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Improving consent form documentation and introduction of procedure-specific labels in a district general hospital

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ABSTRACT

Informed consent is an important aspect in patient care. Failings in this area may result in patient dissatisfaction or litigation. The aim of this project was to assess our practice in consenting and institute changes to maintain best practice. A consecutive series of 140 patients undergoing elective and trauma procedures were randomly identified over a nine-month period. The consent forms were reviewed and the following information collected: patient/ consentor details, procedure, legibility, if copy was offered/ given to patient and adequacy of procedure-specific complications listed (scored 0-3). The issues identified included: 25% of consents were not fully legible particularly in the complications section. 62% were noted to have inadequate complications listed (score 0 [>5 risks missing]) when compared to an accepted standard. None of the consent form copies were offered or given to the patients. Focused teaching to juniors as well as procedure-specific complication stickers were implemented to improve the documentation of complications. Following several improvement cycles all consents (100%) were fully legible and had the adequate procedure-specific labels with all complications listed. There was an increase to 38% of consent forms offered to patients. We have asked surgeons in the department to comment on which consent method they prefer and all consenters felt that the procedure-specific labels were easier to read and understand. Departmental education as well as introduction of simple procedure-specific complication stickers has resulted in significant improvements in practice.

PROBLEM

The Oxford English Dictionary defines consent as ‘permission for something to happen or agreement to do something’.¹ However, this does not entail understanding of the action agreed to. So in healthcare we use the term ‘informed consent’ which is the ‘permission granted in the knowledge of the possible consequences’.¹ The General Medical Council guidance on consent “Consent: patients and doctors making decisions together”² states that valid consent

revolves around a partnership between patient and doctor. This includes explaining the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The guidelines advice that documentation should be recorded of the key elements of the discussion. In Wales, all NHS health boards use the “All Wales” consent form which have been issued by the Welsh Government to “help clinicians obtain properly informed consent from patients undergoing examination or treatment”.³ Nevertheless, these forms are generic documents which leave blank spaces for pertinent information to be added by hand. Thus, time-constraints, legibility, and personal aptitude often limits the extent to which these forms are completed. Unfortunately, this puts hospital trusts and individual surgeons at risk of litigation following a poor documentation of consent.⁴ Further, a study in the United States found that risks of procedure accounted for 70% of informed consents complaints, concluding that improved informed consent would decrease these complaints.⁵

The aim of this project was to find out if we were completing our consent forms for orthopaedic procedures completely and improve any shortcomings by at least 30% within a 9 month period using simple interventions. 30% is an arbitrary figure which we felt would be achievable within this time frame.

This study was based in two district general hospitals covering trauma and orthopaedics in both an acute and elective setting, serving a population of 184,000. Collectively, there are 70 dedicated trauma and orthopaedic beds with 4000 procedures performed annually, both acutely and as elective cases. The department comprises of 11 consultants, 10 middle grades, 11 senior house officers (SHOs) and 2 specialist nurses. Of these, 1 middle grade, 2 SHOs and 2 consultants make up the team conducting this study.



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BACKGROUND

Several publications have highlighted the problem of consent in orthopaedics. Ahmad *et al*⁶ have reported poor documentation of risks for distal radius fracture fixation. Similarly, other publications showed inadequate consent in hip fracture surgery and elective total hip or knee surgery.^{7,8} These studies hypothesized that utilizing pre-printed consent forms could improve outcomes. For purposes like these, the Orthoconsent website has been created. Designed by a group of orthopaedic surgeons and originally endorsed by the British Orthopaedic Association, this website contains procedure-specific information and consent forms to complement the consent process.^{4,9} The approach has been shown to improve patient understanding of risks and procedure involved. However, with the latter a generic hand written consent form still needs to be completed. Still, St John *et al*.¹⁰ reported on an audit cycle utilizing electronically generated procedure specific consent forms in elective general surgery. This approach improved the quality and consistency of consent documentation.

BASELINE MEASUREMENT

A consecutive series of 40 patients undergoing elective and trauma procedures were randomly identified over a

three-month period. The “All Wales” consent forms (type 1; for people aged 16 years and over with mental capacity and people under 16 years of age who are Gillick competent) were reviewed and the following information collected: patient and consent details, type of procedure, whether a copy of consent form was offered to the patient, adequacy of procedure-specific complications risks listed and legibility. The complication risks listed were scored on a scale of 0-3 as follows: 3 – all risks mentioned, 2 – one risk missing, 1 - < four risks missing 0 - > five risks missing when compared to an accepted standard. This standard being the Orthoconsent website which lists specific complication risks for common orthopaedic procedures.^{4,8} In addition, documentation of whether consent forms were offered to the patients were evaluated (Figure 1).

80% of patients were consented by senior house officers, 15% by consultants and 5% by registrars. Adequate full patient identification was present in 95%. Adequate procedure and side was present in 100%. Full consent details were present in 70%. 0% of consent copies were offered to the patients. 25% of consents were not fully legible particularly in the complications section. 62% were noted to have inadequate complications listed (score 0 [>5 risks missing]) when compared to the standard. A low score was also present when patients

Consent Form 1: Patient agreement to examination or treatment

This form is to be used for people aged 16 years and over with mental capacity and people under 16 years of age who are Gillick competent.

Patient details (or pre-printed label) Patient's surname/family name Patient's first names Date of birth <input type="checkbox"/> Male <input type="checkbox"/> Female NHS Number (or other identifier)	Special requirements (e.g. other language/other communication method) (Please press hard to ensure all 3 copies are legible)
Name of proposed procedure or course of treatment (include brief explanation if medical term not clear)	
Anaesthetic This procedure will involve: <input type="checkbox"/> general and / or regional anaesthesia <input type="checkbox"/> local anaesthesia <input type="checkbox"/> sedation <input type="checkbox"/> none	
Any extra procedures which may become necessary during the procedure <input type="checkbox"/> None expected <input type="checkbox"/> Blood transfusion <input type="checkbox"/> Other procedure (please specify)	
Statement of health professional (health professional must have appropriate knowledge of proposed procedure) People aged 16 years and over (are presumed to have capacity to consent to treatment). Please tick ONE box: <input type="checkbox"/> In my opinion there are no reasons to doubt the patient's capacity to make this decision; OR <input type="checkbox"/> The patient's mental capacity to consent/refuse this treatment has been assessed and the patient has the mental capacity to make this decision. A note of the assessment has been placed on the patient's record. People under 16 years of age <input type="checkbox"/> After a full explanation of the procedure and its risks and benefits, I believe that the child has sufficient maturity and intelligence to be capable of understanding fully the treatment proposed and making a decision based on the information provided. I therefore believe that the patient is <i>Gillick competent</i> to make this decision. The child has <input type="checkbox"/> agreed / <input type="checkbox"/> declined to involve someone with parental responsibility in this decision. Advance Decisions (for patients aged 18 years and over only) <input type="checkbox"/> The patient has made a valid and applicable advance decision refusing this treatment / procedure or a treatment or procedure which may become necessary during the treatment / procedure in question. (Ensure the patient completes full details in the Advance Decisions section on the opposite page.)	
Information about the procedure/treatment I have explained the procedure to the patient. In particular, I have explained: Intended benefits: Significant, unavoidable or frequently occurring risks: I have also discussed: <input type="checkbox"/> what the procedure is likely to involve <input type="checkbox"/> any particular concerns of this patient <input type="checkbox"/> the benefits and risks of any available alternative treatments (including no treatment) Please include details: <input type="checkbox"/> I have provided the following leaflet / cd / dvd / weblink (please specify title of the leaflet and date of issue; title of the cd/dvd and 'version' if it has been amended) Signed Date Name (PRINT) Job title Professional registration number (e.g. GMC, NMC, GDC, HCPC, etc) Contact details (if patient wishes to discuss options later)	

Statement of Interpreter (where appropriate). I have interpreted the above information to the patient to the best of my ability and in a way in which I believe s/he can understand. Signed Date Name (PRINT) Contact details
Statement and signature of patient You will be offered a copy of this form. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form. I understand: <ul style="list-style-type: none"> the information that I have been given about the examination or treatment described on this form. that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience. that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.) that any procedures in addition to those described on this form and which are not the subject of an advance decision (see below) will only be carried out if it is necessary to save my life or to prevent serious harm to my health. I agree to the procedure or course of treatment described on this form. I do / do not agree* that students may be present during the procedure (*please delete as appropriate). Advance Decisions (for patients aged 18 years and over only) <input type="checkbox"/> I have previously made an advance decision refusing this treatment or procedure, but have now changed my mind and am happy to have the treatment / procedure described on this form. <input type="checkbox"/> I have an existing advance decision refusing a treatment / procedure which may become necessary during the treatment / procedure described on this form. This includes: (If the advance decision is in writing, file a copy in the medical record. If it is verbal, make detailed notes. If it refuses life sustaining treatment it must be in writing, signed, dated, witnessed, and clearly state that the decision applies even if the patient's life is at risk.) <input type="checkbox"/> I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures which I do not wish to be carried out without further discussion, even if not performing such procedures immediately could or would lead to serious permanent injury or death.
Patient's signature Date Name (PRINT) A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people / children may also like a parent to sign here (see notes). Signature Date Name (PRINT) Relationship to patient
Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance) On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead. Signed Date Name (PRINT) Job title Professional registration number (e.g. GMC, NMC, GDC, HCPC, etc) I confirm that I still want the procedure / treatment to go ahead. Patient's signature Date Name (PRINT)
Patient has withdrawn consent Ask patient to sign / date here and write "VOID" across all pages of the form. Patient's signature Date Name (PRINT)

Top copy of form must be retained in the patient's notes.
 Copy offered to patient: Welsh copy / English copy / Declined by patient (please circle)

Figure 1 “All Wales” consent form; adequacy and improvement of documentation was the aim of this study.

were consented by consultant and registrar level. Only 5% had a score of 3 – that is all complications listed. The above data sets were measured throughout the project to evaluate whether our aim had been met.

DESIGN

When considering the underlying cause of this problem, it became clear that most of the consenting, particularly in trauma situations, were performed by senior house officers. Through informal discussions with the juniors, the overwhelming sentiment was a lack of knowledge and confidence regarding orthopaedic procedures. Thus, focused teaching to juniors including a regular rota to theatre sessions was introduced. A lack of adequacy, legibility and reproducibility of risk and complications documented was noted. The simplest approach identified was to utilize the current, generic consent forms and prepare procedure-specific stickers which fit the complications and risk section at an adequately readable font. This design was reviewed by the trust consent managerial lead and trust lawyers. It was noted that in view of the Montgomery vs Lanarkshire Health Board Supreme court judgment¹¹ which indicates that risk assessment should not only be generic but also reviewed for significance to the particular patient, a further note was inserted in the sticker stating; "Please consider and add patient specific risks by hand". This was aimed at not only advising but also reminding the consenter of their legal obligation to pause and engage in the discussion with the patient. The procedure-specific stickers with the complications listed were then reviewed by the consultant body and adjusted accordingly. Teaching on their use and application was then given to the surgical team.

STRATEGY

The issues identified in the baseline measurement that we felt needed to be improved included: 1. consent forms not offered to the patients. 2. Consent forms were not fully legible, particularly in the complications section. 3. 62% were noted to have inadequate complications listed (score 0 [>5 risks missing]) when compared to the standard. 4. full consenter details in 70%.

Plan, Do, Study, Act (PDSA) Cycle 1 (November 2015) – the first aim was to divulge our results and find ways to prepare pre-printed consent stickers. These were prepared utilising patient detail label stickers and were discussed between consultants in charge of audit, and during departmental meeting. The first test was to assess its legibility, ability to put enough complications and ease of use. Following review by 6 consultants, whilst being satisfied with the ability to improve quality, it was felt that it should be reviewed by the Hospital Trust's management and legal team. Legal advice regarding the use of the consent stickers by the Trust's consent team and lawyers was obtained. These were then modified accordingly to add changes to allow for Montgomery

legal judgment on consent. These changes were then re-reviewed by the consultants and approved for use.

PDSA Cycle 2 (December 2015) – the aim was to trial the changes in a small number (10) of orthopaedic trauma patients to review for ease and adequate use by the surgical team. Similarly, we checked if patients can easily read the stickers. As predicted, patients were able to read adequately and these were easy to use.

PDSA Cycle 3 (January 2016 – March 2016) – the introduction of consent stickers was trialed over a three month period in 50 patients. Adequate full patient identification and procedure was present in 100%. Full consenter details were present in 95%. All consents were fully legible and had the adequate procedure-specific label used. We have asked surgeons in the department to comment on which consent method they prefer and all consenters felt that the procedure-specific labels were easier to read and understand.

PDSA Cycle 4 (May 2016 - July 2016) - in the previous cycles it was noticed that none of the patient copies (English or Welsh versions) were offered to the patients. The aim of this cycle was therefore to improve the offering of the consent forms to patients. We discussed this concern with the junior surgeons and consenters, provided encouragement and small group teaching aimed at improving this outcome. From our preceding PDSA cycles we have found open dialogue to be quite a successful method in our setting. Subsequently, we performed another study cycle where 50 consent forms were reviewed. There was an increase from 0% to 38% of consent forms offered to patients before and after intervention.

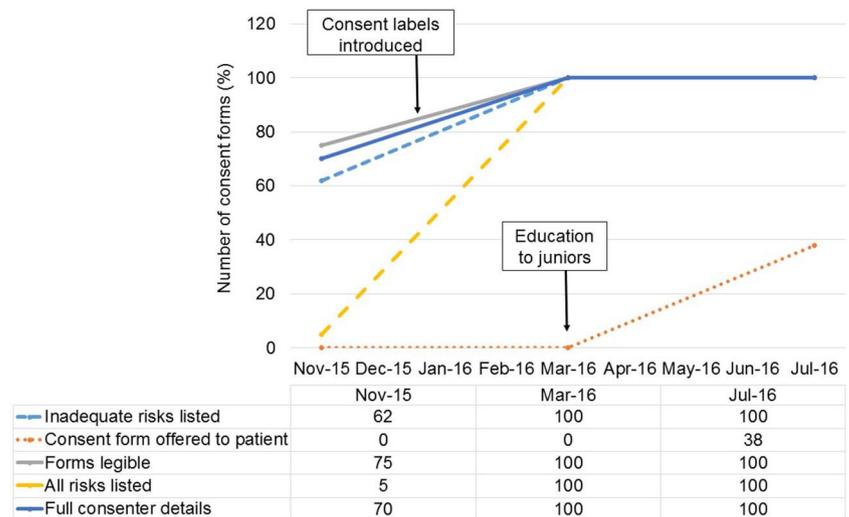
RESULTS

In the baseline measurement we found that consenter details was present in 70%, 25% of consents were not fully legible particularly in the complications section. 62% were noted to have inadequate complications listed (score 0 [>5 risks missing]) when compared to an accepted standard. Also, 0% of consents were offered to the patients. Following our interventions, all consenter details was present in 100%, all consent forms were fully legible and had the adequate procedure-specific label used. Thus, all consents had now achieved a score of 3 (all relevant complications and risks present). 38% of consents were now offered to patients (Figure 2). We have asked surgeons in the department to comment on which consent method they prefer and all consenters felt that the procedure-specific labels were easier to read and understand. Departmental education as well as introduction of simple procedure-specific complication stickers has resulted in significant improvements in practice and patient satisfaction. It was noted that there was improvement in the documented benefits listed for the procedure.

LESSONS AND LIMITATIONS

We learnt a number of lessons from carrying out this project. Simple interventions by junior staff are

Figure 2 Run-through chart showing improvement of baseline parameters over time.



achievable. When designing an intervention on consent, discussion with the trust managerial team on consent allows for improved design and implementation. The confidence that this has been vetted by the trust's legal department allows for a better adoption rate by seniors and juniors alike. Ultimately, teaching and training in small groups can achieve change.

Nevertheless, there are limitations with this study. First, the duration of review (9 months) following implementation of the interventions was short, meaning that we could not adequately assess for sustainability and continual improvement in the long term. Also, our results might be secondary to chance due to sampling bias. This is particularly so since the patients were sampled randomly rather than the whole population being studied over an extended period to time. In addition, this has been trialled on trauma patients which represent a mixed cohort of patients of different ages, diagnosis and pathologies. Still, structures have been introduced for more data to be collected regularly over 2 years to maintain quality improvement, and feedback questionnaires will be given to the team to assess any barriers to sustainability. Another limitation to the study is the potential for observer bias. The individuals collecting the data were from the orthopaedic team thus the risk of leniency in data collection could exist to allow for a more favourable outcome for the department. Nonetheless, this was mitigated by using a standardised proforma for collecting the data which is clear and limits individual interpretation, and will be further mitigated in the future by using a data collector from outside the department. Finally, although the advent of electronic health records and digital consent forms may limit the transferability of the procedure-specific labels to certain trusts in the UK, for places like Wales where currently the consent forms require handwritten input, these labels can be adapted and utilised in other surgical and medical teams offering procedures to patients.

CONCLUSION

Informed consent is an important aspect in patient care. Failings in this area may result in patient dissatisfaction or litigation. The aim of this project was to assess our practice in consenting and institute changes to maintain best practice. The most important findings of the first cycle was that consent forms were not fully legible particularly in the complications section. Lack of legibility was previously noted in

consent forms in several specialties. In this study, we also noted that our consent forms had inadequate complications listed when compared to an accepted standard. As previously reported and as found in our study, some of the important complications like infection and bleeding are usually listed.^{6,7} However, with the increasing complexity of orthopaedic surgery, a more procedure specific approach including its particular complications should be applied. Similarly, in view of the Montgomery judgment¹¹ a novel approach which is more patient centred should be implemented. As an intervention, we focused on teaching to juniors as well as procedure-specific complication stickers to improve the documentation of complications. We found this very effective and on re-audit we report that all consents were fully legible and had the adequate procedure-specific label used. We have asked doctors in the department to comment on which consent method they prefer. All consenters felt that the procedure-specific labels were easier to read, use and understand. In the long term, we felt that this simple approach will improve communication between consenters and patients. Ultimately, in improving the informed consent process, we expect increased patient satisfaction and reduction of complaints and risk of litigation⁵. Moreover, the use of procedure-specific stickers is simple and easily generalizable to other surgical and medical departments that use consent forms requiring handwritten input. In view of its ease and satisfaction of use, this implementation should be sustainable in the long term.

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Declaration of interests None declared

Ethical approval This study has been reviewed and approved by the hospital audit unit and did not require formal ethical approval.

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