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Informing the process of consent for surgery: identification of key constructs and quality factors

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ABSTRACT

Background: Informed consent is a fundamental requirement of any invasive procedure. Failure to obtain appropriate and informed consent may result in unwanted or unnecessary procedures, as well as financial penalty in case of litigation. The aim of this study was to identify key constructs of the consent process which might be used to determine the performance of clinicians taking informed consent in surgery.

Methods: A multimodal methodology was used. A systematic review was conducted in accordance with PRISMA guidelines to identify evidence-based components of the consent process. Results were supplemented by semistructured interviews with senior trainees and attending surgeons which were transcribed and subjected to emergent theme analysis with repeated sampling until thematic saturation was reached.

Results: A total of 710 search results were returned, with 26 articles included in the final qualitative synthesis of the systematic review. Significant variation existed between articles in the description of the consent procedure. Sixteen semistructured interviews were conducted before saturation was reached. Key components of the consent process were identified with broad consensus for the most common elements. Trainers felt that experiential learning and targeted skills training courses should be used to improve practice in this area.

Conclusions: Key components for obtaining informed consent in surgery have been identified. These should be used to influence curricular design, possible assessment methods, and focus points to improve clinical practice and patient experience in future.

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Introduction

Informed consent is an ethical and legal obligation prior to performing any invasive procedure. Consent is a complex process; it is not simply the giving of information by a health professional, but a dialogue between the patient and the physician.[1] Consent requires sophisticated communication and interpersonal skills to engender trust, explore patients' understanding and concerns, and deliver accurate information regarding the planned procedure.[2] Patients who have incurred harm or developed complications following surgery may feel that this possible outcome was not explained explicitly as a recognized risk of the procedure. These patients may elect to initiate complaints procedures and seek legal advice regarding compensation.[3] Litigation resulting from consent errors and omissions places a significant financial burden on health service providers and individual surgeons.[4] Indeed, between 2008 and 2013, more than £1 billion was paid to patients by the National Health Service Litigation Authority for surgical litigation claims in the UK alone. Despite this, the taking of consent by trainees rather than those with independent practice privileges remains frequent.[5] Furthermore, training and assessment of competency to enable informed consent is poorly described in the literature and widely variable.

The consent process is a vital component of high-quality patient care in surgery as it establishes a contract of trust between patient and doctor. The quality of patient care is a key priority for the healthcare industry, and recent research has demonstrated the importance of placing patients at the forefront of their own care.[6,7] Some subsets of patients may also require careful forethought regarding their capacity to give consent. Patients with altered mental status due to mental illness, intoxication, or traumatic injury may not have the ability to understand, retain, weigh, and make a decision on information that is provided to them.[8,9] In order to make this determination and guide the patient through the consent process, surgeons need to possess both technical knowledge of the procedure and, crucially, solid nontechnical skills such as communication, judgment, teamwork, and situational awareness.[10]

Communication and teamwork skills are already being measured in the operating theater and on the surgical ward.[11-13] In order to objectively assess the consent process, it is first necessary to identify the key constructs and factors which determine the quality of informed consent. The assessment of medical students to take consent from simulated patients has been previously described by Kiehl *et al.*[14] but has involved the use of arbitrarily defined performance measures selected without the benefit of any evidence-based process. In addition, this study was limited by the use of medical student participants rather than trained clinicians. There are no available reports of a robust and evidence-based development of an assessment framework to measure the quality of consent among practicing clinicians. This is important because before attempts are made to improve the consent process, it first needs to be measured.

The aim of this study was to identify key constructs of the consent process, which could in turn be used to determine the quality and competency of a surgeon obtaining informed consent from an adult patient for a routine surgical procedure.

Methods

A multimodal methodology was adopted, incorporating both existing evidence via a systematic literature review and semistructured interviews with practicing surgeons.

Systematic review

A systematic review of the literature was performed, following the PRISMA guidelines (Figure) to identify the key components of the consent process and any studies that assessed a clinician's competency in obtaining informed consent. Electronic databases (OVID Medline, Embase, PsycINFO) were searched using the following keywords and their combinations: (1) "consent" AND "surgery", (2) "consent" AND ("skill" OR "competenc*" OR "evaluation" OR "assessment"). Limits were set from January 1980 to April 2015. Reference lists of retrieved articles were also hand searched to augment the sensitivity of the primary search. Gray literature articles including position statements published by The American College of Surgeons, The Centers for Medicare & Medicaid Services, and the United Kingdom General Medical Council were also evaluated.

To be considered for inclusion in the review, articles needed to describe components of the consenting process relating to an interventional procedure. Due to the paucity of data, both clinical data and expert opinion pieces were considered. Conference abstracts, dissertation abstracts, and extracts for book chapters were excluded. All articles evaluating patients aged under 18 y, patients with mental incapacity, surrogate consent, or patients not undergoing interventional procedures were also rejected. Studies evaluating consent for research purposes only or exclusively the quality of consent form documentation were also eliminated. Finally, any references that did not describe components of the consent process or only described the harms associated with a single procedure were also excluded.

Eligibility of articles was judged independently by two reviewers (N.M.B. and S.A.), and disagreement resolved through discussion with a third reviewer (M.J.). Data on first author, publication year, country, type of article, surgical specialty, and components of consent were extracted and input into an Excel (Microsoft Corp, Redmond, WA) spreadsheet and qualitatively summarized. Owing to the low level of available evidence, with the majority consisting of reviews, narratives, and surveys, study quality was not explicitly assessed.

Interviews

Semistructured interviews were conducted, with purposive sampling of senior trainees and attending surgeons with extensive experience of the consent process and use of it in clinical practice. In the absence of a formalized metric to select surgeons particularly skilled at taking consent, the purposive sample included interviewees who excelled in terms of their communication skills, based on both formalized