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Discerning quality: an analysis of informed consent documents for common cardiovascular procedures

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INTRODUCTION

Informed consent provides a powerful opportunity to build trust between the patient and clinician while supporting patient autonomy, transparency and shared decision-making.[1 2] However, it is often relegated to a perfunctory task, performed as an ethical-legal formality minutes prior to a procedure.[3–5] As such, basic elements necessary for achieving the espoused goals of informed consent may be missing or suboptimally implemented, undermining patient-centred, high-quality decision-making. The types and extent of gaps in quality have not been systematically studied, limiting efforts to improve implementation. Our aim was to assess variation in quality of informed consent documents associated with three commonly performed cardiovascular procedures: left heart catheterisation, transesophageal echocardiography and implantation of a cardioverter defibrillator. We focused on basic elements of consent documents with the goal of illuminating opportunities to establish minimum standards for informed consent.

METHODS

Between 1 April and 30 June 2014, we conducted a medical chart review of informed consent documents associated with three electively performed cardiovascular procedures performed at a large, urban hospital: left heart catheterisations (not associated with acute coronary syndrome or in the context of another acute illness; n=79), transesophageal echocardiography (n=39) and implantation of a cardioverter defibrillator (n=36). We developed an abstraction tool to rate basic components of consent documents that a reasonable patient would deem important for decision-making, derived from reliable sources that patients could access on the internet. The final tool assessed presentation (legibility of handwritten information, assessed subjectively as 'legible', 'barely legible' or 'illegible' by three independent abstractors without clinical experience and concordance with patients' preferred language, as documented in the medical record); content (documentation of purpose of procedure, procedure-specific risks and benefits and the probability of them occurring, and alternatives to the procedure); and timing (interval between patient signature and administration of sedation medication). We chose to use abstractors without clinical experience because their assessment of legibility was not likely to be enhanced by prior medical knowledge, and thus was similar to how patients would rate legibility.

RESULTS

Among the informed consent documents that we evaluated, an identical, generic consent template, typed in 10-point font, was used in all cases (table 1). Most (catheterisation: 89%; echocardiography: 77%; defibrillator: 97%) consent documents contained additional handwritten information. Legibility varied by abstractor. Additionally, legibility increased as abstractors gained experience with evaluating the documents. All abstractors agreed that the documents were either barely legible or legible in at least one-third of all cases (catheterisation: 51%; echocardiography: 38%; defibrillator: 47%). At least one of the abstractors rated the documents as illegible in about one-half of cases (49%, 62% and 53%, respectively), though all three raters rarely agreed that a document was illegible (1%, 5% and 2%, respectively) (see online supplementary appendices 1 and 2). The purpose of the

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Table 1 Characteristics of informed consent documents associated with three electively performed cardiovascular procedures

	Left heart catheterisation	Transesophageal echocardiogram	Implantable cardioverter defibrillator
Number of procedures	79	39	36
Consent document present in medical record	100%	100%	100%
Presentation			
Generic consent template	100%	100%	100%
Concordant with patient's preferred language*	99%	97%	97%
Content documentation			
Any procedure-specific information	89%	77%	97%
Purpose for procedure specified	81%	92%	94%
Any procedure-specific risk(s) specified	68%	82%	58%
Any procedure specific risk(s) benefits specified	0%	0%	14%
Probability of any risk occurring	0%	10%	11%
Any alternative(s) specified	0%	0%	0%
Specific risks†			
Bleeding	61%	–‡	47%
Infection	41%	–	50%
Heart attack	61%	–	–
Stroke	63%	–	–
Arrhythmia	20%	8%	14%
Hypertension/hypotension	0%	28%	–
Breathing difficulty	–	26%	–
Aspiration/aspiration pneumonia	–	44%	–
Pneumothorax	–	–	44%
Pain or bruising (access site)	0%	–	0%
Damage to blood vessel	43%	–	22%
Damage to teeth, throat (includes bleeding)	–	54%	–
Damage to oesophagus (tear, perforation, bleeding, pain)	–	62%	–
Heart damage (puncture; pericardial effusion; tamponade; perforation)	8%	–	53%
Kidney damage (worsening creatinine; dialysis)	47%	–	–
Extra/inappropriate shocks	–	–	0%
Lead failure/displacement	–	–	14%
Contrast allergy	15%	–	–
Adverse reaction to sedation	1%	–	19%
Death	42%	10%	19%
Timing			
Median time from consent to administration of medication for sedation (range)	32 min (0–30 days)	29 min (0–253 min)	1.6 days (18 min to 60 days)
Legibility			
Documents rated as 'barely legible' or 'legible' by all three abstractors	51%	38%	47%
Documents rated as 'illegible' by at least one abstractor	49%	62%	53%
Documents rated as 'illegible' by all three abstractors	1%	5%	3%

*Only three patients' preferred language was not English (two Spanish, one Arabic)—none of the documents for these patients were written in their preferred languages.
†The specific risks for each procedure were determined from information provided on medical websites accessible to patients (eg, Mayo Clinic; National Institute for Health), used as a proxy for what a reasonable patient would deem material to making an informed decision. For each procedure, we report the proportion of documents that listed each risk as a possible complication of the procedure.
‡A dash (' –') indicates that the risk is not applicable for the procedure.

procedure (eg, condition for which the procedure was being performed) was usually but not always noted (catheterisation: 81%; echocardiography: 92%; defibrillator: 94%). Documentation of at least one procedure-specific risk (distinguished from risks noted in a generic consent template) was common (catheterisation: 68%; echocardiography: 82%; defibrillator: 58%), though there was substantial heterogeneity in

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the types of risks documented. Only eight documents cited any probabilities of risk (quantitative or qualitative; catheterisation: 0%; echocardiography: 10%; defibrillator: 11%). Benefits were infrequently specified (catheterisation: 0%; echocardiography: 0%; defibrillator: 14%) with no probabilities reported. Alternatives were not listed on any of the documents. Timing of consent prior to the three procedures varied (median time: 32 min for catheterisation; 29 min for echocardiography; and 1.6 days for defibrillator). Many patients signed the consent document <30 min before the start of the procedure (catheterisation: 43%; echocardiography: 49%; defibrillator: 3%).

DISCUSSION

In this single-site study of informed consent documents associated with three electively performed cardiovascular procedures, we observed significant variation in the presentation, content and timing of informed consent. While a generic template was used with nearly all procedures, consent documents commonly lacked information specific to the procedure and patient. When present, information was nearly always handwritten and was sometimes assessed as being illegible (see online supplementary appendix 3). Additionally, there was substantial variation in abstractor ratings of legibility. These results suggest that any handwritten information on an informed consent document may be subjectively illegible to an individual patient. In this study, at least half of the informed consent documents were rated as illegible by one or more abstractors, a finding that may underestimate the problem given that abstractors, while non-clinical, had some familiarity with the health professions field and may be better able to discern the handwritten information than an average patient. For these reasons, we propose that, when possible, all information on informed consent documents should be typed.

Many documents were signed minutes prior to the procedure, a time when patients are especially vulnerable.[3] All three procedures require the patient to take a day off of work and to fast the night prior to the procedure. Thus, presenting information to patients the day of the procedure not only reduces informed consent to a perfunctory signature, but also may cause anxiety and harm. Patients may feel pressure to sign even though they have additional questions. Informed consent documents for elective procedures should be signed in advance of the procedure date, unless the patient opts out of this standard.

Our findings need to be viewed in the context of some limitations. These findings come from a single institution; however, we suspect that, with some exceptions, deficiencies in basic components of informed consent quality are pervasive throughout the health system.[1 5 6] The extent to which shortfalls in informed consent implementation occur in other healthcare systems is an important area for future research. Additionally, we assessed only basic components of informed consent. While standardising these components is necessary for improving patient-centred decision-making, it may not be sufficient. Efforts such as those in Washington State to legislate shared decision-making as an alternative to informed consent are commendable and needed.[7]

Consistent with national priorities to improve patient-centred care,[6] the informed consent process represents a well-entrenched medical practice that can be leveraged to support safe, effective, high-quality decision-making.[5] Ultimately, there is a need to define universal patient-centred standards for informed consent and to incentivise health systems to consistently apply these standards across procedures.

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Contributors AS and ESS had full access to the data and take responsibility for the accuracy of the data analysis and interpretation of findings.

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Competing interests ESS, JS, SMB, HMK and MP report receiving support from the Centers for Medicare and Medicaid Services to develop and maintain performance measures that are used in public reporting programmes; they are currently developing a measure of informed consent document quality. HMK is a recipient of research agreements from Medtronic and from Johnson & Johnson (Janssen), through Yale University, to develop methods of clinical trial data sharing and chairs a cardiac scientific advisory board for UnitedHealth.

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