A Descriptive Study of Consent Documentation

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Abstract

The aim of this study was to observe the error rate in the consent process of a university hospital and to illicit the opinions of the consenting doctors on the process. A prospective observational review of theatre consent forms was performed along with an anonymous survey of non-consultant hospital doctors (NCHDs). No potential risks were documented in 85.3% of the 64 scrutinized consents and late alterations were required in 9%. Respondents to the NCHD survey estimated they were unsure of the procedure or risks involved in an average of 29% of occasions. Interns admitted to being unsure of the details of the procedure in almost a third (32%) of cases, making them less well informed than their senior colleagues (p=0.024). This study highlights the difficulties encountered by consenting doctors, an issue which may lead to patient dissatisfaction, threaten the efficient running of a surgical unit and potentially expose its staff to avoidable litigation. It also recommends the use of multimedia adjuncts to facilitate both patient and doctor education in the consent process.

Introduction

The consent process has the potential to cause theatre delays, engender patient dissatisfaction and provoke litigation. There are a number of factors that may contribute towards this. Firstly there exists considerable variability between individual surgeons regarding the risks that are required to be disclosed. McDonald et al of several authors to demonstrate this by specifically focusing on disclosures relating to laparoscopic cholecystectomy. Secondly, the obtaining of consent is often undertaken by non-consultant hospital doctors (NCHDs), who are frequently not involved in the carrying out of the consented procedure. In their study of a West London NHS trust hospital, McDonald et al also found that 80% of consents were obtained by junior staff who were not involved in the procedure. Thirdly, consents are often taken by junior staff, who have little knowledge of the procedure itself. In a survey of NCHDs based in an English ENT unit, Houghton et al reported that 37% of the junior doctors questioned, admitted to obtaining consent for procedures of which they had little or no understanding.

Results

A total of 78 consent forms were completed over the 48 hour period studied. Of these, 64 (82%) were analysed giving an attrition rate of 18%, resulting from logistical difficulties in data recording related to simultaneous procedures being carried out in different parts of the hospital. The origins of these consents can be seen in Figure 1. The procedure or its complications. Data was collected and tabulated in Microsoft Excel format and analysed using Minitab version 15 statistical software.

Methods

Forty eight hours midweek were used to reflect a typical two day period in a university hospital. All consent forms and case notes completed within this period for procedures carried out in theatre or the interventional radiology suite, were examined applying the guidelines recommended by the Irish medical council (Irish Medical Council Guide to Ethical Behaviour 2004-004). The following data was recorded: The grade of doctor completing the study; The adequate completion of all aspects of the consent; The indication of side or site where applicable; The risks specific to the procedure; The necessity for corrections made to the consent. Secondly an anonymous survey of non consultant hospital doctors (NCHDs) was undertaken (Figure1). Information recorded included basic demographics such as the grade and department of the consenting NCHD. The participants were asked to fill in the questionnaires while attending scheduled NCHD meetings. In addition, respondents were requested to self assess their suitability to take consent and asked to estimate the percentage of consents which they have attained during the preceding 12 months while they were unsure of the procedure or its complications. Data was collected and tabulated in Microsoft Excel format and analysed using MinTab version 15 statistical software.

Discussion

A total of six (9.4%) of consents were incompletely filled or contained discrepancies requiring further alteration prior to the procedure commencing. None of these alterations (0%) resulted in the cancellation of the procedure. Four of the six incompletely filled forms were completed by four different interns giving a significant difference between the interns and junior consultant doctors in their compliancy (p=0.024). The reasons for correction were to add more detail relating to the surgical site or side (23%), to add more detail regarding the potential procedure additions (23%), to document a risk (17%) and to complete the consent form from the beginning (17%). The procedures that the consent forms in this study pertain to, were performed by either consultants or registrars with consultant supervision as well as SHO or registrar assistance in both instances.
A total of 76 NCHDs were invited to complete the questionnaire, of which 46 (60%) consented to participate. Included in the 46 participants were 29 interns, 11 senior house officers (SHOs) and 6 registrars/specialist registrars. There were 18 males and 22 females (Table 2). Forty-three (93%) NCHDs reported that they were satisfied with their awareness of the risks associated with procedures for which they were consenting. On average, NCHDs were not fully aware or content with their knowledge of complications in 28.7% of consent forms completed. Interns responded more favourably in this manner with 31.4% denying full knowledge of the consenting process. This was statistically more then their senior NCHD colleagues (p=0.024). The majority of respondents (31.8%) reported that they do not routinely document the risks discussed when taking consent. All contributors (46.1%) agreed that interns should not take consent, with the majority (32.7%) concluding instead that registrars were most suited to this task.

Discussion

This study has documented the potential for error and inefficiency in the consent process of a typical university hospital. A correction rate of 9.4% was recorded. Additionally, just 5% of consents in this series included a record of the specific procedure to which consent was given. A recent recommendation by the Medical Council has advised that we strive for the inclusion of all details of the discussion to be recorded in the medical notes of the patient. Furthermore this study sought to illicit the opinions of practicing doctors regarding their role in the consent process. Almost one third of interns involved in obtaining consent do not feel qualified to take consent, while 100% of respondents agreed that interns should not consent patients. This raises questions regarding our current practice and also reaffirms that suggested by Houghton et al.

Several authors have suggested mechanisms through which we might address those issues highlighted through this study. Arey et al have examined the use of pro forma consent forms, or pre-written consent forms (PSCFs). These involve using pre-written, procedure specific forms, which outline the risks and possible complications of the common procedures. A system such as this has limitations, particularly in the area of emergency surgery where the procedure has to be individualised and it also may not offer the patient an adequate forum to ask questions. It would however in the elective setting provide a standardised template for both the patient and the consenting doctor. Examples of these can be found online at the British Orthopaedic Association website. It is generally understood that the person performing the procedure should undertake the consenting process but in this study that clearly was not the case. As a result an alternative is to restrict the consenting process to interns only, with more junior members of the team accompanying their senior colleagues and learning through the traditional apprenticeship model. No study in the literature however has examined this strategy in depth.

A third approach, and one favoured by the authors, involves improving the education of both doctor and patient through the use of multimedia delivered information. Several authors have attempted this approach. A study by Tait et al showed that the use of a multimedia tool led to a statistically significant increase in patient understanding of the risks, benefits, alternative treatment and treatment outcomes. Similar results in their study of patient understanding of metastasosaphageal joint (MTPJ) arthroscopy following the employment of a multimedia tool. In our own institution, a recently developed online multimedia system has improved the clinical experience of patients undergoing cardiac surgery (personal communication). Studies have also shown the benefit of written information provision to patients. In another example, Hong et al showed that the employment of written information led to a significant improvement in recall and understanding amongst patients undergoing rhinoplasty. Overall the provision of leaflets or multimedia data that contain information on the procedure, viable alternatives, and potential complications, would be a welcome addition. While the formal training of doctors in consenting for specific procedures is potentially time consuming and logistically difficult, the use of multimedia to deliver such education would appear to represent a viable solution. Additionally the integration of patient-doctor interaction through such a medium would be an exciting adjunct to the traditional consultation. In the time since this data has been collected we have integrated such a system into our multimedia package, along with shifting the educational emphasis for our junior doctors.

This study has reported some of the problems associated with the consent process as it is currently practised in many hospitals. Although a challenging problem to all of us practising procedure based medicine, it has the potential to affect the efficient running of our hospitals, our relationship with our patients, the patient experience and our participation in judicial proceedings. Given this it is paramount that we develop an effective strategy to improve on current deficiencies. It is the opinions of the authors that this is best served through a combination of pro forma consents for common procedures and, with the help of multimedia tools, the education of both doctors and patients.

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