Informed consent and the readability of the written consent form

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ABSTRACT

INTRODUCTION The aim of this study was to objectively ascertain the level of readability of standardised consent forms for orthopaedic procedures.

METHODS Standardised consent forms (both in summary and detailed formats) endorsed by the British Orthopaedic Association (BOA) were retrieved from orthoconsent.com and assessed for readability. This involved using an online tool to calculate the validated Flesch reading ease score (FRES). This was compared with the FRES for the National Health Service (NHS) Consent Form 1. Data were analysed and interpreted according to the FRES grading table.

RESULTS The FRES for Consent Form 1 was 55.6, relating to the literacy expected of an A level student. The mean FRES for the BOA summary consent forms ($n=27$) was 63.6 (95% confidence interval [CI]: 61.2–66.0) while for the detailed consent forms ($n=32$), it was 68.9 (95% CI: 67.7–70.0). All BOA detailed forms scored >60 , correlating to the literacy expected of a 13–15-year-old. The detailed forms had a higher FRES than the summary forms ($p<0.001$).

CONCLUSIONS This study demonstrates that the BOA endorsed standardised consent forms are much easier to read and understand than the NHS Consent Form 1, with the detailed BOA forms being the easiest to read. Despite this, owing to varying literacy levels, a significant proportion of patients may struggle to give informed consent based on the written information provided to them.

KEYWORDS

Informed consent – Ethics – Orthopaedics – Readability

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Informed consent constitutes an integral part in the practice of modern medicine and ultimately underpins patient autonomy.¹ The process of gaining informed consent relies on the fulfilment of three criteria: disclosure of adequate information, patient capacity and voluntariness.² Furthermore, patients should be actively engaged in the process so they can make an autonomous decision and subsequently authorise or refuse proposed treatment(s).^{1,5} Consent is a process that hinges primarily on the open and non-coerced discussion(s) between patient and clinician, and is not a singular issue of documentation.⁴ Nevertheless, gaining written consent acts as a prompt to ensure consent is not assumed as well as documentary evidence that it (at the very least) has been thought about.

Written consent or a signed consent form is recommended by the General Medical Council and the Department of Health before any major treatment or investigation, and may help defend litigation in the event of court or professional proceedings.^{5–7} The National Health Service (NHS) Consent Form 1 is utilised across the UK. It varies slightly between hospitals but shares an overall similar layout and is

designed for patients with the capacity to consent for treatment.⁵

The General Medical Council recommends that all serious material risks are discussed and recorded with patients undergoing surgery, regardless of how likely they are to occur.⁶ This is further supported by the Royal College of Surgeons of England's good practice guide on consent, in which the test of materiality is outlined as 'whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would likely attach significance to it'.⁸

Failure to adhere to this has been challenged successfully in court. The UK tort law case *Chester v Afshar* established that there was a causal connection between failure to inform a patient of all risks of surgery and consequential harm from surgery, irrespective of whether the surgery was performed competently.⁹ If the patient was aware of all risks, he or she may have declined surgery and consequently would not have sustained a surgical complication (which in that particular case was cauda equina syndrome).

The move from a paternalistic to a patient centred approach was further exemplified by the *Montgomery v Lanarkshire Health Board* judgement, where an expectant mother underwent a vaginal delivery that was complicated by shoulder dystocia and a subsequent brachial plexus injury to her child.¹⁰ The basis for the judgement in favour of the patient (despite vaginal delivery being a completely acceptable and reasonable treatment) was that alternative treatments such as Caesarean section were not discussed. In the knowledge of all alternatives, the patient may have opted for a Caesarean section, potentially reducing the risk of shoulder dystocia albeit exposing her to other risks of surgery.

This case highlights some of the complexities of the consent process as it stands. The process is open to legal challenge, and it is therefore important that all reasonable treatment options, benefits and risks of surgery are explained carefully to patients, that understanding is tested and finally, that this is documented appropriately to protect both patients and clinicians alike.

Within the limits of space on Consent Form 1, listing all serious risks may be impractical. For this reason, supplementary information may be provided in the form of pamphlets, multimedia applications or even interactive sessions such as hip and knee classes to illustrate fully the nature of surgery, potential benefits, risks and alternative treatments.

Standardised consent forms are used on an ad hoc basis in the NHS either as a supplement to Consent Form 1 or in place of it. For orthopaedic operations, the British Orthopaedic Association (BOA) has endorsed standardised consent forms, which can be adapted to individual surgeons' practice for a vast array of specific operations.¹¹ These forms are provided in a summary format, which lists surgical risks, as well as in a detailed format with comprehensive explanations of the benefits and risks of surgery.

The capacity to obtain, interpret and understand basic health information coupled with the competence to use this to enhance health is defined as health literacy.¹² This is considered a significant predictor of individuals' health status and one component that may affect health literacy is the accessibility to written health information that is sufficiently easy to understand.¹³

One way of theoretically improving accessibility to health information in addition to maintaining patient autonomy is to provide a copy of a patient's consent form to him or her prior to surgery so the patient can read, understand and challenge any treatment prior to making a decision. The Department of Health recommends that a copy of the form is given to all patients well in advance of their surgery.⁵

Best practice would dictate that every effort should be made to ensure that the form and any other literature provided is simple, and as easy to read and understand as possible. With up to 15% of the adult population in England only having the literacy rate expected of an 11-year-old child and the average adult having a reading age below that of a 16-year-old,¹⁴ some patients could struggle to read and understand any health literature including the consent form, which may be written without bearing this in mind.

In the US, the written information provided on the consent form is bound by the Plain Writing Act, which ensures that all healthcare materials are readable by the target consumer.¹⁵ The UK has yet to follow suit as the consent form itself is not a legally binding contract. The Department of Health, however, has attempted to encourage better written communication in healthcare via the introduction of the Information Standard, an organisation that helps rigorously test and improve healthcare information including written materials provided to patients so as to ensure that they are clear, accurate and easy to understand.¹⁶ While the Information Standard has been involved in improving an array of online and written materials in the NHS, it has not to our knowledge been applied to Consent Form 1, which has remained largely unchanged since 2001.

Assessing the suitability of written material (including the consent form provided to patients) is complex and multifaceted. The information needs to be accurate, free of jargon and formatted appropriately.¹⁷ It also needs to be easy to read, termed readability.¹⁸ Readability may be measured quantitatively using a variety of methods.^{19–22} These assess words, syllables and sentences to calculate an overall readability score. One of the most commonly used formulas is the Flesch reading ease score (FRES), which is a reliable, reproducible and valid system for measuring readability (Fig 1).¹⁹ Scores can range up to 100, with a higher score indicating that the material is easier to read.^{19,20} Although a number of studies have assessed the readability of healthcare literature in orthopaedics,^{23–25} this is the first study of its kind to evaluate and compare the readability of Consent Form 1 with that of standardised orthopaedic consent forms.

Methods

All standardised orthopaedic consent forms endorsed by the BOA for a range of elective and trauma procedures ($n=32$) were retrieved from orthoconsent.com. These forms were either in a summary format ($n=26$) or a detailed format ($n=32$). In addition, a sample template for the NHS Consent Form 1 was retrieved from the Department of Health website. Text intended for the clinician (eg guidance notes) was removed from Consent Form 1. All forms were assessed for readability employing an online tool (<https://readable.io/>) to calculate the validated FRES.²⁰ The mean FRES for the BOA summary and detailed forms was compared with that for Consent Form 1 using the paired standardised t-test.

Results

The FRES for the NHS Consent Form 1 was calculated as 55.6, relating to the literacy expected of an A level student (Table 1). The mean FRES for the BOA standardised summary consent forms was 63.6 (95% confidence interval [CI]: 61.2–66.0) and for the detailed forms, the mean FRES was 68.9 (95% CI: 67.7–70.0).

All the detailed consent forms scored >60, correlating to the literacy expected of a 13–15-year-old, and 25% of these were at a standard that an average 12-year-old could read

$$206.835 - 1.015 \left(\frac{\text{Total words}}{\text{Total sentences}} \right) - 84.6 \left(\frac{\text{Total syllables}}{\text{Total words}} \right)$$

Figure 1 Flesch reading ease score formula

(Fig 2). Only 70% (*n*=19) of the summary consent forms scored >60. The difference between the scores for the summary and detailed forms was statistically significant (*p*<0.001). Most notably, the summary consent forms for total knee and hip arthroplasty did not score as well as most other forms, with a FRES of 55 and 58 respectively (equating to the literacy expected of an A level student).

Discussion

This study demonstrates that the current NHS Consent Form 1 is not as easy to read and understand as the majority of the standardised consent forms endorsed by the BOA, with up to 43% of the general population (based on the 2011 Skills for Life survey)¹⁴ potentially struggling to read it. The detailed consent forms delivered the most encouraging results; however, up to 15% of the English population may still be unable to give informed consent based solely on the written information provided.

Our study used a blank Consent Form 1 without any specific risks listed. While this may appear to be not immediately comparable with a BOA standardised form (which already has risks filled in), by the very nature of the FRES formula, adding a long list of risks to the text of Consent Form 1 would be likely to reduce the readability score further by virtue of increasing sentence length. As a result, it is possible that the readability of Consent Form 1 may even have been overestimated.

The results of the study reaffirm the importance of ensuring that written material is designed appropriately for patients of all reading abilities and that the standardised detailed consent forms endorsed by the BOA are a vast

improvement on the NHS Consent Form 1. Despite this, the current study does question the validity of asking patients to sign a form that some may effectively not be able to read (or at least understand). Although the advice to give a copy of the form to patients appears to be good practice, if the patient cannot read or grasp what is written down, the value in doing so is limited and could even alienate patients.

There may be a case for audio-recorded consent with patients or a recorded interactive session where the validity of informed consent is tested in an active process to ensure that the patient is able to understand and express his or her wish to proceed with treatment. While this may not be immediately achievable in the short term, the BOA endorsed standardised detailed consent forms provide a reasonable alternative to the current NHS Consent Form 1 and this goes some way to ensuring that the written form is accessible to a wider group of patients.

Various US organisations have stipulated that the readability of healthcare materials for patients should be no higher than sixth-grade level (ie what would be expected of a child aged 11 years).²⁴ Readability formulas may be perceived as a blunt tool in assessing the wider suitability of written text for patients. Nevertheless, they are a quick, simple and objective measure of assessing reading ease. After taking into consideration current national literacy levels,¹⁴ a formal acknowledgement of a target FRES of >70 with a statutory minimum FRES of 60 for all consent forms could help to protect at least 85% and up to 93% of patients from being overwhelmed by information that they may not be able to read or understand.

Despite our study highlighting the importance of ensuring the readability of written text, there should not be an overreliance on written information when seeking consent. Ultimately, a two-way conversation with the patient remains the cornerstone of informed consent, with special attention given to patients with poor literacy skills, visual impairment and language barriers.

The present study does not assess the factual content or accuracy of information provided on the standardised consent forms and it is acknowledged that a readable consent

Table 1 Relationship between FRES and minimum level of education required to comprehend text				
FRES	Readability level	Age / education level	National population literacy levels ¹⁴	FRES for consent forms
90–100	Very easy	9-year-old	93%	
80–89	Easy	11-year-old	85%	
70–79	Fairly easy	12-year-old		
60–69	Standard English	13–15-year-old		SF: mean 63.6 DF: mean 68.6
50–59	Fairly difficult	GCSE grades A*–C / A level student	57%	NHS Consent Form 1: 55.6
30–49	Difficult	Undergraduate		
0–29	Very difficult	Postgraduate		
DF = standardised detailed consent form; FRES = Flesch reading ease score; GCSE = General Certificate of Secondary Education; NHS = National Health Service; SF = standardised summary consent form

Figure 2 Flesch reading ease scores for Consent Form 1 as well as standardised summary and detailed consent forms

form does not in itself guarantee that the text makes sense. It is therefore imperative that even with such aids, which clearly improve provision of information for patients, clinicians should actively seek to assess patients’ understanding of the information in order to facilitate informed consent.

Conclusions

This study has shown that the BOA endorsed standardised consent forms are much easier to read and understand than the NHS Consent Form 1, with the detailed BOA forms being

the easiest to read. Nevertheless, owing to varying literacy levels, a significant proportion of patients may struggle to give informed consent based on the written information provided to them.

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