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ORIGINAL ARTICLE

# Consent documentation for elective orthopaedic surgery

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## Abstract

**Objectives** Currently in Ireland, there is a lack of uniformity regarding the method in which the consent process is routinely documented. The purpose of this study was to evaluate the standard consent forms used in elective orthopaedic hospitals in Ireland. In addition, this paper explores the relevant guidelines from the UK and Ireland relating to consent documentation.

**Methods** Standard consent forms used in the 24 public hospitals that perform elective orthopaedic surgery were analysed and compared, based on the inclusion or exclusion of 22 unique consent-related items or statements selected by the authors. In addition, each form was analysed for format, word count, and readability.

**Results** Within 24 hospitals with elective orthopaedic surgery, there were 21 unique consent forms being used. There was a mean inclusion of 9.5 of the 22 unique items per form with a standard deviation of 5.1 (range 2–18), indicating a wide discrepancy. For each unique consent-related item in the analysis, the mean rate of inclusion was 43.4% (SD 26.7%). The mean Flesch Reading Ease Score was 43.3. The format varied from 1 to 4 pages, with a word count of 109 to 1041 (mean 414.7).

**Conclusion** The findings demonstrate a lack of uniformity of both format and content amongst the consent forms currently being used in elective orthopaedic hospitals in Ireland. This paper supports the use of a nationally standardised consent documentation method in order to improve the efficiency of the consent process and ensure greater protection against litigation.

**Keywords** Arthroplasty · Consent · Consent form · Documentation · Elective surgery · Litigation · Orthopaedic

## Background

The consent process is an important part of a patient's interaction with his or her surgeon. The establishment of consent is an on-going process which begins from the moment the option of surgery is broached with the patient during the outpatient consultation and continues up until the procedure takes place. The discussion, exchange of information and informed decision-making that typically takes place during the outpatient consultation may be considered the initial consent, however consent should not be considered concluded upon the signing of a document. Nonetheless, the completion of the consent form remains an integral part of the process. Patients and healthcare professionals alike tend to attach a degree of significance to the form itself and in particular the act of signing it, and indeed the consent form can often have a significant role to play should issues relating to the surgery arise in the future [1–4]. Despite the commonplace practice of consenting, many aspects of consent documentation may be poorly understood and inconsistently executed by healthcare professionals in the UK and Ireland [5, 6].

In Ireland, efforts have been made to address the uncertainties that surround consent, in particular with the establishment of the National Consent Advisory Group in 2011. The National Consent Policy (2014) seeks to define the role of consent in Irish healthcare [7]. Despite these guidelines, however, the preferred method of documentation of consent remains poorly defined and is largely left to the discretion of the individual surgeon or institution. This widespread inconsistency suggests that some of the implications of consent documentation may be underappreciated by practitioners throughout the country. Formal consent forms have typically been independently devised by individual hospitals, generally in accordance with national guidelines. Differing interpretations of these guidelines have given rise to a situation in which nearly all hospitals operate with unique consent forms. This further compounds the uncertainty surrounding the use of these documents.

The aim of this paper is to examine the consent documentation used in elective orthopaedic surgery in Ireland. In

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addition, the paper outlines various national and international guidelines and legal precedents pertaining to consent and attempts to clarify some relevant issues relating to consent documentation.

## Methods and materials

The surgical consent forms used in the 24 public hospitals performing elective orthopaedic procedures throughout Ireland were obtained and reviewed. For situations in which a hospital employed more than one consent form, the standard form used for adult patients with capacity was used in the analysis. Where two or more centres used the same or similar consent forms, each centre was considered as a separate entity in the data analysis. The format was assessed under the following headings: number of pages; font size; length of space provided to input title of procedure; area of free space available for free text. The word count of each form was determined from the text in its entirety. The readability of the document was determined using the Flesch Reading Ease Score and the Flesch-Kincaid Grade Level. This was applied only to the portions of the form that were written in complete sentences and were intended for reading by the patient. The content of all forms were reviewed and transcribed for the purpose of readability scoring by a single reviewer.

The number of distinct information points or paragraphs to be read by the patient and the number of tick boxes that require completion were determined. In order to determine the consistency of the content, each form was assessed for the inclusion of 22 separate consent-related features that were selected by the authors. The items that were chosen for the analysis were each a distinct point with inherent relevance to the consent process and each were present in two or more separate consent forms. These were subdivided into the following two groups: declarations that specific consent-related topics had been discussed with the patient; and additional sections with safety checks, questions, or boxes for completion. The selected items are outlined in Table 1. Descriptive statistics were calculated using Microsoft Excel, to illustrate the number of items included per form and conversely the rate of inclusion of each separate consent item.

## Results

Within the 24 public hospitals in which elective orthopaedic surgery takes place, there were 21 unique consent forms in use. The format of these varied from a single page to four separate pages (mean 2.1). The font size used on the page ranged from 10 to 14 (mean 11.7). The mean word count was 414.7 (range 109–1041). The mean length of space provided to input the title of the procedure was 33.5 cm (range 11 cm–68 cm). A dedicated space was provided for recording risks discussed or other relevant comments in 8 of 24 (33%). The layout of the forms varied such that the average blank space available on the form in which free text could potentially be recorded ranged from 20 $cm^2$ to 420 $cm^2$ (median 46 $cm^2$).

The median number of distinct information points or paragraphs to be read by the patient was 7.5 (range 1–16). The median number of tick boxes that require completion was 2.5 (range 0–19). The mean Flesch Reading Ease Score was 43.3 (range 33.5–59.5) and the mean Flesch-Kincaid Grade Level was 11.3 (range 9.4–12).

Of the 22 unique consent-related topics chosen for the analysis the mean number of items included per consent form was 9.5. The range was 2–18 and the standard deviation was 5.1, indicating a wide discrepancy. This distribution is represented in the box plot in Fig. 1. Figure 2 and Fig. 3 individually outline the percentage of the 24 elective orthopaedic centre consent forms that feature each of the unique consent related items. The overall mean rate of inclusion for each item was 43.4% (range 8.3%–95.8%, standard deviation 26.7%).

## Discussion

The findings from this study demonstrate a gross lack of uniformity amongst the basic consent forms used in Irish orthopaedic hospitals. The overall layout and amount of reading required by the patient varies significantly. The word count of the forms ranged from 109 in one to 1041 in another. Some forms had as many as 19 tick box questions requiring completion while many had none. Furthermore, a mean Flesch Reading Ease Score of 43.3 could mean that to many patients the information contained is difficult to process. The box plot in Fig. 1 illustrates the variation in content amongst the various consent forms. The fact that the majority of the 'topics discussed' (Fig. 2) lie in the middle of the table (30%–70% range) indicates that there is little consistency in the manner in which these forms have been devised. The findings suggests that not only do the documents contain varying amounts of information, but also that there is very little consensus as to the relative importance of the various information that may be included.

Written consent is not a legal requirement when undertaking surgery according to UK and Irish law [7, 8]. The UK Department of Health guidelines state that "If consent has been given validly, the lack of a completed form is no bar to treatment" [8]. There are exceptions to this in certain instances in which mental health is an issue, as outlined in the Mental Health Act 2001 in Ireland and the Mental Health Act 1983 in the UK, and also with certain fertility treatments [7, 8]. The Irish National Consent Policy states that for written consent there are no stipulations as to the manner in which the consent

**Table 1** Glossary of consent-related items used for analysis

| | | |
|---|---|---|
| Topics discussed | | |
| 1 | Patient details verified | Confirmation that the patient details have been verified as correct |
| 2 | Anaesthetic explained | Confirmation that the anaesthetic details have been explained |
| 3 | Surgical risks explained | Confirmation that the risks of the procedure have been discussed |
| 4 | Alternative options discussed | Confirmation that any relevant alternative treatment options have been discussed |
| 5 | Provision of leaflet confirmed | Confirmation that an information leaflet has been provided to the patient |
| 6 | All questions answered | Confirmation that all of the patient's queries/concerns have been addressed |
| 7 | Blood products discussed | Confirmation that the use of blood products has been discussed |
| 8 | Additional procedures discussed | Confirmation that the potential need for additional procedures intraoperatively has been discussed |
| 9 | Permission to obtain tissues | Confirmation that the procurement of tissue for the sake of on-going treatment has been discussed |
| 10 | Permission to use tissues for research | Confirmation that the use of tissue for research purposes has been discussed |
| 11 | States "no specific operating surgeon" | Confirmation that the patient is aware that there is no guarantee of which surgeon will be performing the operation |
| 12 | Teaching hospital – students may be present | Confirmation that there may be students or other trainees present for the purpose of education/training |
| 13 | Radiation exposure risk explained | Confirmation that the patient may be exposed to radiation intraoperatively |
| 14 | Photography may be obtained | Confirmation that visual or audio recordings may be made intraoperatively |
| Additional sections/boxes for completion | | |
| 15 | Treating consultant specified | An area to specify the treating consultant |
| 16 | Interpreter required | A tick box indicating whether an interpreter was required |
| 17 | Allergies recorded | An area to record allergies |
| 18 | LMP/pregnancy status established | An area to record LMP/pregnancy status if relevant |
| 19 | Site marked | A tick box verification that the site has been marked |
| 20 | Specific treatments declined | An area to record specific treatments that the patient has requested not be performed |
| 21 | Refusal of consent box | A separate box that the patient may sign if he/she expressly refuses consent for the procedure |
| 22 | TSE Exposure Risk Questionnaire | A questionnaire to screen for Transmissible Spongiform Encephalopathies exposure risk |

must be documented and a formal signed consent form is not an absolute necessity [7]. However, it does recommend that there should be a clearly documented record that the consenting process took place, whether this may take the form of a standardised patient-signed form or a note made by the clinician in the medical records. Although not strictly required, patient signed consent forms are recommended as routine practice for any invasive procedure and are strongly encouraged by both UK and Ireland guidelines for any procedure that may carry a significant risk to health or livelihood, or any procedure in which the primary purpose is not the patient's clinical care (e.g., research) [7, 8].

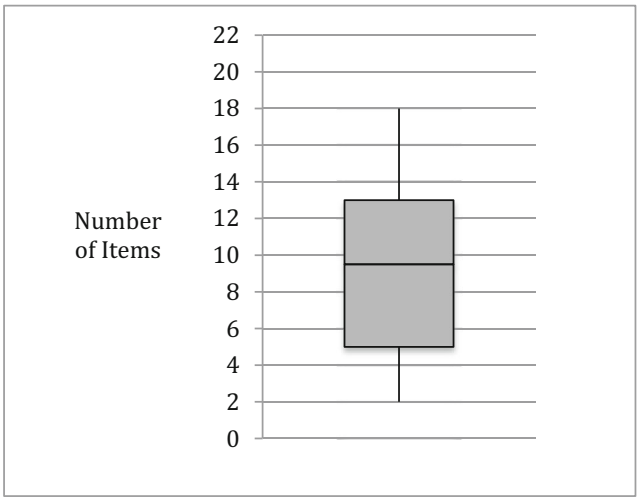


**Fig. 1** Box plot representing the number of unique consent-related items per consent form

Consent-related issue are amongst the most common causes of litigation in orthopaedics, alongside infection and clinical mismanagement [1–4, 9]. A review of 1473 orthopaedic litigation cases taken against English health trusts found that 78 cases were ruled in favour of the claimant primarily because of poor consenting practices [1]. A review of litigation in orthopaedic surgery in the US suggested that a surgeon's own notes describing the consenting process may in some instances carry more weight and relevance than a formal patient signed consent form [2]. The legal interpretation of consent is ever evolving. A recent high profile case in the UK (Montgomery v Lanarkshire Health Board) resulted in a precedence that has direct bearing on how consent is sought and indeed how it is documented [10, 11]. In this case, the parent of an infant that had suffered injury during delivery sought legal action on the grounds of medical negligence. The plaintiff claimed that the obstetrician had failed to discuss the risk of shoulder dystocia from vaginal delivery or the

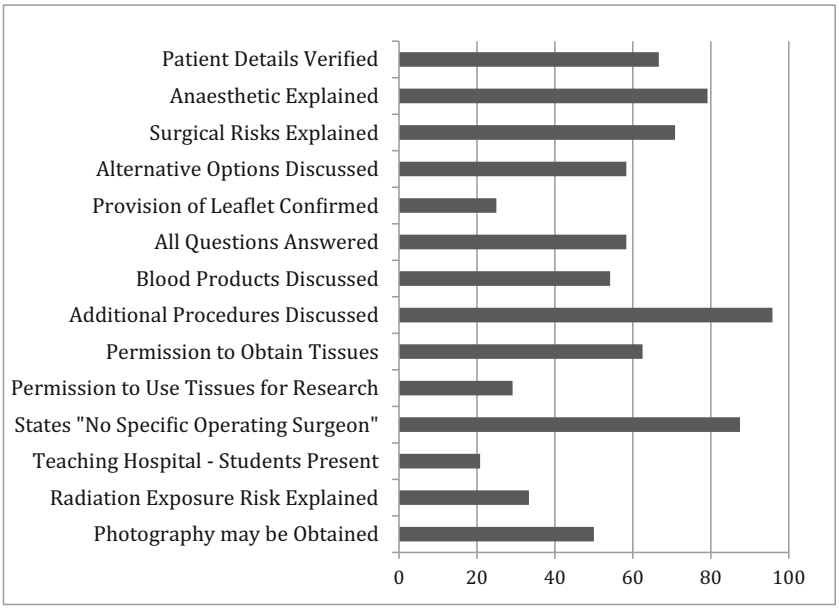


**Fig. 2** Topics discussed: the percentage of consent forms that specifically document that the stated topic was discussed

potential alternatives relevant to her situation (elective caesarean section). The Supreme Court ruling in favour of the claimant essentially heralded a change in the law regarding consent and consequently it is now imperative that a patient be made fully aware of all material risks and viable alternatives. This marks a departure from the previously relied upon "Bolam test", which justified a medical action if it was supported by a responsible body of medical opinion. It is now considered that the "Bolam test" is no longer applicable in cases of consent [10, 12].

UK and Ireland guidelines both agree that, for practical reasons, it is not always feasible or necessary for the treating consultant to have personally performed and documented the consent [7, 8, 13]. The Irish Medical Council "Guide to Professional Conduct and Ethics for Registered Medical Practitioners 2016 8th edition" recommends that, when it is not possible for the treating consultant to obtain consent, it is appropriate for another suitably trained and experienced individual to be delegated with the responsibility [13]. It is not recommended that an intern perform the consent process, unless it is a minor procedure and the doctor has been suitably briefed [13]. UK guidelines emphasise the role of the treating consultant in ensuring that the healthcare professional designated with the responsibility of obtaining consent has adequate knowledge of the procedure. If this provision has not been observed the consent may not be valid [8]. None of the relevant guidelines from Ireland or the UK specifically stipulate that the consenting process and documentation necessarily be performed by an individual that is either performing or assisting in the procedure [7, 8, 13–15]. Eight of 24 (33%) consent forms examined in this study specifically state that the doctor obtaining the consent may not necessarily be involved in the procedure.

Many studies have demonstrated very poor patient recall of risks following the consent process [16–21]. One study examining the accuracy of patient's postoperative recall in which an audio recording of the consent discussion had been recorded preoperatively, found that, in some instances, patients were actually found to incorrectly deny that certain pieces of information had been provided [22]. UK and Irish guidelines emphasise the importance of documenting details about the consent discussion, rather than just recording that the consent

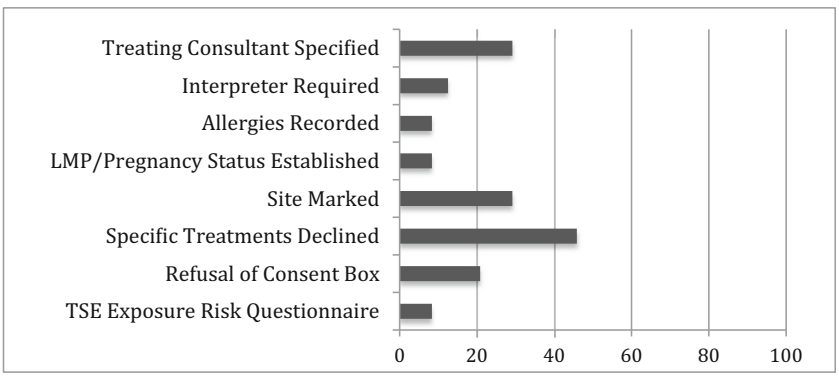


**Fig. 3** Additional sections/boxes for completion: the percentage of consent forms that include the stated safety check, question or box for completion

process had taken place [7, 8]. Atrey et al. remarked in their study that the successful claims following orthopaedic procedures that they attributed to poor consenting practices frequently featured a failure to specifically document commonly occurring complications, in particular leg length discrepancy, sciatic nerve injury and fracture [1]. The practice of routinely documenting risks discussed tends to be highly variable amongst orthopaedic surgeons [5, 23–27]. In this study, it was found that specific risks were only printed on 2 of the standard consent forms examined. One documented the individual risks associated with anaesthetics and the other documented "pain, scarring, bleeding and infection" as general risks of any surgery. It has been shown that consent documentation may be suboptimal when clinicians are not provided with adequate structure within a consent form [5, 23, 25, 28]. Notable efforts have been made in the UK to optimise and standardise the consent process in elective orthopaedic surgery. The British Orthopaedic Association (BOA) recently implemented a series of procedure-specific consent forms [29]. Procedure-specific consent forms have been shown to improve levels of information retention amongst patients undergoing elective arthroplasty and also encourage more diligent consent documentation practices. [5, 16, 27, 28]

On average the text of each consent form contained 7.9 of the 14 individual consent 'topics discussed' that were examined in this study (Table 1). These included important topics such as the permission to obtain tissue for research (included in 29% of forms) and the permission to obtain photographic images (included in 50% of forms). The implication inherent is that by completing the form the patient was satisfied that these topics had each been addressed. However, the inclusion of multiple preprinted statements on a patient signed consent form may risk creating false reassurance for the consenting clinician that those documented issues have each been adequately covered. This was referred to in a case from the UK in which the plaintiff, a patient who had suffered a complication as a result of a surgical treatment for intractable pain, made claims of trespass on person and negligence [30] The claim was ultimately defended, however the judge confirmed that a patient having signed a form expressing consent to undergo a procedure of which "the effect and nature have been explained to me" offers no defence against litigation if adequate explanation has not in fact been provided. It would follow from this point that a document containing multiple tick box articles implying that specific details had been discussed and understood, in addition to being cumbersome and time consuming, may not necessarily add value to the consent process.

## Conclusion

Issues surrounding informed consent are central to many cases of litigation in orthopaedics [1–4, 9]. It is imperative that an orthopaedic surgeon be familiar with the relevant guidelines and legislation regarding the consent process. At present, the information that is routinely recorded during the consenting process in Irish elective orthopaedic centres is discordant and this is reflective of a widespread lack of consensus regarding key aspects of this important step in patient care. Based on the findings of this study and review of the relevant published literature, the authors of this paper recommend the following points. Consent documentation should be standardised, with similar consent forms used throughout all hospitals within a given legal jurisdiction. Consideration should be given to the use of procedure specific consent forms, particularly for elective orthopaedic procedures. Consent documentation should avoid the use of perfunctory tick box checklists. Wherever possible, the consent process for elective surgery should be performed comprehensively during the outpatient consultation and specific details about the content of the discussion should be documented. At the time of surgery consent should be reaffirmed, and the details of this discussion should also be documented.

## Compliance with ethical standards

**Conflict of interest** Author Robert Kenyon declares that he has no conflict of interest.
Author Eoghan Pomeroy declares that he has no conflict of interest.
Author Robert Yeo declares that he has no conflict of interest.
Author James Cashman declares that he has no conflict of interest.

**Human and animal rights** This article does not contain any studies with animals performed by any of the authors.
This article does not contain any studies with human participants or animals performed by any of the authors.

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