Development of a core outcome set for informed consent for therapy: An international key stakeholder consensus study

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Abstract

**Background:** 300 million operations and procedures are performed annually across the world, all of which require a patient’s informed consent. No standardised measure of the consent process exists in current clinical practice. We aimed to define a core outcome set for informed consent for therapy.

**Methods:** The core outcome set was developed in accordance with a predefined research protocol and the Core OutcoMes in Effectiveness Trials (COMET) methodology comprising systematic review, qualitative semi structured interviews, a modified Delphi process and consensus webinars to ratify outcomes for inclusion in the final core outcome set. (Registration—https://www.comet-initiative.org/Studies/Details/1024). Participants from all key stakeholder groups took part in the process, including patients and the public, healthcare practitioners and consent researchers.

**Results:** 36 outcome domains were synthesised through systematic review and organised into a consent taxonomy. 41 semi-structured interviews were performed with all consent stakeholders groups. 164 participants from all stakeholder groups across 8 countries completed Delphi Round 1 and 125 completed Round 2. 11 outcomes met the ‘consensus in’ criteria. 6 met ‘consensus in’ all stakeholder groups and were included directly in the final core outcome set. 5 remaining outcomes meeting ‘consensus in’ were ratified over two consensus webinars. 9 core outcomes were included in the final core outcome set: Satisfaction with the quality and amount of information, Patient feeling that there was a choice, Patient feeling that the decision to consent was their own, Confidence in the decision made, Satisfaction with communication, Trust in the clinician, Patient satisfaction with the consent process, Patient rated adequacy of time and opportunity to ask questions.

**Conclusion:** This international mixed-methods qualitative study is the first of its kind to define a core outcome set for informed consent for intervention. It defines what outcomes are of importance to key stakeholders in the consent process and is a forward step towards standardising future consent research.

**Keywords:** Informed consent, Core outcome set, Surgery

Background

Over 300 million operations and procedures take place around the world annually. All these procedures require the patient to give informed consent [1]. Consent, alongside shared decision making are cornerstones of Good Medical Practice as outlined by the General Medical
Council (GMC) [2]. Consent is an integral part of medical and public health ethics and international law. Failings in the informed consent process can lead to dissolution of the clinician-patient relationship, complaints and occasionally litigation [3]. In the United Kingdom alone, National Health Service (NHS) England compensated patients £134.5 million between 2013 and 2018 in cases relating directly to deficiencies in the informed consent process [4].

Numerous studies exist evaluating the effects of various techniques (e.g. audio-visual/multimedia assisted consent) designed to improve informed consent. However, systematic review of this evidence has highlighted the heterogeneous nature of data in terms of study design and the choice of outcome measures which ultimately limits the generation of consensus on which interventions are most effective. Only one study, at high risk of bias, has attempted to measure informed consent as a unified concept [5]. It has been highlighted that trialists should recognise the complexity of the informed consent process by considering the overall patterns of outcomes and not simply use a measure of knowledge that has often been the case previously. Therefore, there has been a call for greater consensus on appropriate, validated and reliable tools for assessing the effects of interventions for the consent process to facilitate comparison between studies and to enable the meaningful synthesis of results [6–9]. In addition, it is unclear as to whether the outcomes that have been measured in previous consent research are the things that are of importance to key stakeholders during the consent process.

Core outcome sets (COS) aim to define a minimum set of outcomes that should be considered essential in the evaluation and reporting of studies of a particular intervention or condition [10]. There are well-defined guidelines with a growing evidence base to support the use of COS and the methodology employed to develop them [10–15]. Increasingly, researchers are inviting different stakeholder groups to identify the important outcomes for future evaluations of interventions in a variety of health areas such as cancer, rheumatology and otorhinolaryngology [16–18]. These activities have demonstrated that each stakeholder group may rate the importance of outcomes differently, reflecting their own priorities [15, 19]. Additionally, these priorities may not always align with the priorities of researchers who have traditionally been in control of the outcomes being investigated.

Knowledge and with that patient understanding have been the predominantly measured primary outcomes in consent research however, there are a range of other issues that may matter to stakeholders in the process.

The development of a Core Outcome Set (COS) may help researchers select and measure the most relevant outcomes that are most important to stakeholders involved in the process [20]. The primary benefit of using a COS allows the most important outcomes to be consistently measured and reported, thus allowing comparisons between studies, the synthesis of data in meta-analyses and a reduction in reporting bias [10].

The aim of this study was to define a COS to evaluate interventions to improve consent for surgery and other invasive procedures, in adult patients (over 18 years) with adequate mental capacity to make their own consent decisions.

Methods

This study was developed in accordance with the guidance published in the Core Outcome Measures in Effectiveness Trials (COMET) Handbook and the Core Outcome Set-Standards for Development (COS-STAD) statement [10, 21]. The reporting of the study methods and findings has been undertaken in accordance with the Core Outcome Set-Standards for Reporting (COS-STAR) [13]. The protocol for the development of this COS was registered prospectively on the COMET database and published in full before work on the consensus building components of the project were undertaken [22, 23]. Prospective ethical approval for the study was obtained from the Office of Research Ethics Northern Ireland (RECA 17/NI/0234) and the Research and Development Office of the South Eastern Health and Social Care Trust (SET.17.36_SEHSCT). All methods were carried out in accordance with the ethical principles of the Declaration of Helsinki.

Study advisory group (SAG) and patient and public involvement (PPI)

The study advisory group was formed from members of the authorship list (LMC, SMcC, SJK, MC, WJC) as well as an experienced patient participant who has worked with the Research & Development department of the South Eastern Health and Social Care Trust on a wide range of clinical trials and other clinical research for several years.

The GRIPP2-Short Form Checklist (Table 1) outlines the Patient Involvement in Research in this study [24]; Our methods are reflective of some of the learning points from previous studies defining and evaluating novel procedures for involving patients and the public in COS research [25]. We defined “Public involvement”, “Public participation” and “Public engagement” according to those definitions from the INVOLVE advisory group members document [26].
Recruitment of participants
This study captured the views of four stakeholder groups of which the future uptake of the COS is dependent upon. (Patients, Clinicians, Researchers who have conducted previous consent research and Academics working in bioethics). Solicitors and barristers who practice medical negligence law were also included in the process to provide a legal perspective and offer additional potential validity to the core outcome set.

Semi-structured interviews and Delphi consensus

1. Patients were recruited from a database of patients involved in qualitative research previously conducted by our group investigating the question “What is important to patients in the consent process?” who had indicated that they would participate in future research. These patients had undergone emergency or elective surgery for a wide range of conditions, including day surgery and in-patient surgery for benign and malignant conditions. In addition, an advertisement was posted on the NIHR Peoples in Research website to recruit other willing patient participants.

2. Non-patient groups were approached through the research group’s professional networks, through social media promotion and email contact facilitated by professional bodies such as the Association of Surgeons of Great Britain and Ireland (ASGBI), the Association of Surgeons in Training (ASiT), the Royal College of Surgeons England (RCSEng), the American Society of Bioethics and Humanities and the Department of Legal Services Department of Health and Social Services Northern Ireland among others.

All stakeholder groups were invited to participate via email. A social media page was created by a member of the SAG on twitter® (@IconsStudy) to create direct engagement with professional patient organisations nationally and internationally.

Generating the survey information
The list of outcomes chosen for prioritisation in this Delphi survey were developed through a series of initial steps. Firstly, a systematic review of outcome reporting in existing trials was conducted to determine which outcomes had been measured previously [7]. Secondly, a systematic review of trial protocols of ‘as yet unpublished’
studies was undertaken to determine if outcome reporting in future trials was likely to be significantly different to that in existing studies. A systematic review of qualitative studies examining patients and clinicians’ attitudes to the consent process determined what mattered most to these stakeholders in the consent process and identified novel outcomes that could be measured. The outcomes identified from these reviews were organised into a consent outcomes taxonomy [27]. Additionally, semi-structured interviews with 41 stakeholders, including patients (n = 12), clinicians (n = 9), consent researchers (n = 10) and medico-legal lawyers (n = 10), explored the opinions on how the quality of the informed consent process should be determined and identified additional outcomes that had not been included in existing research. Semi-structured interviews were conducted by a single member of the SAG (LJC) and a reflective diary was kept. The list of outcomes was reviewed and organised into categories by the study advisory group. Duplicate outcomes were removed and outcomes with different names, but which captured the same phenomenon were amalgamated. A small number of outcomes that were not relevant to the consent process generally were removed from the prioritisation process. The final list of 36 potential outcomes was organised into six categories for prioritisation. These categories (domains) were knowledge, decision making, communication, trust, process, and patient characteristics. The wording of each outcome and explanatory text to describe the meaning of each outcome was developed with the help of the study advisory group’s patient and public representative. To ensure that the items included in the Delphi survey would be understood by all participants and, by patients, four “think out loud” cognitive interviews with lay participants were conducted. These cognitive interviews were undertaken in accordance with recognised methodology in this field [29]. Participants were asked to read aloud the outcome and explanatory text and to describe what they believed the outcome meant. Participants were observed while they read the outcomes to assess for physical cues that might indicate that they did not understand or were unsure such as, grimacing or appearing confused. Where a participant was not clear on the meaning of an outcome, it was discussed with them contemporaneously, and an alternative wording was developed. The wording of the items and their explanatory text was revised following each cognitive interview until no further amendments were deemed necessary. This process was designed to ensure items included in the Delphi would be understood by all participants, particularly patients. The full list of outcomes and accompanying explanatory text is included in Table 2.

The consensus process
An anonymous online Delphi survey was chosen for the consensus process (January-April 2019). The short timeline for completion between rounds aimed to maximise interest and engagement whilst minimising attrition. Summary videos for the Delphi Process (https://www.youtube.com/watch?v=R3bjcESu5SM) were developed with consultation with the COMET POPPiE Group to provide an audio-visual summary of the study, help participants understand the reason for this research and to optimise recruitment. Participants were asked to rate the importance of each outcome measure in determining the quality of the informed consent process for surgery or another invasive procedure. Outcomes were rated using the Grading of Recommendations, Assessment, Development and Evaluations scale of 1 to 9. In the Delphi exercise, the scale was presented as 1–3 labelled ‘not important’, 4–6 labelled ‘important but not critical’ and 7–9 labelled ‘critical’ [30].

Participants were given the opportunity to suggest additional outcomes not included in the survey at the end of Round 1. These outcomes were reviewed by the study advisory group and duplicate recommendations were removed. Suggested outcomes that were like existing outcomes were excluded and suggested outcomes that were like each other were amalgamated. Participants who suggested an outcome were contacted by email to explain the fate of their suggestion and the reasons for the associated decision, to ensure their ideas had not been misinterpreted and to afford them a right of reply. The included additional outcomes were incorporated into Round 2 of the survey. All outcomes, despite their score, were carried forward to Round 2 to ensure that participants had the opportunity to review their scores for each outcome considering feedback from other participants. Additionally, the number of outcomes identified for prioritisation meant that carrying all outcomes forward to Round 2 would not be unduly onerous. Taking part in Round 1 was a prerequisite for completion of Round 2. A further video was created to remind participants about the rationale for the survey and explain how Round 2 differed from Round 1. (https://youtu.be/iFoB_Eeq0-os) Round 2 provided graphical feedback of the distribution of each stakeholder group’s responses to all participants and reminded them of their previous scores. Presenting participants with feedback from all stakeholders appears to; improve consensus, reduce the variability of responses and improve agreement on those items to keep at the conclusion of the process [31]. Graphical feedback demonstrating the entire distribution of scores was chosen for this study as it was deemed the most easily interpreted form of feedback to demonstrate the spread of scores for
Table 2  Final list of outcome domains and accompanying explanatory text for Round 1 of Delphi survey

| Outcome Category | Domain name | Help text |
|------------------|-------------|-----------|
| Knowledge        | Measured patient knowledge | Assessment of patient knowledge that they have gained through the consent process. This might involve a written or spoken survey undertaken by another researcher not involved in the consent process. |
| Knowledge        | Self-rated patient knowledge | For example, asking patients how well informed they feel as a result of this consent process? This might be rated on a scale from 10–1. Where 10 is very well informed and 1 is not informed at all. |
| Knowledge        | Clinician rated patient knowledge | Clinician (e.g., Doctor) rating of patient knowledge obtained through the consent process. This would be rated by the clinician undertaking the consent process. This might be rated on a scale from 10 – 1. Where 10 is very well informed and 1 is not informed at all. |
| Knowledge        | Patient rated clinician knowledge | Patient rating of the clinician’s (e.g., Doctor) level of knowledge during the consent process. |
| Knowledge        | Self-rated clinician knowledge | Clinician (e.g., Doctor) rating of their own knowledge and their ability to answer patient questions during the consent process. |
| Knowledge        | Patient desire for extra information after the consent discussion | Patient desire for extra information after the consent discussion. For example, searching for info on the internet or speaking with friends and family who have had a similar procedure. |
| Knowledge        | Patient rated satisfaction with the quality and amount of information disclosed during the consent process | Patient rated satisfaction with the quality and amount of information disclosed during the consent process. |
| Decision making  | Patient feeling that there was a choice in the consent process | Patient rating of whether they felt they had a choice in the consent process or were aware of alternative options. For example, the choice between surgery and no surgery or a choice between different surgical options. |
| Decision making  | Confidence in the decision made | Patient rated confidence in their decision to consent or not to consent to the procedure. |
| Decision making  | Patient rated feeling that the decision to consent or not to the procedure was their own | Patient rated feeling that the decision to consent or not to consent to the procedure was their own. |
| Decision making  | Patient rating of the influence other people have on their decision to consent. For example, family, friends, other health care workers or other patients | Patient rating of the influence other people have on their decision to consent. For example, family, friends, other health care workers or other patients. |
| Communication    | Satisfaction with communication | Patient rating of their satisfaction with the quality of communication in the consent process. This communication may be oral, written or audio-visual. |
| Communication    | External rating of communication | This means another researcher observing the consent process and scoring the quality of communication. This could be by direct observation or by watching a video of the consent discussion. |
| Trust            | Trust in the clinician | Patient rated level of trust in the clinician guiding them through the consent process. |
| Trust            | Trust in the hospital | Patient rated trust in the hospital the patient is being treated in. |
| Trust            | Trust in medicine | Patient rated trust in the science and profession of healthcare. |
| Process          | Time | This means the total length of time that it takes to complete the informed consent process. This might be measured in terms of minutes or hours. |
| Process          | Adequacy of time for consent | Patient rated feeling that the length of time for the consent process was neither too rushed nor too long. |
| Outcome | Category | Domain name                                                                 | Help text                                                                 |
|---------|----------|-----------------------------------------------------------------------------|---------------------------------------------------------------------------|
| 19      | Process  | Number of consultations                                                     | Number of separate consultations undertaken as part of the consent process |
| 20      | Process  | Time between consent process and the procedure                              | How long before the proposed procedure was the consent process conducted   |
| 21      | Process  | Presence of friend or relative                                              | Was a friend, relative or other trusted person present with the patient during the consent process |
| 22      | Process  | Was the consent process conducted in an emergency situation or in a planned (elective) setting | Was the consent process conducted in an emergency situation or in a planned (elective) setting |
| 23      | Process  | Consent technique                                                           | How the consent process was conducted. For example, did it involve a face-to-face discussion, patient information leaflets, audio-visual aids or other techniques |
| 24      | Process  | Patient satisfaction with consent process                                   | Patient rated satisfaction with the consent process. This includes the situation for the consent consultation (for example, emergency vs. elective), the timing of the discussion, the number of consultations and the techniques used to undertake the consent process |
| 25      | Process  | Clinician satisfaction with the consent process                             | Clinician rated satisfaction with the process used to undertake consent    |
| 26      | Patient characteristics | Age                           | Patient age                                                                  |
| 27      | Patient characteristics | Intelligence                  | For example, IQ or asking patients about their level of education            |
| 28      | Patient characteristics | Previous experiences of healthcare                                         | Prior experience of surgery and healthcare                                  |
| 29      | Patient characteristics | Motivation for surgery                                                      | Patient motivation for procedure. Patient preference for a particular procedure before the consent process begins |
| 30      | Patient characteristics | Physical state                                                             | Assessment of a patient’s physical state which may impact on their ability to consent. For example, level of pain at the time of consent |
| 31      | Patient characteristics | Emotional State                                                            | Assessment of a patient’s emotional state which may impact on their ability to consent. For example, anxiety level at the time of the consent |
| 32      | Patient characteristics | Decision making style                                                      | Patient desire to be involved in the decision-making process. For example, happy for others to make decisions on their behalf or want to be in control of all the decisions related to their health care |
| 33      | Patient characteristics | Desire for information                                                     | Some patients like to have a lot of information. Other patients may not want any information related to their healthcare |
| 34      | Patient characteristics | Diagnosis                                                                  | The medical problem that the patient is being treated for. For example, cancer or benign conditions |
| 35      | Patient characteristics | Risk Perception and Risk-Taking Behaviour                                   | The level of risk the patient perceives the procedure to involve. Patient attitude to taking risks in general |
| 36      | Patient characteristics | Patient rating of how important they think the consent process is. For example, does the patient feel it is simply a box ticking exercise? | Patient rating of how important they think the consent process is. For example, does the patient feel it is simply a box ticking exercise? |
each stakeholder group. No specific evidence currently exists to support one form of feedback over another [10].

The distribution of scores for each outcome was calculated as a percentage of total responses. Consensus that an outcome should be considered for inclusion in the COS was defined as 70% or more of total respondents rating it as critical by giving a score in the 7–9 range and no more than 15% rating it as unimportant by giving it a score of 1–3. Conversely, an outcome would be considered for exclusion if 70% or more of respondents rated it as unimportant and no more than 15% rated it as critical. Additionally, if an outcome met the ‘consensus in’ criteria in three of the four stakeholder groups, but did not reach these criteria overall it was considered for inclusion in the COS. All other measures were thought to be equivocal [11, 32].

**Patient focus group and consensus webinars**

Consensus meetings for patient and other stakeholders were conducted separately. All stakeholders who completed both rounds of the Delphi process were eligible for the consensus webinars and were invited by email. However, many of the patients who had completed the online Delphi survey were not interested in attending such a meeting. For those patients who were prepared to attend a face-to-face meeting, it was not possible to find a mutually convenient date and time to obtain a critical mass. Additionally, the language and non-verbal communication used in such meetings can undermine or exclude patient participants [10]. Indeed, some COS developers recommend that professional and patient consensus meetings should always be conducted separately to allow patients to speak freely and to prevent contamination of their ideas [14]. As such, a patient focus group session was organised with patient participants from the Royal College of Surgeons England (RCSEng) Patient and Lay Group (PLG). The focus group discussion was convened at the Royal College of Surgeons, London on 4 April 2019 over a 1-h period. The PLG was established in 1999 and aims to ensure patient voices are adequately represented in the standards and policies of the RCSEng, raising areas of patient concern to the RCSEng, and advise the RCSEng about the optimal manner to engage patients. This meeting explored patients’ thoughts and perceptions regarding all outcomes prioritised in the Delphi process. Patients were not asked to vote on whether to include outcomes in the final COS. The aim, rather, was to determine patients’ views regarding each of these outcomes meeting consensus in the Delphi process and to use that feedback to inform the discussion during the consensus webinars. Participants were provided with a brief overview of the research and the rationale for the focus group session one week before the session. The patient focus group meeting opened with a brief presentation on the history and development of informed consent for surgery. The results of the online Delphi survey were briefly summarised before discussion was opened to the floor on the outcomes identified for discussion in the consensus meetings. The discussion was semi-structured and participants were asked to indicate their thoughts on all outcomes reaching unanimous ‘consensus in’ across all stakeholder groups as well as each of the five borderline outcomes in turn and to highlight any outcomes that they believed were important but not included among the 11 prioritised outcomes.

Two separate consensus webinars were conducted. Participants who completed both rounds of the Delphi survey were invited by e-mail to attend the webinars to produce a consensus panel. Webinars were chosen over an exclusively face-to-face meeting to facilitate participation from a wide geographic area, without the time and financial constraints that international travel would have imposed. These were held on two separate days (one of the webinars was conducted in the morning (UK time) and the other in the afternoon) to facilitate participation of experts from different time-zones and to maximise international attendance and determine the concordance between the panels. An anonymised online voting system was used, and the results were broadcast immediately. In cases where there was no clear consensus result, a discussion was held and a revote was taken. Participants in webinar 2 were not advised how participants in webinar 1 had voted. The decision to include or exclude any outcome was determined by a simple majority across both consensus meetings. Each consensus webinar was recorded using the Adobe Connect software package which recorded the audio, video, online presentation, and online chat generated from the meeting. Voting from each round and salient points of discussion was noted contemporaneously.

**Statistical analysis**

DelphiManager Version 3.0 (University of Liverpool) was used to build and manage the Delphi survey. Descriptive statistics and the distribution of scores for each outcome were assessed using SPSS for Windows, Version 24. (IBM Inc., Armonk, NY, USA). Cohen’s kappa scores were calculated to assess the level of agreement between each Delphi round for all outcomes meeting the consensus criteria at the end of Round 2. This was to examine whether consensus might be overestimated because participants with minority opinions do not complete Round 2. Mean and standard deviations were also calculated for these outcomes and an independent t-test was performed to detect a difference in the mean scores entered by completers and non-completers between the rounds.
to evaluate the level of this attrition bias. Graphs for feedback to participants were produced using the R statistical package (R Foundation for Statistical Computing, Vienna, Austria).

**Results**
A total of 164 participants completed all elements of Round 1, and a further 5 participants provided usable partial responses: with 125 (76.2%) complete responders in Round 2 and a further 3 participants providing partial responses to that round. Participants completing all elements of the survey came from eight countries and all four key stakeholder groups (Table 3). This included 53 (42.4%) patient participants who completed both rounds. Most respondents from all stakeholder groups originated from the UK.

During Round 1, participants suggested 29 additional outcomes that they believed were not represented in the original survey. These are included in Additional file 1. Review and discussion among the study advisory group resulted in four of these additional outcomes being added to Round 2 (Table 4).

Table 5 displays all outcomes scored in the Delphi process and shows which met the ‘consensus in’ criteria per stakeholder group in both rounds. In most cases, outcomes that met consensus criteria did so in at least two stakeholder groups, but consent technique, diagnosis, shared language of communication, trust in the hospital and trust in medicine were prioritised by patients only. Solicitors alone prioritised measured and self-rated patient knowledge in both rounds of the survey while consent researchers and bioethicists were the only group to prioritise whether the consent process had been conducted in an emergency or elective setting in Round 2, which the lawyer group had rated as critical in Round 1.

When the responses of participants completing both rounds of the survey were analysed, there were 527 of 4392 opportunities for change instances where a participant moved score categories between the two rounds. Five clinicians and four patients upgraded their rating of an outcome from unimportant to critical between rounds. Conversely, three clinicians and two patients changed their ratings from critical in Round 1 to unimportant in Round 2.

At the end of the Delphi process, 11 of 40 (27.5%) outcomes met the consensus criteria (Table 6). Of these, 6 outcomes met the “consensus in” criteria in each of

| Table 3 | Demographics of Delphi participants completing all rounds |
|---------|----------------------------------------------------------|
| **Stakeholder** | Clinicians | Consent researchers/ bioethicists | Patients | Solicitors/ barristers | Total (%) |
| **Country** | **Clinicians** | **Consent researchers/ bioethicists** | **Patients** | **Solicitors/ barristers** | **Total (%)** |
| Australia | 2 | 1 | 1 | 0 | 4 (3.2) |
| Canada | 1 | 0 | 0 | 0 | 1 (0.8) |
| Denmark | 0 | 1 | 0 | 0 | 1 (0.8) |
| Ireland | 4 | 0 | 0 | 0 | 4 (3.2) |
| Netherlands | 2 | 0 | 0 | 0 | 2 (1.6) |
| New Zealand | 1 | 0 | 0 | 0 | 1 (0.8) |
| UK | 41 | 7 | 52 | 6 | 106 (84.8) |
| USA | 2 | 4 | 0 | 0 | 6 (4.8) |
| **Total (%)** | 53 (42.4) | 13 (10.4) | 53 (42.4) | 6 (4.8) | 125 |

| Table 4 | Additional outcomes suggested by respondents of Round 1 and included in Round 2 |
|---------|---------------------------------------------------------------------------------|
| **Domain** | **Outcome** | **Help text** |
| Process | Who is the consenting clinician? | For example; is the doctor seeking consent a consultant (attending) surgeon or a trainee? Is the person undertaking the consent process and the surgical procedure the same? |
| | Opportunity to ask questions | Did the patient feel there was an opportunity to ask questions during the consent process? |
| | Shared language of communication | Are the patient and doctor able to communicate in the same language? |
| Patient characteristics | Patient’s motivation for a particular treatment compared to clinician’s motivation for a particular treatment | Is there a difference between the treatment preference or motivation between the clinician and the patient? |
| Domain                  | Measures scored (n=40) | Patient | Clinician | Consent research/bioethics | Solicitor/barrister | Overall |
|------------------------|------------------------|---------|-----------|---------------------------|---------------------|---------|
| Knowledge              |                        |         |           |                           |                     |         |
|                        | Measured patient knowledge |        |           |                           |                     |         |
|                        | Self-rated patient knowledge |        |           |                           |                     |         |
|                        | Clinician rated patient knowledge |        |           |                           |                     |         |
|                        | Patient rated clinician knowledge |        |           |                           |                     |         |
|                        | Self-rated clinician knowledge |        |           |                           |                     |         |
|                        | Patient desire for extra information |        |           |                           |                     |         |
|                        | Satisfaction with the quality and amount of information |        |           |                           |                     |         |
| Decision making        |                        |         |           |                           |                     |         |
|                        | Patient feeling that there was a choice |        |           |                           |                     |         |
|                        | Confidence in the decision made |        |           |                           |                     |         |
|                        | Patient feeling that the decision to consent was their own. |        |           |                           |                     |         |
|                        | Patient rating of the influence other people have on their decision to consent |        |           |                           |                     |         |
| Communication          |                        |         |           |                           |                     |         |
|                        | Satisfaction with communication |        |           |                           |                     |         |
|                        | External rating of communication |        |           |                           |                     |         |
| Trust                  |                        |         |           |                           |                     |         |
|                        | Trust in the clinician |        |           |                           |                     |         |
|                        | Trust in the hospital |        |           |                           |                     |         |
|                        | Trust in medicine |        |           |                           |                     |         |
| Process                |                        |         |           |                           |                     |         |
|                        | Time |        |           |                           |                     |         |
|                        | Adequacy of time |        |           |                           |                     |         |
|                        | Number of consultations |        |           |                           |                     |         |
|                        | Time between consent process and the procedure. |        |           |                           |                     |         |
|                        | Presence of friend or relative |        |           |                           |                     |         |
|                        | Was the consent process conducted as an emergency |        |           |                           |                     |         |
|                        | Consent technique |        |           |                           |                     |         |
|                        | Patient satisfaction with consent process |        |           |                           |                     |         |
|                        | Clinician satisfaction with the consent process |        |           |                           |                     |         |
| Patient characteristics | Age |        |           |                           |                     |         |
|                        | Intelligence |        |           |                           |                     |         |
|                        | Previous experiences of healthcare |        |           |                           |                     |         |
|                        | Motivation for surgery |        |           |                           |                     |         |
|                        | Physical state |        |           |                           |                     |         |
|                        | Emotional State |        |           |                           |                     |         |
|                        | Decision making style |        |           |                           |                     |         |
|                        | Desire for information |        |           |                           |                     |         |
|                        | Diagnosis |        |           |                           |                     |         |
|                        | Risk Perception and Risk-Taking Behaviour |        |           |                           |                     |         |
|                        | Patient rating of how important they think the consent process is. |        |           |                           |                     |         |
| Added after round 1    | Opportunity to ask questions |        |           |                           |                     |         |
|                        | Patient's motivation for a particular treatment compared to clinician's motivation for a particular treatment |        |           |                           |                     |         |
|                        | Shared language of communication |        |           |                           |                     |         |
|                        | Who is the consenting clinician? |        |           |                           |                     |         |
four stakeholder groups that took part in the survey, in addition to meeting the criteria overall. These outcomes were:

1. Patient rated satisfaction with the quality and amount of information disclosed during the consent process.
2. Patient believing that there was a choice in the consent process.
3. Patient rated perception that the decision to consent or not to the procedure was their own.
4. Trust in the clinician.
5. Patient satisfaction with the consent process.
6. Opportunity to ask questions.

There were a further 4 outcomes that while achieving the “consensus in” criteria, did not achieve this level of support in all four stakeholder groups. These were:

7. Confidence in the decision made.
8. Satisfaction with communication.
9. Trust in the hospital.
10. Adequacy of time for consent.

Additionally, one outcome, namely, patient desire for extra information after the consent discussion, met “consensus in” criteria in three of the four stakeholder groups but was just short of meeting the criteria when results were analysed overall (69% critical ratings versus 70% required for “consensus in” criteria).

Following discussion among the study advisory group it was determined that the 6 outcomes achieving unanimous consensus should be included in the final COS without the need for prolonged discussion at a consensus meeting. It was also agreed that the other 5 outcomes would be taken forward to the consensus meeting to determine if they would be included in the final COS.

There was substantial agreement in the responses of participants between Round 1 and Round 2 for most outcomes, as indicated by the kappa value > 0.6. The outcomes: “Adequacy of time”, “Patient feeling that there was a choice” and “Patient feeling that the decision to consent was their own” demonstrated moderate agreement between rounds. The proportion of respondents rating these measures as critical increased between rounds, accounting for the lower levels of agreement between rounds but increased agreement between stakeholders.

Comparing mean ratings for outcomes meeting the consensus criteria between participants completing both rounds and those completing Round 1 only does show evidence of attrition bias in the case of “Patient satisfaction with the quality and volume of information” (Table 7). In this case, non-responders rated this outcome significantly lower than responders (7.55 v. 7.98 p = 0.03). However, it should be noted that this outcome very clearly made inclusion criteria in both Rounds (Round 1: Critical = 82.8%, Unimportant = 0%
and Round 2: Critical = 91.3% Unimportant = 0%) and the difference is small.

**Patient focus group and consensus webinars**

The focus group meeting with the RCSEng Patient Liaison (PLG) Group comprised 20 patient representatives from throughout the United Kingdom (8 female and 12 male). Participants endorsed the inclusion of the six outcomes that had reached ‘consensus in’ criteria among all stakeholder groups during the Delphi process in the final COS. The focus group discussions regarding the remaining 5 borderline outcome were presented to participants in the consensus webinars. The PLG reported that clear verbal communication, avoiding medical jargon and checking for understanding were integral to the consent process. Also, the use of good quality information leaflets would augment the consent discussion. Participants valued the patient rating on the adequacy of time and felt this was a better metric than simply an arbitrary time taken to obtain consent. While members of the group suggested that the need for additional information after the consent discussion and the level of trust patients have in the hospital were important variables, they believed these measures reflected a patient’s personality rather than the quality of the informed consent process. Overall, participants from the RCSEng PLG welcomed a change in the discourse around informed consent and were pleased to see that patient voices were adequately represented in the development of this COS.

The consensus webinars were hosted from the Ulster Hospital Dundonald, Northern Ireland on 6th June 2019, starting at 09:00 BST and 17th June 2019, starting at 14:30 BST. Participants across the two meetings included 12 clinicians, 2 medico-legal lawyers and 3 consent researchers. (Table 8) Most participants originated from the UK with 2 participants from the USA and one each from Australia and Canada.

Participants endorsed the six outcomes that had met unanimous ‘consensus in’ criteria during the Delphi process without further discussion. A summary of the outcome scoring from both webinars is included in Table 9. At the conclusion of both meetings, three of the five outcomes exceeded the 50% threshold to be included in the COS. These were; confidence in the decision made, satisfaction with communication and adequacy of time. This resulted in a final COS consisting of 9 core outcomes (Table 10).

**Discussion**

This is the first study that has attempted to standardise the important outcomes that should be measured in the informed consent process. It has captured the attitudes of patients, clinicians, lawyers and academics in the field of

| Table 7 | Assessment of attrition bias between completers and non-completers of Round 2 |
|-----------------|---------------------------------|---------------------------------|-----------------|
| **Outcome** | **Responders round 2** | **Non-responders round 2** | **P-value** |
| | **N** | **Mean** | **SD** | | **n** | **Mean** | **SD** | **t-test** |
| Adequacy of time | 125 | 7.1 | 1.4 | 42 | 7.31 | 1.54 | 0.42 |
| Opportunity to ask questions* | 125 | 8.05 | 1.13 | N/A | N/A | N/A | N/A |
| Patient satisfaction with process | 125 | 7.52 | 1.21 | 42 | 7.24 | 1.49 | 0.22 |
| Patient feeling there was a choice | 126 | 8.27 | 1.05 | 41 | 8.05 | 1.84 | 0.34 |
| Patient feeling that the decision was their own | 125 | 8.15 | 1.11 | 42 | 7.95 | 1.19 | 0.33 |
| Confidence in the decision made | 125 | 8.09 | 1.23 | 42 | 8.05 | 1.13 | 0.82 |
| Satisfaction with the quality and amount of information | 126 | 7.98 | 1.06 | 42 | 7.55 | 1.31 | 0.03 |
| Patient desire for additional information | 125 | 6.46 | 1.47 | 42 | 6.93 | 1.61 | 0.08 |
| Satisfaction with communication | 125 | 7.95 | 1.2 | 42 | 7.69 | 1.85 | 0.29 |
| Trust in the clinician | 125 | 8.21 | 1.28 | 42 | 7.76 | 1.61 | 0.07 |
| Trust in the hospital | 125 | 7.34 | 1.76 | 42 | 6.9 | 2.24 | 0.19 |

*Opportunity to ask questions was added to Round 2

| Table 8 | Participant characteristics in Consensus Webinars 1 and 2 |
|----------|----------------------------------------------------------|
| | **Webinar 1** | **Webinar 2** | **Total (%)** |
| **Stakeholder** | **Clinician** | **Lawyer** | **Consent Researcher / Bioethicist** | **Clinician** | **Lawyer** | **Consent Researcher / Bioethicist** | **Total** |
| **Country** | **UK** | **USA** | **Canada** | **Australia** | **UK** | **USA** | **Canada** | **Australia** |
| **Clinician** | 6 | 1 | 1 | 1 | 6 | 1 | 1 | 1 |
| **Lawyer** | 6 | 1 | 1 | 1 | 6 | 1 | 1 | 1 |
| **Consent Researcher / Bioethicist** | 6 | 1 | 1 | 1 | 6 | 1 | 1 | 1 |

At the conclusion of both meetings, three of the five outcomes exceeded the 50% threshold to be included in the COS. These were; confidence in the decision made, satisfaction with communication and adequacy of time. This resulted in a final COS consisting of 9 core outcomes (Table 10).
informed consent internationally. There was a high level of patient involvement throughout the process across various qualitative elements. Patients provided as many complete responses (n = 53 (42.4%) in the Delphi Survey as the clinician group. Collectively, the patients have experience of both emergency and elective surgery for a wide range of conditions, including minor day surgery and major surgery for benign and malignant conditions ensuring a diverse group of patients in terms of age, surgical procedures, and clinical outcomes because of surgery. Furthermore, the consent researcher / bioethicist and clinician groups came from a variety of geographic areas and diverse professional backgrounds and practices.

The prioritisation of outcomes using a Delphi survey and consensus meetings has defined a list of nine outcomes that reflect “what matters” most in the consent process. However, this COS does not preclude the measurement of other outcomes in future consent trials. Despite most of the research to date focusing on knowledge, recall and comprehension as primary outcomes this has not been reflected in the final COS. Measurement of patient knowledge either by objective or subjective means was only rated as critical by the lawyer stakeholder group. Stakeholders preferred a patient satisfaction rating on the quality and volume of information they were provided, as opposed to an attempt to prove whether the information was remembered or understood. The COS aligns with ethical, legal and professional standards and public opinion [33] of seeking to understand what matters to each patient, building trust, communicating effectively, promoting autonomous choice and allowing appropriate time for patients and clinician to make an informed shared decision about treatment. These elements combined highlight that achieving valid consent more likely an reflects a “process” rather than simply satisfying the standards of signing a consent form at a particular point in time.

5 of the outcomes in the final COS have not been reported in any randomised trial of interventions designed to improve the consent process. These are patient rated adequacy of time, opportunity to ask questions, patients feeling like they had a choice in the consent process, that the decision the patient made was their own and trust in the clinician. The fact that these outcome measures, despite being of critical importance to stakeholders in the consent process have not been reported in existing consent research may be because no validated tools exist for measuring some of them, researchers may have considered them but did not think them important to stakeholders, or they have not been considered at all. The remaining outcomes have been measured in existing trials.

This study adds to a paucity of literature on the development of a COS for the evaluation of communication interventions [34]. Additionally this study adds to a limited number of examples where COS developers have used simple statistics to demonstrate stability between rounds and to assess the level of attrition bias. The analysis in this study demonstrated evidence of attrition bias for only one of the eleven outcomes rated as ‘consensus in.’ The protocol for the development of this COS was registered prospectively on the COMET database, the full protocol was published prospectively and the parameters for determining consensus were established a priori and mirror the standards used by other COS developers [14, 18, 35]. No deviations from the published protocol were necessary.

| Table 9 | Outcome voting in both Consensus Webinars |
|---------|------------------------------------------|
| Outcome | Webinar 1 vote in (n = 8) | Webinar 2 vote in (n = 8) | Total vote in (%) | Outcome In/Out |
| Knowledge: desire for extra information | 6 | 2 | 8 (50.0) | Out |
| Decision making: confidence in the decision made | 7 | 3 | 10 (62.5) | In |
| Communication: satisfaction with communication | 1 | 8 | 9 (56.25) | In |
| Trust: trust in the hospital | 0 | 0 | 0 (0) | Out |
| Process: adequacy of time | 4 | 8 | 12 (75) | In |

| Table 10 | Final COS to evaluate interventions designed to improve the informed consent process for surgery |
|----------|--------------------------------------------------|
| Domain   | Outcome                                          |
| Knowledge| Satisfaction with the quality and amount of information |
| Decision making | Patient feeling that there was a choice |
|                | Patient feeling that the decision to consent was their own |
|                | Confidence in the decision made |
| Communication | Satisfaction with communication |
| Trust        | Trust in the clinician |
| Process      | Patient satisfaction with consent process |
|             | Patient rated adequacy of time |
|             | Opportunity to ask questions |
Overall, a key question of “what” should be measured in future trials to improve the informed consent process has been satisfied which paves the way to identifying “how” and “when” the outcomes should be measured. This work will follow the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) to identify a complementary core measurement set [36, 37].

**Limitations**

Despite participation from stakeholders in multiple continents most participants included in this research originate from the UK with a significant proportion of the patient participants coming from a single NHS trust in Northern Ireland. As such, it is possible that these findings may not be generalisable to consent practices in other countries. While several clinicians, ethicists and consent researchers involved in the studies included live and work in countries outside of the UK, the findings presented may have limited applicability in other settings. As a group of surgeons undertaking this work, it is possible that our professional background may have subjected the design and findings of the study to some unconscious bias. As is the case with all Delphi surveys, limitations of this study could be considered to be responder bias, reduced accountability of views on account of the anonymity afforded to participants and the potential for attribution bias. The outcome “trust in hospital” whilst meeting the wider research group. Furthermore, as the study progressed it became clear that the themes identified in a relatively small number of participants during the semi-structured interviews were strongly reinforced by a larger cohort during the Delphi process.

**Implications for clinical practice**

Consent to undergo intervention applies to all patients in all specialities of medicine and surgery and therefore has the broadest potential application of any developed core outcome set. The COS from this study has the potential to influence consent practices on a global scale. Many of the outcomes included in the final COS have not been reported in existing consent trials yet these appear to be the aspects that are most important to the key stakeholders in the process. This presents an opportunity to redefine the direction of consent-based research. Regulatory bodies and guideline development groups e.g., National institute of clinical excellence (NICE) endorse the use of core outcome sets and investment to ensure future consent researchers adopt the COS when undertaking and reporting their research is necessary. This would facilitate comparisons between interventions and the synthesis of data while reducing the level of reporting bias. There remain several fields of consent and Shared decision making (SDM) research that may be able to adopt this COS for their own purposes including the trialling of novel communication interventions, Shared decision-making tools and Core Information Sets [8, 38].

**Conclusion**

We propose that this COS represents the minimum number of outcomes to report in all future studies of interventions designed to improve the quality of informed consent for invasive procedures. Future work is required to identify the best mechanism of assessment of each core outcome.

**Abbreviations**

ASGBI: Association of Surgeons of Great Britain and Ireland; ASIT: Association of Surgeons in Training; COMET: Core outcomes in effectiveness trials; COS: Core outcome set; COS-STAR: Core outcome set-standards for development; COS-STAD: Core outcome set-standards for reporting; GMC: General Medical Council; INVOLVE: INVOLVE national advisory group; NHS: National Health Service; NICE: National institute of clinical excellence; PLG: Patient liaison group; PoPPIE: People and patient participation, involvement and engagement; ORECNI: Office of research ethics Northern Ireland; RCSEng: Royal College of Surgeons England; SAG: Study advisory group; SDM: Shared decision making; SEHSC: South Eastern Health and Social care trust.

**Supplementary information**

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**Author contributions**

LJC, SJK, MC, JC conceived the informed consent COS. LJC, SMcC, JC, SJK, MC contributed to the development of the protocol and systematic review.
LJC recruited participants, conducted the semi-structured interviews, led the Delphi exercise, patient focus groups and consensus meetings. JMC wrote the first manuscript draft and all authors critically reviewed the paper to create the final manuscript.

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Availability of data and materials
All data generated or analysed during this study are included in this published article.

Declarations

Ethical approval and consent to participate
Prospective ethical approval for the study was obtained. All experimental protocols were approved by the Office of Research Ethics Northern Ireland (ORECNI) (Ethical approval reference—RECA 17/NI/0234) and the Research and Development Office of the Southern Health and Social Care Trust (SET.17.36_SEHSC) aligning with relevant guidelines and regulations and ethical principles of the Declaration of Helsinki. Informed consent was obtained from all study participants.

Consent for publication
Not applicable.

Competing interests
None.

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