OXFORD Collaborative Research

BJS, 2025, znaf140
https://doi.org/10.1093/bjs/znaf140
Original Article

Information standards for innovative surgery: what patients need to know

Christin Hoffmann[1], Daisy Elliott[1], Leila Rooshenas[1], Cynthia Ochieng[1], Barry Main[1,2,3], Pete Wheatstone[4], Samuel Lawday[1,5], Abigail Vallance[1,5], Jane M Blazeby[1], Angus G K McNair[1,5,*] and wider study team

[1]National Institute for Health and Care Research Bristol Biomedical Research Centre, University Hospitals Bristol and Weston NHS Foundation Trust and the University of Bristol, Bristol, UK
[2]Bristol Dental Hospital, University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK
[3]Bristol Dental School, Faculty of Health and Life Sciences, University of Bristol, Bristol, UK
[4]Patient Representative, Macmillan Cancer Support Research Advisory Panel, Cancer Research UK Patient Data Reference Panel, Selby, UK
[5]Department of Gastrointestinal Surgery, North Bristol NHS Trust, Bristol, UK

*Correspondence to: Angus McNair, National Institute for Health and Care Research Bristol Biomedical Research Centre, University Hospitals Bristol and Weston NHS Foundation Trust and University of Bristol, Canynge Hall, 39 Whatley Road, Bristol BS8 2PS, UK (e-mail: angus.mcnair@bristol.ac.uk)

Members of the wider study team are co-authors of this study and are listed under the heading Collaborators.

Abstract

Background: There are repeated and ongoing failures in shared decision-making and informed consent for innovative surgical procedures. Governments and regulatory bodies internationally recommend establishing information standards to support safe and transparent surgical innovation. The aim of this study was to develop a core information set (CIS) for surgical innovation.

Methods: This was a mixed-method study in three phases: a provisional CIS was generated from multiple data sources (interviews with patients/professionals (44), recorded consultations (34), policy documents (58), and published studies (213)) using qualitative content analysis; the CIS was refined, with input from key stakeholders (patient representatives, surgeon innovators, anaesthetists, lawyers, ethicists, medical directors, academic experts, and regulatory representatives) using a modified nominal group technique; and the CIS was finalized through public consultation.

Results: The final CIS comprised seven themes that included: what is 'new' about the procedure; potential conflicts of interest; reasons for the innovation (including why the innovation is believed to be appropriate for the patient); treatment alternatives; unknowns (including uncertain safety/efficacy and that the procedure may be abandoned/modified); expertise with the innovation; and governance, oversight, and accountability (including how safety will be monitored and recompense if anything goes wrong). Two themes require follow-up discussions after the procedure.

Conclusion: A seven-theme CIS for surgical innovation was co-developed, with input from key stakeholders. International implementation of these information standards may support safe and transparent surgical innovation.

Introduction

Innovation is critical to improving the care of patients undergoing surgery and other invasive procedures. Scientific advances have led to a proliferation of new techniques and technologies, including wholly new procedures[1], modifications to existing procedures[2], and new devices/implants[3]. However, global standards of governance and oversight of surgical innovation differ greatly compared with those required for the introduction of new drugs[4,5]. Surgeon innovators develop and introduce novel invasive procedures in clinical practice often without rigorous mechanistic, clinical, or financial evaluation[5–9]. Formal research ethics approval is rare and methods for institutional oversight are inconsistent or not well enforced[10–12]. Haphazard innovation can significantly impact patient safety, as highlighted in recent international inquiries into the use of implanted pelvic mesh[13,14].

A key theme from these inquiries was a failure in informed consent; as one woman explained, 'I feel as though I am an unsuspecting, unwilling participant in a cruel experiment that has gone wrong.'[13]. High-quality, patient-centred communication is a cornerstone of clinical practice in health services worldwide. International legal guidance[15–18], regulatory guidance[19–21], and professional guidance[22–26] all state that communication for all treatments should be framed around individuals' information needs. This facilitates patients' understanding of the nature and potential consequences of treatment based upon personal values and priorities. However, decisions about whether to have new surgical treatments are challenging because the outcomes/consequences of innovative treatment are unknown[27]. Discussions may be biased by overly optimistic articulation of benefits[28] or assumptions that innovation is synonymous with

Received: March 17, 2025. Accepted: June 09, 2025

improvement[29]. Furthermore, it was previously found that surgeons do not routinely discuss the novelty and uncertainty of surgical innovation[30,31]. This means that patients may have a therapeutic misconception resulting from insufficient understanding of the experimental nature of the proposed new surgery[32].

The UK-based public inquiry concluded by recommending that patient decision aids or core sets of information, co-designed by patients and clinicians, be produced for surgical procedures[13]. A core information set (CIS) represents baseline information, determined by patients and clinicians, necessary to stimulate further patient-centred communication[33,34]. It serves as a guide for stimulating discussion around topics that are established as important to the wider community, with built-in flexibility to tailor the depth of discussion around these issues, depending on individual preferences. The aim of this study was to co-develop a CIS, with input from patients and professionals, to facilitate consultations before and after patients undergo all types of innovative surgery.

Methods

Ethics

An institutional ethics committee at the University of Bristol approved the methods of this study (reference 111362). Participants provided written informed consent to participate.

Study registration

This study was registered in the Core Outcome Measures in Effectiveness Trials (COMET) database before commencement (https://comet-initiative.org/Studies/Details/1872).

Study design

The CIS was developed according to modified guidelines for the development of core outcome sets[33,35]. There were three phases: generation of a provisional CIS from multiple data sources; refinement and agreement of information themes; and public consultation to finalize the CIS (*Fig. 1*). Methods are presented below in brief, with detailed descriptions provided in the *supplementary material*.

Scope

The scope of the CIS includes consultations involving adult (>18 years) patients discussing an innovative procedure or device for elective or emergency treatment in the UK.

Definitions

There is no universally recognized definition of surgical innovation. This study is conceptualized by considering that the lack of knowledge about the potential benefits, risks, and consequences of a subset of surgical activity is important and that this surgical activity needs to be safer and more transparent[36].

Surgical innovation is defined as invasive procedures with planned or unplanned changes that result in uncertain potential benefits, risks, and consequences. It includes: wholly new or modified procedures, technologies, devices, or implants; and existing procedures used for a new purpose, in a new patient population/indication, or by new practitioners. Invasive procedures are defined as when purposeful/deliberate access to the body is gained via an incision, percutaneous puncture, where instrumentation is used in addition to the puncture needle, or instrumentation via a natural orifice[37].

Phase 1: generation of a provisional CIS from multiple data sources

Multiple literature and primary data sources were used to inform the CIS: published studies of innovative invasive procedures from literature reviews; reviews of hospital policies and guidance documents related to the introduction of new procedures; transcripts of interviews with patients and professionals about surgical innovation; and transcripts of recorded consultations between patients and professionals where innovative procedures were discussed. Methods describing these data sources are published elsewhere[38–40]. Data sources were analysed using principles of qualitative content analysis[41,42]. Emergent themes were organized into a draft CIS to carry forward to phase 2.

Phase 2: refinement and agreement of information themes

A modified nominal group technique was used to refine the draft CIS and gain consensus on a finalized version, with input from key stakeholders[43]. Individuals who represented a wide variety of relevant stakeholder groups were purposely selected (patient representatives, consultant surgeons, ethicists, lawyers, researchers, and representatives of regulatory bodies) and were diverse in terms of sex, ethnicity, geographical location, surgical specialty (for professional participants), and experience of surgery (for patient participants).

A consensus meeting was conducted using video conferencing software (Zoom). The meeting was in two halves. First, participants were allocated to five parallel nominal groups, each consisting of at least two patients, one surgeon, and one other stakeholder to ensure internal heterogeneity. Discussions were facilitated using a topic guide to explore participants' views on the relevance and comprehensibility of the draft CIS. Next, key discussion points and recommendations to refine the CIS were brought forward from each group for wider discussion. Dissenting views were sought and issues debated until agreement was reached.

The draft CIS was circulated to all participants for anonymous online voting. Participants were asked 'Do you agree with the CIS as presented?' and responded on a nine-point Likert scale range from strongly disagree (1) to strongly agree (9). Consensus was defined as achieving responses of seven to nine for >70% of responses and responses of one to three for <15% of responses. Further rounds of refinement and voting were planned if consensus was not reached.

Phase 3: public consultation to finalize the CIS

The CIS was circulated for public consultation with a wider group of stakeholders through online public consultation. The seven information themes were operationalized into an online questionnaire in collaboration with two patient representatives to ensure adequate readability and comprehensibility. The importance of each item was reported on a nine-point Likert scoring scale. Responses were analysed using descriptive statistics.

Results

Detailed results from each phase are presented in the *supplementary material*. The final CIS is available in *Table 1*. Explanations are provided to describe why the theme is relevant to new invasive procedures/devices beyond standard care. Elaborations are used to illustrate details that may support

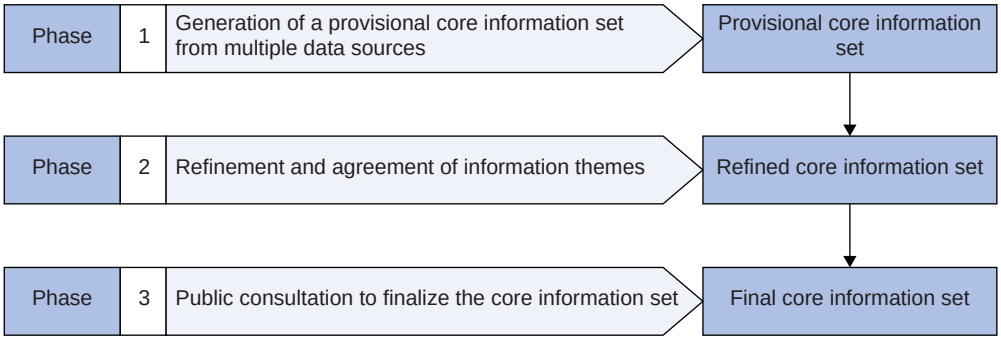

Fig. 1 Study flow chart

Table 1 Core information set themes and subthemes organized into discussions before and after surgery

Theme	Subtheme Discussions before surgery	Subtheme Discussions after surgery
1. New procedure details	1.1 Statement that the procedure/device is new 1.2 Details about what makes the procedure/device new	
2. Conflicts of interest	2.1 Statement of any relevant conflicts of interest	
3. Reasons for the innovation	3.1a Expected benefits, risks, and/or consequences of the new procedure/device	3.1b Actual benefits, harms, and/or consequences experienced
	3.2a Reasons why the new procedure/device is believed to be appropriate for the patient	3.2b Changes to which types of future patients the new procedure/device is suitable for resulting from the benefits, harms, and/or consequences experienced
4. Choice of treatment alternatives	4.1 Existence/availability of treatment alternatives, including no treatment 4.2 Freedom to choose the new procedure/device or alternative care, including no treatment	
5. Unknowns	5.1a Statement that there are unknowns about the new procedure/device in the context of relevant evidence	5.1b Actual modifications to the new procedure/device or explanation of why it was stopped or changed to an alternative
	5.2a Possibility that the new procedure/device may be modified, stopped, or changed to an alternative	5.2b Unexpected benefits, harms, and/or consequences
6. Expertise with the innovation	6.1 Statement that the surgeons' level of skill in the new procedure/device may not be the same as standard care 6.2 Description of surgeons' level of skill in the new procedure/device	
7. Governance, oversight, and accountability	7.1 Relevant approvals in place for the introduction of the new procedure/device in the context of national and/or international regulatory guidance 7.2 Details of how patient safety is monitored 7.3 Relevant processes in place if anything goes wrong	

tailored discussions with patients. The CIS optimized for end-users can be obtained with a free non-commercial user license at: https://express-licences.bristol.ac.uk/product/core-information-set-for-surgical-innovation.

Theme 1: new procedure details

1.1 Statement that the procedure/device is new. 1.2 Details about what makes the procedure/device new.

Explanation: The innovative nature of the invasive procedure/device, including details about what the new procedure/device is and what makes it new, to be stated to differentiate the proposed treatment from standard care.

Elaboration: Individually tailored discussions about the new procedure/device may include details about: what parts of the procedure are new or recently modified (for example the technical steps/processes); whether it is new to the health professional, centre, anatomical site, or context (for example elective *versus* emergency surgery); the magnitude of change (for example minor variation of technique *versus* entirely new procedure); and the experience with the new procedure/device elsewhere (for example availability in other hospitals or countries, considered established or new in other departments or trusts).

Theme 2: conflicts of interest

2.1 Statement of any relevant conflicts of interest.

Explanation: Conflicts of interest to be disclosed to provide transparency as to how personal or organizational interests relevant to the new procedure/device may influence decision-making.

Elaboration: Tailored discussions may include relevant financial, corporate, reputational, and emotional (for example enthusiasm) interests that may be relevant at an individual (for example surgeon) or organizational (for example department, hospital) level.

Theme 3: reasons for the innovation

Discussions before surgery

3.1a Expected benefits, risks, and/or consequences of the new procedure/device. 3.2a Reasons why the new procedure/device is believed to be appropriate for the patient.

Explanation: The expected benefits, risks, and/or consequences of the proposed new procedure/device to be discussed as distinct from standard care. Benefits, risks, and/or consequences should also be discussed in the context of known evidence (see theme 5, below).

Elaboration: Expected benefits, risks, and/or consequences may include those that occur before, during, or after the procedure and in the short and/or long term. Tailored discussions may describe: clinical outcomes (for example lower morbidity); patient-reported outcomes (for example more/less pain); surgeon-reported outcomes (for example procedure is more/less technically challenging); or other relevant procedure/device-specific outcomes (for example needing more/less resources, longer/shorter operating time).

Discussions about why the new procedure/device can be appropriate for the individual may include: disease-related factors (for example cancer stage or fracture pattern); patient factors (for example people with frailty or a high BMI); procedure factors (for example lack of alternatives); or wider contextual factors (for example availability of the new procedure/device, local expertise).

Discussions after surgery

3.1b Actual benefits, harms, and/or consequences experienced. 3.2b Changes to which types of future patients the new procedure/device is suitable for resulting from the benefits, harms, and/or consequences experienced.

Explanation: Personalized feedback describing the outcomes (including clinical, patient-reported, surgeon-reported, and other relevant outcomes) of the new procedure/device should be provided to support patients' understanding of their experience. Any subsequent changes to patient selection should be disclosed to help explain how patients' current experience will impact future patients being offered the new procedure/device.

Elaboration: Feedback may mirror tailored discussions before surgery.

Theme 4: choice of treatment alternatives

4.1 Existence/availability of treatment alternatives, including no treatment. 4.2 Freedom to choose the new procedure/device or alternative care, including no treatment.

Explanation: Alternative care options should be discussed to support an informed choice between the new procedure/device, standard care, and no treatment. The choice between new and alternative care options should be made clear, including an explanation that the patient's decision will not impact their overall care.

Elaboration: Tailored discussions may include information about the benefits, risks, and/or consequences of alternative care options. These discussions may form a major part of the decision-making process; however, elaborations about standard care options are considered outside the scope of this CIS. Tailored discussions may include stating that the choice will not impact the processes (for example waiting times) or quality (for example surgeon expertise or intensive perioperative care) of standard care and that choices may change over time (for example patients can change their mind).

Theme 5: unknowns

Discussions before surgery

5.1a Statement that there are unknowns about the new procedure/device in the context of relevant evidence. 5.2a Possibility that the new procedure/device may be modified, stopped, or changed to an alternative.

Explanation: New procedures/devices have varying levels of evidence for safety, efficacy, and effectiveness. This theme represents unexpected events and the uncertain outcomes (that is benefits, risks, and/or consequences) of undergoing such treatment, as opposed to the expected benefits, risks, and/or consequences described in theme 2. The presence of unknowns should be clearly stated to differentiate the relative uncertainty of new procedures/devices compared with standard care.

Similarly, innovation is a dynamic process where procedures/devices evolve and change, sometimes unexpectedly. The possibility of unplanned changes to the new procedure/device, abandonment of the new procedure/device, or changes to an alternative procedure should be discussed.

Elaboration: Tailored discussions may explore areas of uncertainty before, during, and after the new procedure/device as appropriate to individuals' needs. This may include descriptions of the current evidence for the new procedure/device (for example the number of published studies that evaluate the procedure or the quality of the current evidence) or professional opinion about the magnitude of (un)certainty about the new procedure/device.

Tailored discussions about unplanned changes to the new procedure/device may include detailed descriptions of contingency plans (for example details about modifications to the surgical technique or alternative procedures should there be a need to abandon) and reasons why unplanned changes occur.

Discussions after surgery

5.1b Actual modifications to the new procedure/device or explanation of why it was stopped or changed to an alternative. 5.2b Unexpected benefits, harms, and/or consequences.

Explanation: Personalized feedback should provide a description of unexpected events, benefits, harms, and/or consequences that occurred as a result of the new procedure/device but were unknown and/or not discussed before surgery.

Elaboration: Tailored feedback may include whether the new procedure was completed as planned, abandoned, or changed, including reasons. Unexpected benefits, harms, and/or consequences may be discussed, alongside feedback of expected benefits, harms, and/or consequences (theme 2, above), and include outcomes that occurred before, during, or after the procedure and in the short and/or long term.

Theme 6: expertise with the innovation

6.1 Statement that the surgeons' level of skill in the new procedure/device may not be the same as standard care. 6.2 Description of surgeons' level of skill in the new procedure/device.

Explanation: New procedures/devices are characterized by a learning phase where healthcare professionals may not be as skilled in the new procedure/device compared with standard care. Discussions about relevant professional expertise and training in the new procedure/device should be provided as distinct from standard care.

Elaboration: Tailored discussions may include what specific training standards have been achieved or what other measures are in place to support training (for example presence of a proctor, industry representative, or other professional not normally present). This may include discussions about objective (for example outcomes of formal learning curve assessments) or subjective (for example where surgeon thinks he/she is on the learning curve) measures of surgeon expertise. Further details about surgeon/department/hospital-level expertise with the new procedure/device may be relevant (for example number of times the new procedure/device has been performed/used) in the context of wider professional expertise (for example number of times the new procedure/device has been performed/used elsewhere).

Theme 7: governance, oversight, and accountability

7.1 Relevant approvals in place for the introduction of the new procedure/device in the context of national and/or international regulatory guidance. 7.2 Details of how patient safety is monitored. 7.3 Relevant processes in place if anything goes wrong.

Explanation: New invasive procedures/devices may be introduced within different regulatory frameworks. Discussions about governance, oversight, and accountability should provide patients with clarity about regulatory processes relevant to the new procedure/device beyond those established for standard care.

Elaboration: Tailored discussions may include whether any necessary approvals for the introduction of the new procedure/device were sought (for example research governance, new procedure committees), including whether any relevant local, national, and international regulatory guidance exists/was adhered to (for example National Institute for Health and Care Excellence (NICE), General Medical Council). Any requirements set by approval committees (for example specific consent or quality assurance processes) may be explained and details of any rejected applications may be relevant.

Discussions relevant to new procedure/device oversight mechanisms and safety monitoring may include details about: how and on what timescale outcomes/processes are monitored; how and on what scale (for example locally, nationally, or internationally) outcomes/processes are shared and assessed; and how safety monitoring may impact the care of the individual and future patients.

Existing processes for professional accountability may be clarified in the context of new procedures/devices, including explanations of complaint pathways and their consequences. Duty of candour may be explained to patients with consideration of new procedures context.

Discussion

A seven-theme CIS was co-developed, with input from key stakeholders, for surgeons to use to provide baseline information in consultations with patients with whom innovative surgical procedures are discussed. The CIS comprised details of the new procedure, reasons for the innovation, and the existence of routine care alternatives to address evidence that patients may not be aware of the innovative nature of treatments. Innovation, by its nature, is characterized by uncertainty about risks, potential benefits, and consequences, and the CIS included these innovation-specific unknowns, together with information regarding surgeons' level of skill, conflicts of interest, and governance, oversight, and accountability. This is to achieve appropriate transparency and to give patients an informed choice. The CIS recognizes that new procedures will require additional learning by including information regarding surgeons' level of skill. It addresses the importance of declaring conflicts of interest ('we deserve to know'[13]) and patients' desire to be informed of outcomes of innovation. The CIS is intended to be applied flexibly within established processes of shared decision-making within consultations between surgeons and patients that include a discussion about surgical innovation. It will provide baseline information intended to catalyse personalized discussions and set standards for future practice internationally.

Robust methods were used to co-develop a novel CIS for surgical innovation, with input from broad stakeholder groups. The information themes and subthemes emerged from rich data sources, including real-life data from consultations involving novel procedures or devices. The development process benefited from significant involvement of a diverse set of patient representatives in all aspects of the study, including patients directly impacted by innovative surgery. There were some limitations. This study was conducted in the context of the UK healthcare system because of the need to address recommendations of a national public inquiry. It is likely that the CIS will have relevance to other similar health systems internationally because of challenges comparable to optimizing informed consent for innovative surgery. The scope was similarly limited to adults with the capacity to make healthcare decisions. While this accounts for most participants in surgical innovation in the UK, it does not address the needs of potentially vulnerable patients and children who may benefit from advances in surgical care. The applicability of the CIS to a wide range of surgical procedures, devices, and settings may also be a limitation. Themes are intentionally broad and generic. Although explanations and elaborations have been included, patients and professionals will need to reflect on the proposed innovation and consider specific details relevant to the context.

This research has addressed recommendations of patient safety inquiries internationally and fulfilled a key action of the UK Independent Medicines and Medical Devices safety Review review (2.22), but there remain significant challenges for implementation. Research investigating policies for surgical innovation has demonstrated significant variability in the governance and oversight of the introduction of new procedures/devices[10,44–46]. There was a lack of consistent advice for when to apply for research ethics approval. New procedures introduced without a research framework lack some of the safety nets that are linked to research, such as written patient information sheets and oversight committees. Interviews with surgeons and governance representatives demonstrated a recognition that surgical innovation differs to standard care, but participants were uncertain what information was needed[31]. Policymakers may consider a more standardized approach to clarify expectations for patients and professionals. For example, in the UK, NICE currently classifies new procedures as being recommended for use with standard arrangements (routine care), with special arrangements (enhanced consent and outcome monitoring), or only in a formal research setting[47]. There is local flexibility regarding the interpretation of information content required for 'enhanced consent' and analysis of hospital policies shows remarkable inconsistency[48]. Integrating the CIS into health technology appraisal guidance for 'enhanced consent' and into research ethics committee

advice for patient information leaflets, alongside training and support for clinicians, may provide an appropriate health system-wide approach to implementation.

The CIS represents 'what' information should be considered before and after innovative surgery, but it does not describe 'how' to integrate such information into effective shared decision-making. Further research is needed to understand how to best operationalize the CIS for specific innovations. Guidelines globally provide recommendations to support effective implementation of shared decision-making in clinical practice that are relevant to this context[49–51]. This includes making health service leaders accountable and responsible for embedding shared decision-making into organizations and supporting healthcare professionals' skills through continued professional development. It is recommended that intervention be developed and employed before, during, and after consultations to optimize SDM. One approach has been successfully applied to improve informed consent for participation in RCTs[52]. This involves observation and recording of consultations to understand real-life communication, interviews with participants to explore the impact of the conversation, and feedback to better train professionals to discuss surgical innovation. However, it is unclear if such an approach is appropriate outside of clinical trials.

The CIS for surgical innovation was co-developed to optimize shared decision-making and informed consent for surgical innovation. International implementation of these recommended information standards may support safe and transparent surgical innovation in providing innovation-specific information to patients to fully inform them about unknowns and risks unique to innovation.

Collaborators

K. N. L. Avery (NIHR Bristol Biomedical Research Centre, Bristol, UK); N. Wilson (NIHR Bristol Biomedical Research Centre, Bristol, UK); R. C. Macefield (NIHR Bristol Biomedical Research Centre, Bristol, UK); S. Potter (North Bristol NHS Trust, Bristol, UK); A. Clarke (University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK); H. Robertson (NIHR Bristol Biomedical Research Centre, Bristol, UK); H. Richards (NIHR Bristol Biomedical Research Centre, Bristol, UK); J. Zahra (NIHR Bristol Biomedical Research Centre, Bristol, UK); J. A. Mathews (NIHR Bristol Biomedical Research Centre, Bristol, UK); N. Blencowe (NIHR Bristol Biomedical Research Centre, Bristol, UK); S. Cousins (NIHR Bristol Biomedical Research Centre, Bristol, UK); D. Messenger (University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK); E. Alexandridis (University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK); G. Van Boxel (Portsmouth Hospitals NHS Trust, Portsmouth, UK); G. Giddens (Royal United Hospital Bath NHS Trust, Bath, UK); J. Hewes (North Bristol NHS Trust, Bristol, UK); J. Howell (Royal Devon and Exeter NHS Trust, Exeter, UK); M. Turner (University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK); A. D. Toms (NIHR Exeter Biomedical Research Centre, University of Exeter Medical School/Royal Devon and Exeter NHS Foundation Trust, Exeter, UK); N. Patel (University Hospitals Southampton NHS Foundation Trust, Southampton, UK); N. Carter (Portsmouth Hospitals NHS Trust, Portsmouth, UK); S. Mercer (Portsmouth Hospitals NHS Trust, Portsmouth, UK); U. Benedetto (University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK); G. M. Birchley (Centre for Ethics in Medicine, University of Bristol, Bristol, UK); J. Wheeler (Centre for Ethics in Medicine, University of Bristol, Bristol, UK); J. Ives (Centre for Ethics in Medicine, University of Bristol, Bristol, UK); A. Thomas (patient/public representative, Cheltenham, UK); A. Toms (NIHR Exeter Biomedical Research Centre, University of Exeter Medical School/Royal Devon and Exeter NHS Foundation Trust, Exeter, UK); A. Hutchinson (National Institute for Health and Care Excellence, Manchester, UK); B. Gibbison (University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK); D. Leff (NIHR Imperial Biomedical Research Centre, Departments of BioSurgery and Surgical Technology and Hamlyn Centre for Robotic Surgery, London, UK); D. Jayne (NIHR Leeds Biomedical Research Centre, Leeds Teaching Hospitals NHS Trust, Leeds, UK); D. Messenger (University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK); D. Ogunleye (patient/public representative, London, UK); E. Deeson (patient/public representative, Birmingham, UK); H. Bekker (School of Medicine, University of Leeds, Leeds, UK); J. Miola (School of Law, University of Leeds, Leeds, UK); L. Wickham (NIHR Moorfields Biomedical Research Centre, Moorfields Eye Hospital NHS Foundation Trust, London, UK); M. Mistry (patient/public representative, Manchester, UK); M. Caputo (University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK); M. Costa (NIHR Oxford Biomedical Research Centre, Oxford, UK); M. P. W. Grocott (NIHR Southampton Biomedical Research Centre, University Hospital Southampton / University of Southampton, Southampton, UK); M. Tanna (patient/public representative, Bristol, UK); M. Selassie (patient/public representative, Bristol, UK); R. Huxtable (NIHR Bristol Biomedical Research Centre, Bristol, UK); R. Hinchliffe (NIHR Bristol Biomedical Research Centre, North Bristol NHS Trust, Bristol, UK); S. Squire (patient/public representative, Oxford, UK); V. Snelgrove (patient/public representative, Bristol, UK); Y. Bradbury-Birrell (General Medical Council, London, UK); P. Goss (patient/public representative, Rectopexy mesh victims and support, Bristol, UK); S. Cox (patient/public representative, North Bristol NHS Trust, Bristol, UK).

Funding

This study was partly supported by a National Institute for Health and Care Research (NIHR) Clinician Scientists awarded to A.M. (CS-2017-17-010) and by the NIHR Biomedical Research Centre (BRC) at University Hospitals Bristol and Weston NHS Foundation Trust and the University of Bristol (BRC-1215-20011, NIHR203315). J.B. is an Emeritus NIHR Senior Investigator. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care.

Acknowledgements

The authors wish to thank all public consultation participants for their input into the study. The authors would also like to thank Chris Foy and Dolapo Ogunleye for their valuable contribution to the consensus meeting.

Author contributions

Christin Hoffmann (Data curation, Formal analysis, Investigation, Methodology, Project administration, Validation, Visualization, Writing—original draft, Writing—review & editing), Daisy Elliott (Data curation, Methodology, Formal analysis, Validation,

Writing—review & editing), Leila Rooshenas (Methodology, Validation, Writing—review & editing), Cynthia Ochieng (Data curation, Formal analysis, Validation), Barry Main (Methodology, Validation, Writing—review & editing), Pete Wheatstone (Investigation, Validation, Writing—review & editing), Samuel Lawday (Formal analysis), Abigail Vallance (Formal analysis), Jane Blazeby (Conceptualization, Funding acquisition, Supervision, Validation, Writing—review & editing), Angus McNair (Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Supervision, Validation, Writing—original draft, Writing—review & editing), and the wider study team (Data curation, Validation, Writing—review & editing)

Disclosure

All authors have disclosed their interest in accordance with the ICMJE recommendations and declare: support from the funding bodies listed above for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work. Other interests, not impacting the submitted work: RH has received grants from the Elizabeth Blackwell Institute, University of Bristol (Co-app), NIHR (Co-app), Wellcome Trust (PI), has received consulting fees from Jersey Government, consultancy (personal payment), Nuffield Council on Bioethics, public engagement project on assisted dying (personal payment), and has a leadership or fiduciary role in UK Clinical Ethics Network (Chair and member of board of trustees), Bristol Clinical Ethics Advisory Group (Vice chair and member), European Association of Centres of Medical Ethics (Chair of board), Institute of Medical Ethics (Non-voting member of board of trustees). MG has received consulting fees from Edwards Lifesciences and Medical Advisory Board and Trial Monitoring, has received support for attending meetings and/or travel from Edwards Lifesciences and for travel to Medical Advisory Board, has a leadership or fiduciary role in the Royal College of Anaesthetists (Elected council member and trustee), the Centre for Perioperative Care (Vice-chair), the National Institute of Academic Anaesthesia (Board chair), and the Bristol Journal of Anaethesia (Board member). Perioperative Quality Initiative (POQI) (Board member), has received equipment from Massimo (Loan of medical devices for trial) and Edwards Lifesciences (Loan of medical devices for trial), and is Journal editor-in-chief for Perioperative Medicine. MC has a British Heart Foundation chair to support his research and has received consulting fees from Medtronic for the evaluation of the Harmony valve. LW has received grants for research support from the NIHR Moorfields BRC and NIHR UCLH BRC and has a leadership or fiduciary role as Trustee of Moorfields Eye Charity Board, Executive Board member of Moorfields Eye Hospital NHS Foundation Trust. BG has received grants from the NIHR, British Heart Foundation and University Hospitals Bristol and Weston NHS Foundation Trust. AD has received grants from the NIHR, Versus Arthritis Research, and Stryker MSA Research IIS, has received royalties for Corin Total Knee, and has received consulting fees from Stryker and Corin. GB has received grants from the Wellcome Trust, Grant no. 209841/Z/17/Z, and Arts and Humanities Research Council, Grant Ref: AH/X013146/1, and has a leadership or fiduciary role in the Royal College of Paediatrics and Child Health, Ethics and Law Advisory Committee. SP has a leadership or fiduciary role in the Royal College of Surgeons Surgical Specialty Lead for breast surgery and held an NIHR Clinician Scientist award (NIHR CS 2016 16 019), Secretary to the British Breast Group. SL is NIHR Academic Clinical Fellow at University of Bristol, has received a grant from the Royal Devon & Exeter Hospital (REACT study) and has a leadership or fiduciary role as Academic Representative on SouthWest Surgical Training Committee. GD has received NIHR i4i grant unrelated to this project, has received payment for expert testimony to undertake medico-legal reporting work unrelated to this project, is applying for patents related to the above i4i grant, has a leadership or fiduciary role as the Chair of the Committee of Management of the Journal of Hand Surgery on behalf of the British Society for Surgery of the Hand. JH has received royalties from Stryker Corporation (Royalties within last 36, ceased over the last 12months), has received honoraria from Stryker Corporation (for teaching on hip courses), and has a leadership or fiduciary role with the British Hip Society (Past president of the society), and the Surgeon Performance Committee of the National Joint Registry (Current member of the Committee). NC and GvB are proctors for Intuitive Surgical and receive reimbursement for training surgeons in robotic surgery without bearing on this study.

Supplementary material

Supplementary material is available at *BJS* online.

Data availability

This study employed secondary data analysis and references to studies where primary data were collected are included in the bibliography. All relevant additional information and analyses, summaries, and examples of anonymized data have been included as *supplementary material*. This manuscript is published under a CC BY-NC licence, which allows the core information set (CIS) to be shared, but not modified or used for commercial purposes. The CIS is available free of charge across not-for-profit organisations, not-for-profit research organisations, or not-for-profit healthcare establishments (e.g. National Health Service Trusts). The non-commercial user license, and full CIS optimised for end-users can be obtained at: https://express-licences.bristol.ac.uk/product/core-information-set-for-surgical-innovation. To inquire about commercial use or adapting the CIS, please contact: red-innovation@bristol.ac.uk

References

1. Feng Q, Yuan W, Li T, Tang B, Jia B, Zhou Y *et al.* Robotic versus laparoscopic surgery for middle and low rectal cancer (REAL): short-term outcomes of a multicentre randomised controlled trial. *Lancet Gastroenterol Hepatol* 2022;**7**:991–1004
2. Thompson JE, Egger S, Böhm M, Haynes AM, Matthews J, Rasiah K *et al.* Superior quality of life and improved surgical margins are achievable with robotic radical prostatectomy after a long learning curve: a prospective single-surgeon study of 1552 consecutive cases. *Eur Urol* 2014;**65**:521–531
3. Berenson J, Pflugmacher R, Jarzem P, Zonder J, Schechtman K, Tillman JB *et al.* Balloon kyphoplasty versus non-surgical fracture management for treatment of painful vertebral body compression fractures in patients with cancer: a multicentre, randomised controlled trial. *Lancet Oncol* 2011; **12**:225–235

4. Meakins JL. Innovation in surgery: the rules of evidence. *Am J Surg* 2002;**183**:399–405
5. McCulloch P, Altman DG, Campbell WB, Flum DR, Glasziou P, Marshall JC *et al.* No surgical innovation without evaluation: the IDEAL recommendations. *Lancet* 2009;**374**:1105–1112
6. Hirst A, Philippou Y, Blazeby J, Campbell B, Campbell M, Feinberg J *et al.* No surgical innovation without evaluation: evolution and further development of the IDEAL framework and recommendations. *Ann Surg* 2019;**269**:211–220
7. Cook JA, McCulloch P, Blazeby JM, Beard DJ, Marinac-Dabic D, Sedrakyan A; IDEAL Group. IDEAL framework for surgical innovation 3: randomised controlled trials in the assessment stage and evaluations in the long term study stage. *BMJ* 2013:**346**:f2820
8. Ergina PL, Barkun JS, McCulloch P, Cook JA, Altman DG; IDEAL Group. IDEAL framework for surgical innovation 2: observational studies in the exploration and assessment stages. *BMJ* 2013:**346**:f3011
9. McCulloch P, Cook JA, Altman DG, Heneghan C, Diener MK; IDEAL Group. IDEAL framework for surgical innovation 1: the idea and development stages. *BMJ* 2013:**346** f3012
10. Cousins S, Richards HS, Zahra J, Robertson H, Mathews JA, Avery KNL *et al.* Healthcare organization policy recommendations for the governance of surgical innovation: review of NHS policies. *Br J Surg* 2022;**109**:1004–1012
11. Brown K, Solomon MJ, Young J, Seco M, Bannon PG. Addressing the ethical grey zone in surgery: a framework for identification and safe introduction of novel surgical techniques and procedures. *ANZ J Surg* 2019;**89**:634–638
12. Karpowicz L, Bell E, Racine E. Ethics oversight mechanisms for surgical innovation: a systematic and comparative review of arguments. *J Empir Res Hum Res Ethics* 2016;**11**:135–164
13. Cumberlege J. *First Do No Harm: The Report of the Independent Medicines and Medical Devices Safety Review*. 2020. https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf (accessed 17 March 2025)
14. Siewert R. *Number of Women in Australia Who Have Had Transvaginal Mesh Implants and Related Matters*. 2018. https://apo.org.au/sites/default/files/resource-files/2018-03/apo-nid138991.pdf (accessed 10 March 2025)
15. Sokol DK. Update on the UK law on consent. *BMJ* 2015;**350**:h1481
16. European Medicines Agency. *Medical Devices, Human Regulatory: Overview*. 2025. https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices (accessed 10 March 2025)
17. Skene L, Smallwood R. Informed consent: lessons from Australia. *BMJ* 2002;**324**:39–41
18. Albolino S, Bellandi T, Cappelletti S, Di Paolo M, Fineschi V, Frati P *et al.* New rules on patient's safety and professional liability for the Italian health service. *Curr Pharm Biotechnol* 2019;**20**:615–624
19. General Medical Council. *Good Medical Practice*. 2013. https://www.gmc-uk.org/-/media/documents/good-medical-practice-2024—english-102607294.pdf (accessed 17 March 2025)
20. Therapeutic Goods Administration. *ICH Guideline for Good Clinical Practice*. 2018. https://www.tga.gov.au/resources/publication/publications/ich-guideline-good-clinical-practice (accessed 17 March 2025)
21. American Medical Association. *Informed Consent, AMA Code of Medical Ethics*. 2024. https://code-medical-ethics.ama-assn.org/sites/amacoedb/files/2024-12/2.1.1%20Informed%20consent%20–%20background%20reports_0.pdf (accessed 17 March 2025)
22. National Health and Medical Research Council. *General Guidelines for Medical Practitioners on Providing Information to Patients*. 2017. https://webarchive.nla.gov.au/awa/20170816072344/https://www.nhmrc.gov.au/guidelines-publications/e57 (accessed 17 March 2025)
23. Royal College of Surgeons. *Good Surgical Practice*. 2013. https://www.rcseng.ac.uk/-/media/Files/RCS/Standards-and-research/GSP/Good-Surgical-Practice-Guide-2025.pdf (accessed 17 March 2025)
24. Royal Australasian College of Surgeons. *Informed Consent (FES-PST-042)*. 2019. https://www.surgeons.org/about-racs/position-papers/informed-consent-2019 (accessed 17 March 2025)
25. American College of Surgeons. *Statements on Principles*. 2016. https://www.facs.org/about-acs/statements/statements-on-principles/ (accessed 10 March 2025)
26. Lamperti M, Romero CS, Guarracino F, Cammarota G, Vetrugno L, Tufegdzic B *et al.* Preoperative assessment of adults undergoing elective noncardiac surgery: updated guidelines from the European Society of Anaesthesiology and Intensive Care. *Eur J Anaesthesiol* 2025;**42**:1–35
27. Keren-Paz T, Cockburn T, El Haj A. Regulating innovative treatments: information, risk allocation and redress. *Law Innov Technol* 2019;**11**:1–16
28. Elliott D, Ochieng CA, Zahra J, McNair AGK, Main BG, Skilton A *et al.* What are patients told about innovative surgical procedures? A qualitative synthesis of 7 case studies in the United Kingdom. *Ann Surg* 2023;**278**:E482–E490
29. Wilson CB. Adoption of new surgical technology. *Br Med J* 2006;**332**:112–114
30. Johnson J, Rogers W, Lotz M, Townley C, Meyerson D, Tomossy G. Ethical challenges of innovative surgery: a response to the IDEAL recommendations. *Lancet* 2010;**376**:1113–1115
31. Zahra J, Paramasivan S, Blencowe NS, Cousins S, Avery K, Mathews J *et al.* Discussing surgical innovation with patients: a qualitative study of surgeons' and governance representatives' views. *BMJ* 2020;**10**:e035251
32. Appelbaum PS, Lidz CW, Grisso T. Therapeutic misconception in clinical research: frequency and risk factors. *IRB* 2004;**26**:1–8
33. Main BG, McNair AGK, Huxtable R, Donovan JL, Thomas SJ, Kinnersley P *et al.* Core information sets for informed consent to surgical interventions: baseline information of importance to patients and clinicians. *BMC Med Ethics* 2017;**18**:29
34. Elwyn G, Montori V. Tools to engage patients in clinical encounters. In: Elwyn G, Edwards A, Thompson R (eds), *Shared Decision Making in Health Care: Achieving Evidence-Based Patient Choice (3rd edn)*. Oxford: Oxford University Press, 2016, 57–63
35. Kirkham JJ, Davis K, Altman DG, Blazeby JM, Clarke M, Tunis S *et al.* Core Sutcome Set-STAndards for Development: the COS-STAD recommendations. *PLoS Med* 2017;**14**:e1002447
36. Ives J, Birchley G, Huxtable R, Blazeby J. Hiding behind 'innovation': the case for regulated risk assessment in surgery. *Br J Surg* 2023;**110**:888–890
37. Cousins S, Blencowe NS, Blazeby JM. What is an invasive procedure? A definition to inform study design, evidence synthesis and research tracking. *BMJ Open* 2019;**9**:28576
38. Cousins S, Richards H, Zahra J, Elliott D, Avery K, Robertson HF *et al.* Introduction and adoption of innovative invasive procedures and devices in the NHS: an in-depth analysis of written policies and qualitative interviews (the INTRODUCE study protocol). *BMJ Open* 2019;**9**:e029963
39. Avery K, Blazeby J, Wilson N, Macefield R, Cousins S, Main B *et al.* Development of reporting guidance and core outcome sets for seamless, standardised evaluation of innovative surgical procedures and devices: a study protocol for content generation and a Delphi consensus process (COHESIVE study). *BMJ Open* 2019;**9**:e029574

40. Elliott D, Blencowe NS, Cousins S, Zahra J, Skilton A, Mathews J *et al.* Using qualitative research methods to understand how surgical procedures and devices are introduced into NHS hospitals: the Lotus study protocol. *BMJ Open* 2021;**11**:e049234
41. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res* 2005;**15**:1277–1288
42. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: implications for conducting a qualitative descriptive study. *Nurs Health Sci* 2013;**15**:398–405
43. Harvey N, Holmes CA. Nominal group technique: an effective method for obtaining group consensus. *Int J Nurs Pract* 2012;**18**: 188–194
44. Spigelman AD. Governance and innovation: experience with a policy on the introduction of new interventional procedures. *ANZ J Surg* 2006;**76**:9–13
45. Hutchison K, Rogers W, Eyers A, Lotz M. Getting clearer about surgical innovation: a new definition and a new tool to support responsible practice. *Ann Surg* 2015;**262**:949–954
46. Biffl WL, Spain DA, Reitsma AM, Minter RM, Upperman J, Wilson M *et al.* Responsible development and application of surgical innovations: a position statement of the Society of University Surgeons. *J Am Coll Surg* 2008;**206**:1204–1209
47. National Institute for Health and Care Excellence. *Interventional Procedures Recommendations*. https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/interventional-procedures-guidance/recommendations (accessed 13 December 2023)
48. Ochieng CA, Richards H, Zahra J, Cousins S, Elliott D, Wilson N *et al.* Qualitative documentary analysis of guidance on information provision and consent for the introduction of innovative invasive procedures including surgeries within NHS organisations' policies in England and Wales. *BMJ Open* 2022; **12**:e059228
49. Carmona C, Crutwell J, Burnham M, Polak L. Shared decision-making: summary of NICE guidance. *BMJ* 2021;**373**:n1430
50. Frosch DL, Moulton BW, Wexler RM, Holmes-Rovner M, Volk RJ, Levin CA. Shared decision making in the United States: policy and implementation activity on multiple fronts. *Z Evid Fortbild Qual Gesundhwes* 2011;**105**:305–312
51. Härter M, Van Der Weijden T, Elwyn G. Policy and practice developments in the implementation of shared decision making: an international perspective. *Z Evid Fortbild Qual Gesundhwes* 2011;**105**:229–233
52. Donovan JL, Rooshenas L, Jepson M, Elliott D, Wade J, Avery K *et al.* Optimising recruitment and informed consent in randomised controlled trials: the development and implementation of the Quintet Recruitment Intervention (QRI). *Trials* 2016;**17**:283