society of Singapore.

Jean-Christophe Bernhard has received consulting fees and honoraria from Intuitive Surgical, and his institution has received equipment, materials, drugs, medical writing, gifts or other services.

Prasanna Sooriakumaran has received consulting fees from Cambridge Medical Robotics. He has also received an Intuitive Surgical Clinical Research Grant and a Urology Foundation Research & Innovation Grant.

Authors who travelled to panel meetings in person received reimbursement for their travel and accommodation from Alira Health. Anastasia Chalkidou did not receive any reimbursement for contribution, travelling or accommodation to the panel meetings.

Data Availability Statement

All data relevant to the study are included in the article or available as supplementary information.

Ethical Approval Statement

No ethics approval was sought as this research did not include either human or animal subjects.

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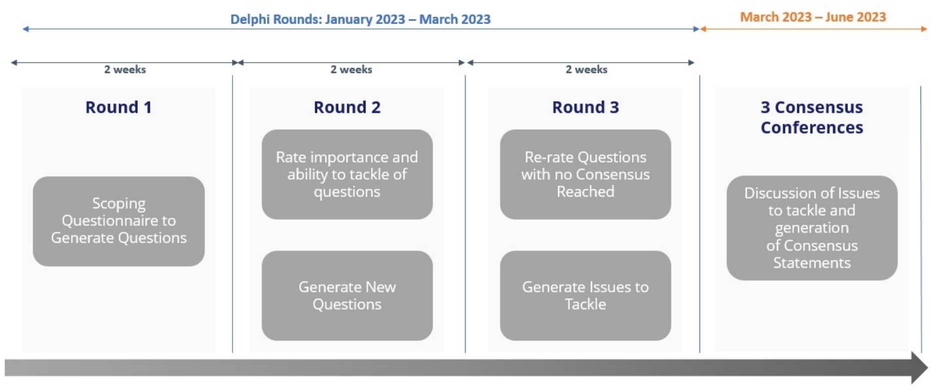

Figure 1 - Structure of Modified Delphi Process

338x190mm (96 x 96 DPI)

Reporting checklist for quality improvement in health care.

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Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

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		Reporting Item	Page Number
Title			
	#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1
Abstract			
	#02a	Provide adequate information to aid in searching and indexing	2
	#02b	Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	2
Introduction			
Problem	#3	Nature and significance of the local problem	3-7

description			
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	3-7
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	3-7
Specific aims	#6	Purpose of the project and of this report	6-7
Methods			
Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	3-7
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	7-9
Intervention(s)	#08b	Specifics of the team involved in the work	7-9
Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	7-9
Study of the Intervention(s)	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	N/A
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	N/A
Measures	#10b	Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	N/A
Measures	#10c	Methods employed for assessing completeness and accuracy of data	N/A
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	N/A
Analysis	#11b	Methods for understanding variation within the data, including the effects of time as a variable	N/A
Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	N/A

Results

	#13a	Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	N/A
	#13b	Details of the process measures and outcome	9
	#13c	Contextual elements that interacted with the intervention(s)	N/A
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	N/A
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	N/A
	#13f	Details about missing data	N/A

Discussion

Summary	#14a	Key findings, including relevance to the rationale and specific aims	10-13
Summary	#14b	Particular strengths of the project	2-3
Interpretation	#15a	Nature of the association between the intervention(s) and the outcomes	N/A
Interpretation	#15b	Comparison of results with findings from other publications	N/A
Interpretation	#15c	Impact of the project on people and systems	10-13
Interpretation	#15d	Reasons for any differences between observed and anticipated outcomes, including the influence of context	N/A
Interpretation	#15e	Costs and strategic trade-offs, including opportunity costs	N/A
Limitations	#16a	Limits to the generalizability of the work	14
Limitations	#16b	Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	14
Limitations	#16c	Efforts made to minimize and adjust for limitations	14
Conclusion	#17a	Usefulness of the work	14-15
Conclusion	#17b	Sustainability	N/A
Conclusion	#17c	Potential for spread to other contexts	12, 14

Conclusion	#17d	Implications for practice and for further study in the field	12, 14
Conclusion	#17e	Suggested next steps	12, 14
Other information			
Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	16

 This checklist was completed on 23. November 2023 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai