

BMJ Open An international consensus panel on the potential value of Digital Surgery

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To cite: Erskine J, Abrishami P, Bernhard J-C, *et al.* An international consensus panel on the potential value of Digital Surgery. *BMJ Open* 2024;**14**:e082875. doi:10.1136/bmjopen-2023-082875

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<https://doi.org/10.1136/bmjopen-2023-082875>).

Received 06 December 2023

Accepted 19 August 2024

ABSTRACT

Objectives The use of digital technology in surgery is increasing rapidly, with a wide array of new applications from presurgical planning to postsurgical 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 to 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 to 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.

INTRODUCTION

Digital technologies are being used increasingly in healthcare systems globally,

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 (DSTs).
- ⇒ This study identifies specific considerations for health technology assessments (HTAs) of 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.

accelerated by the COVID-19 pandemic with the global telehealth market reaching more than US\$80 billion in 2021 and expected to reach over US\$200 billion in 2025.¹ These technologies, known as digital health technologies (DHTs), are extremely diverse. The Food and Drug Administration includes mobile health (mHealth), health information technologies, wearable devices, telehealth, telemedicine and personalised medicine in its definition of digital health² while the National Institute for Health and Care Excellence 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.



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DHTs differ from other health technologies in several ways. First, 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 randomised trial designs are less applicable in some cases compared with other forms of evidence, such as real-world evidence (RWE).⁶ Large-scale Randomised Controlled Trials (RCTs), for example, are often performed by clinical trial networks or contract research organisations 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 preoperative planning and intraoperative guidance to postoperative performance assessment.⁹ Advancements in training and education,¹⁰ virtual reality (VR),¹¹ machine learning,⁹ and telehealth¹² 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 on ‘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 the 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 reviewed six existing European frameworks (table 1) for evaluating digital technologies as part of the further development of their own procedures.

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 three-dimensional 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 on, partially due to the diversity in technologies, in the setting of use and in reimbursement models.²¹

Table 1 Existing frameworks developed by HTA agencies for assessing digital health technologies in Europe, adapted from San Miguel *et al*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 | 2019 |
| France | Loi de financement de la sécurité sociale pour 2022 Guide on specific features of clinical evaluation of a connected medical device | Haute Autorité de Santé | 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 | 2021 |

BfArM, Federal Institute for Drugs and Medical Devices; DiGA, Digital Health Application; DMT, Digital Medical Technology; DT, Digital Technology; FinCCHTA, Finnish Coordinating Center for Health Technology Assessment; HTA, health technology assessment; MIPT, Medical Imaging, Physics and Technology.

Payers and policy-makers 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 (DSTs), 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* 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 the 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 9 countries and 4 continents. The panel included 11 of the members of a previous international expert panel put together to discuss HTAs of RAS²² but also included other members recommended by the existing panel. A total of four new members were chosen for their knowledge and expertise in 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 in assessing health technologies including medical devices and robotic surgery platforms at national and regional HTA bodies. Methodologists had previous experience in developing research and assessment methods for health technologies. Policy-makers had experience in making national and regional-level decisions about the implementation of health policy and adoption of health technologies including medical devices. Many of the panel

Table 2 Panellists' details, listed in alphabetical order

| Panel member | Country | Clinician | HTA* | Methodologist | Economist | Policy-maker | Digital† |
|--------------|-------------|-----------|------|---------------|-----------|--------------|----------|
| Chair: AC | UK | | x | x | x | x | x |
| PA | Netherlands | | x | | | x | x |
| J-CB | France | x | | | | | x |
| RCulbertson | USA | | x | | | x | |
| JCH | USA | x | | | | x | |
| AI | Japan | | | | x | x | x |
| GJ | USA | x | | | | | x |
| GM | Australia | x | x | | | x | |
| JSYN | Singapore | x | | | | | x |
| AP | UK | | x | | x | | |
| KHR | South Korea | x | | | | | x |
| PS | UK | x | | | | | x |
| ST | USA | | | | Industry | | |
| GT | Italy | | x | x | x | x | |

*These panel members have experience in performing health technology assessments at the national or local level.

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

HTA, health technology assessment.



Figure 1 Structure of modified Delphi process.

also had specific experience in using digital technologies in surgery or performing HTAs of digital technologies.

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

An initial scoping questionnaire, developed in Google Forms (Google, California, 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 discussions²² 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 to 9, where 1 indicated 'not important' and 9 indicated 'critical'. The group was also asked to rate the same questions from 1 to 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 summarised in table 3, ranked by their perceived level of importance.

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 was well informed during the discussions, the members who 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

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 using digital technology in training and education, and can we assess how this affects the overall clinical utility of the technology? | 7.2 | 6.5 |
| Respondents voted on their level of knowledge and their perceived level of importance for each statement on a scale of 1 - 9, where 9 was the highest. | | |

and finalised during the third conference, with a total of seven reaching consensus.

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 categorised 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, California, USA). The original list of eight consensus statements was reduced to seven final statements that were agreed on and refined to form the conclusion of the final consensus conference ([table 4](#)).

DISCUSSION

This modified Delphi consensus study used 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 stand-alone 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 preoperative planning, intraoperative VR assistance, simulation-based surgical training, real-time decision support, data recording, postoperative analytics, performance assessments and AI-based clinical decision support are examples of DSTs integrated with robotic platforms.^{14 24}

Table 4 Priority topics for discussion and draft consensus statements

| Topic | Draft consensus statement |
|---|---|
| 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. |
| 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 on the effects of digital technologies. Comparative studies between robotic surgery with and without digital technology are recommended for most digital technologies. |
| Surgical training and 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. |
| 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 (ie, through 5G remote surgery). This ability to reduce health inequalities/inequities should be considered by HTAs. |
| HTA, health technology assessment; VR, virtual reality. | |

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. These ecosystems should be assessed according to the specificities of the setting of use and the specific perspectives of the stakeholders the

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 prerequisite 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 on 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 (eg, through 5G remote surgery). It is important for assessments to consider the value holistically within the entire surgical ecosystem. | 7.5 |

*From 1 to 9, where 9 is the highest level of agreement.
HTA, health technology assessment.

evaluation is relevant 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, that 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 organisational and social benefits of digitising surgery are of particular interest due to their novelty from the perspective of policy-makers and HTA bodies. Teleoperated 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, a 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 standardisation 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-income and middle-income countries (LMICs). Telepresence further enables access to surgical expertise and knowledge irrespective of geographical 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 revolutionise surgical learning models. VR,¹¹ simulation³² and objective performance indicators (OPIs)³³ are increasingly being used 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 practising surgeons. The panel agreed emerging digital surgery technologies may also reduce the 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 on 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 valued 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 postoperative outcomes.³⁸ Early evidence has shown that these metrics may predict outcomes, such as early urinary continence recovery³⁸ and length of stay, particularly when considering confounding patient factors, such as age and body mass index. 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 postoperative 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 to privacy. As Lam *et al* 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 collection⁹ 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 outcomes 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 postmarket 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 Standard Protocol Items: Recommendations for Interventional Trials and Consolidated Standards of Reporting Trials-AI on conducting and reporting trials.^{4 6 40} Patient safety and equity are paramount, and avoiding unexpected consequences that arise due to using 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 the requirement for specific expertise, a smaller group of 14 was considered sufficient, similar to the panel described in Erskine *et al*.²² To make up for the reduced number of responses for the Delphi exercise, the panel met three 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.*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 increase patient access in rural areas and LMICs, 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 at this time, the panel's aim is not to provide methodological guidance for completing assessments of DSTs but rather to advise HTA bodies 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 care²² 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 composed 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 interoperability to fully recognise this value.

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Correction notice This article has been corrected since it was first published. Corresponding author email address has been updated.

Contributors JE is responsible for the overall content as the guarantor. JE 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. RChatter supported the facilitation of the panel meetings and reviewed the manuscript. ML supported the background research for the panel discussions and reviewed the manuscript. AC provided oversight for the design of the research, chaired the expert panel and reviewed the manuscript. PA, J-CB, RCulbertson, JCH, AI, GJ, GM, JSYN, AP, KHR, PS, ST and GT were the members of the panel, attended the panel meetings and reviewed the manuscript.

Funding 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.

Competing interests ST 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. GJ 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. ML is an employee of Intuitive Surgical and as such he receives compensation and benefits as part of his employment agreement. JE is an employee of Alira Health. Alira Health received consulting fees from Intuitive Surgical for the coordination of the panel. RCulbertson and AC are the co-chairs of the HTAi Medical Device Interest Group. RCulbertson has received payment from the American College of Healthcare Executives for past publications. KHR is an executive of NAVER. JSYN is a board member of the Asian Society for Gyn Robotic Surgery and the Robotic Surgery Society of Singapore. J-CB has received consulting fees and honoraria from Intuitive Surgical, and his institution has received equipment, materials, drugs, medical writing, gifts or other services. PS 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. AC did not receive any reimbursement for contribution, travelling or accommodation to the panel meetings.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as online supplemental information. All data are available within the manuscript.

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