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Completion of hand-written surgical consent forms is frequently suboptimal and could be improved by using electronically generated, procedure-specific forms☆

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ABSTRACT

Introduction: Completion of hand-written consent forms for surgical procedures may suffer from missing or inaccurate information, poor legibility and high variability. We audited the completion of hand-written consent forms and trialled a web-based application to generate modifiable, procedure-specific consent forms.

Methods: The investigation comprised two phases at separate UK hospitals. In phase one, the completion of individual responses in hand-written consent forms for a variety of procedures were prospectively audited. Responses were categorised into three domains (patient details, procedure details and patient sign-off) that were considered "failed" if a contained element was not correct and legible. Phase two was confined to a breast surgical unit where hand-written consent forms were assessed as for phase one and interrogated for missing complications by two independent experts. An electronic consent platform was introduced and electronically-produced consent forms assessed.

Results: In phase one, 99 hand-written consent forms were assessed and the domain failure rates were: patient details 10%; procedure details 30%; and patient sign-off 27%. Laparoscopic cholecystectomy was the most common procedure (7/99) but there was significant variability in the documentation of complications: 12 in total, a median of 6 and a range of 2–9. In phase two, 44% (27/61) of hand-written forms were missing essential complications. There were no domain failures amongst 29 electronically-produced consent forms and no variability in the documentation of potential complications.

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Conclusion: Completion of hand-written consent forms suffers from wide variation and is frequently suboptimal. Electronically-produced, procedure-specific consent forms can improve the quality and consistency of consent documentation.

Introduction

Obtaining a patient's informed consent involves much more than having a patient sign a consent form. It is a two-way dialogue between doctor and patient with the aim of facilitating their understanding of a procedure's risks, benefits and alternatives in the context of their own life. Despite this, the hand-written consent form still typically forms the centrepiece of this dialogue, comprises the only written information provided to a majority of patients and represents the sole documented evidence of the consent process that can be referred to for medico-legal purposes. This has acquired even more importance following the recent UK Supreme Court ruling in Montgomery *vs.* Lancashire Health Board.[1] In March 2015 The Court rejected the "Bolam Test", which judges the actions of a doctor against a reasonable body of medical opinion, in favour of requiring a doctor to take *"reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments"*. A material risk is further defined *"as a risk to which a reasonable person in the patient's position would be likely to attach significance or a risk that a doctor knows – or should reasonably know – would probably be deemed of significance by this particular patient"*.[2] A thorough, accurate and legible consent form can be used as evidence that such material risks have been discussed.

Despite their importance, current hand-written consent forms potentially suffer from significant disadvantages. Firstly, hand-written forms may be illegible, particularly the carbon copy version designated for the patient's records. Secondly, there may be considerable variability in the content of the forms as there is no standardisation for specific procedures and completion is performed by the surgeon on an ad hoc basis. Thirdly, fields may be completed incorrectly or not completed at all. Finally, we are gradually moving towards electronic health records and the consent form will need to be rendered digitally.[3]

An electronically generated consent form has the potential to obviate many of these shortcomings. Legibility could be ensured, variability could be minimised by pre-populated procedure-specific elements and required information could be mandated and even drawn from the electronic patient record. With the addition of touch screen technology to facilitate a digital signature the whole process could become paperless.

We performed a prospective audit of the quality of hand-written consent forms for surgical procedures and piloted a web-based system for the generation of procedure-specific consent forms – OpInform.com.

Methodology

This investigation comprised two related phases carried out sequentially at two separate NHS trusts between December 2012 and May 2014. In the first phase, we assessed the quality of completion of standard hand-written consent forms during a ten-week period. All available consent form type 1s (adult consent to treatment) completed by surgical subspecialties for operations during that period were included. Consent forms were completed by doctors of senior house officer grade (minimum one year clinical experience) or above. Non-operative procedures (e.g, endoscopy, interventional radiology) or consent forms 2 (parental consent on behalf of a minor), 3 (consent when consciousness not impaired) or 4 (adults lacking capacity to consent) were excluded from the investigation. Hand-written consent form 1s were generic pre-printed proformas, based on the UK Department of Health's recommended format, that contain blank elements required to be completed by hand and signed off by both patient and surgeon.[4]

Included consent forms were assessed by practising doctors working at the Trust (foundation year one or higher) and the surgeons completing the consent forms were excluded from the process. Assessed criteria compromised the completion of individual elements of the consent form that were recorded as correct, incorrect, illegible or blank. As shown in Table 1, these elements were then grouped into three domains for the purpose of analysis – *patient details*, *procedure details* and *patient sign-off*. Some form elements, such as consent for blood transfusion or other procedures were not assessed. A domain was considered "failed" if a single element was not correctly documented or was illegible. Form fields were rated as illegible if they contained text that was not

Table 1 – Individual form elements were grouped into three domains and assessed as correct, incorrect, illegible or blank.

Patient details	Procedure details	Patient sign-off
First name	Procedure name	Printed name
Surname	Intended benefits	Signature
Date of Birth	Potential risks	
Hospital/NHS No.		

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