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original article

An audit of consenting practices in a district general hospital. Can we improve?

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SUMMARY: **An audit of consenting practices in a district general hospital. Can we improve?**

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Introduction. *Informed consent, as the declaration of patients' will, forms the basis of legality of medical procedures. A standard form based on the Department of Health model is widely used in the National Health Service (NHS). The aim of this audit process was to assess the current consent practice in comparison to the UK's General Medical Council guidance and local policy and make any appropriate improvements.*

Patients and methods. *254 adult consent forms were reviewed during the patients' admission. Data collected included legible documentation, grade of health professional completing the consent form, providing additional written information, use of abbreviations, securing the consent form in the medical records and, providing a copy to the patient. After initial assessment, interventions in an attempt to improve adherence to guidelines were introduced. A repeat audit of a further set of 110 notes was completed to assess the effectiveness of our interventions.*

Results. *Our baseline assessment of 254 consent forms comprised of 198 (78%) elective and 56 (22%) emergency procedures. 87 (34%) consent forms were secure in the medical records. Grade of health professional was recorded in 211 (83%). 191 (75%) forms were legible. 48 (19%) patients were given copy of the consent. Only 24 (9%) patients were given additional written information. Abbreviations were used in 68 (27%) forms. Only 12 (5%) of consent forms met all criteria simultaneously.*

Re-audit after intervention assessed 110 consent forms; 30 (27%) for elective and 80 (72%) for emergency procedures. 52 (47%) of consent forms were secure in medical records, grade of health professional was recorded in 94 (85%), 101 (75%) forms were legible, 42 (38%) patients received copy of consent and 41 (37%) of patients received additional written information.

Conclusion. *Initially only 5% of consent forms completely met GMC guidelines. This demonstrates an alarmingly poor adherence to such guidance that plays a vital role in patient safety, patient ethics autonomy, not to mention potential medico-legal and clinical governance implications for surgical practice.*

Our intervention has improved the quality of consenting within our hospital according to these guidelines. With these interventions set to continue and further develop, we expect that the quality of the consenting process will continue to provide patients with all that it is designed to.

KEY WORDS: Consent practice - Medical ethics - Physician patient relationship - Decision making.

Introduction

In the Western World during the middle twentieth century, the physician has traditionally been regarded as having an authoritative and paternalistic role. Although the historical evidence is ambiguous, informed consent in the sense in which it is understood and practised in the modern clinical setting appears to be relatively recent in medical ethics (1). Currently, a model of mutual participation based on patient education level and involvement is widely employed. Among the adapted changes, one of the clearest themes that emerged was the centrality of the patients. The value of an individual's autonomy entitles him or her to accept or refuse any medical procedure and is the basis of a correct informed consent procedure as active patient participation in health care decisions (2).

In current clinical practice, the patient's consent to therapeutic procedures is a fundamental prerequisite on which medical intervention is based. It is an ethical obligation for the person undertaking the proposed intervention with potentially significant medico-legal im-

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plications (3). The consent form documents the patient's agreement to proceed with the intended examination or treatment with risks and alternatives clearly explained. The General Medical Council in its guidance for doctors to ensure good medical practice clearly stated that the key elements of the consent discussion should be recorded (4). A standard form based on the Department of Health model form is widely used in the NHS. It is an *aide-memoire* to health professionals providing a checklist of the information patients should be offered, and to patients enabling them to have a written record.

Patients are also entitled to change their mind after signing the form, (provided the person retains mental capacity for making this decision). If the consent form has been signed in advance, the health professional should confirm that the patient is still in agreement to have the procedure.

This study aims to evaluate the efficacy of the current consent practice in two large district general hospitals, Queen Mary's Hospital Sidcup and Princess Royal University Hospital, and to compare this to the current GMC guidance and local hospital policy.

Patients and methods

254 medical records for adult patients undergoing procedures were randomly selected during their hospital admission and the consent forms were reviewed, between 28th January 2013 and 17th of March 2013. Data collected as primary outcome measures included legible documentation, grade of health professional, completing the consent form, providing the patient with additional information, use of abbreviations, providing the patient with a copy of the consent form and securing the form in the medical records. Data was recorded in standardised data collection sheets and analysed. The acceptable standard was set as 100% completion.

Results

A total of 254 medical records reviewed. Of these 107 were General Surgery records, 92 Orthopaedic records and 55 Gynaecology records. 198 (78%) patients had elective procedures, 56 (22%) had emergency procedures. 87 (34%) consent forms were secure in the medical records (56 elective & 31 emergencies) while 167 (66%) forms were not securely filed in the case notes (142 elective and 25 emergencies). Type of anaesthesia was recorded in 223 (88%) forms but not recorded in 31 (12%) forms. Grade of health professional was recorded in 211 (83%) consent forms which included: 31 (15%) Consultants, 11 (5%) Associate Specialist/Specialty Doctor (AS/SD), 136 (65%) registrars, 30 (14%) SHOs and 3 (1%) nurses. 191 (75%) forms were legible. 206 (81%) patients were not given copy of the consent. Most of the consent forms 245 (96%) did not have the contact details of health professional recorded. Only 24 (9%) patients were given additional written information. Abbreviations were used in 68 (27%) forms. 26 consent forms were signed by the patient >2 days and <18 weeks before the procedure, patient's consent was confirmed by the health professional on 23 (88%) forms but was not confirmed on 3 (12%) forms. Only 12 (5%) of the consent forms were completed legibly, without abbreviations, securely filed and patients were given a copy of the consent form.

Discussion and conclusion

Although the historical evidence is somewhat ambiguous, informed consent in the sense in which it is understood and practiced today appears to be a relatively recent arrival in medical ethics (1). Consent has been an important area of clinical surgery since the early 20th century, with shift in attitude of clinical practice from an authoritative role of the physician or surgeon to a patient centred approach.

The "reference guide to consent" published by the department of health, stated that although not a legal requirement, the completion of consent forms is good practice where an intervention is to be undertaken (3).

The GMC guidance regarding consent states that the task of seeking consent is the responsibility of the doctor providing treatment. This responsibility may be delegated to someone else, as long as they are suitably trained and qualified. In particular, they must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved (4).

Audiotape analysis showed that consent information provided to patients through verbal discussion is often deficient (5). Ashraff et al. (6), reported that patient recall of the information at the consent interview is generally poor. The GMC guidance also states that information discussed with the patient and any written information given as well as details of any decisions must be recorded in the patient's medical records or a consent form.

However, there remain concerns regarding the quality of documentation of the consent process.

The aim of this study was to assess the documentation of the consent process in two large district general hospitals undertaking a wide range of invasive procedures in different surgical specialities. In our study, we assumed that patients had a copy of the consent form if the "patient's copy" was not found in the medical records. Although the medical records were randomly selected, we believe that this study represents the current practice.

In our study, there were some areas of deficiency: consent forms were mostly (66%) not securely filed, with

the risk of being lost. Abbreviations used in 27% of forms. Use of abbreviations can cause misunderstanding and may lead to unsafe practice (7). 81% of patients were not given copy of the consent form. Grade of health professional obtaining the consent was not recorded in 17% of forms. 96% of the forms did not have the contact details of health professional recorded, making it difficult for patients to discuss the options of their treatment later if they wish. 9% of patients were given additional written information. Only 5% of the consent forms were completed legibly, without abbreviations, securely filed and patients were given a copy of the consent form.

Other authors have reported similar findings. Jeyaseelan L. et al. (8), have reported use of abbreviations in 42.3% of consent forms with incomplete details and only 35.2% of patients were given a copy, they concluded that minor changes in consenting methods and more precise documentation could significantly improve patient experience and satisfaction. Use of abbreviations in consent forms were also reported by Sinha S. et al. and Kheiran A. et al. (7, 9). Kheiran A. et al., also reported that the use of abbreviations was significantly reduced (P=0.03) with odds ratio of 0.04 after adequate training of staff, they recommended specific training sessions for junior doctors during induction on consenting common trauma procedures, and that regular audit is essential to maintain expected national standards.

In our study, consent was mainly obtained by registrars; this is in accordance with GMC guidelines. Our results demonstrated that consent for emergency Orthopaedic procedures was mainly obtained by foundation year 2 (FY2) doctors or senior house officers 17/22 (77%), this result is similar to findings reported by Singh S. et al. (10), who found that senior house officers obtained consent from 30/55 (55%) trauma patients. Singh S. et al. concluded that failure to provide adequate informed consent may constitute a breach of a doctor's duty of care, and they recommended that doctors inadequately trained on providing informed consent, should ask a senior member of the team to take the consent.

The results of this study suggest some important areas for improvement, in particular proper documentation of patient's consent. Bhattacharyya et al. (11), reported that documentation of appropriate informed consent in the patients' notes was associated with a decreased indemnity risk ($p < 0.005$). We believe that additional written information improves patients' recall of the consent discussion and facilitates the process of informed consent; this is in agreement with findings by Ashraff S. et al. (6). Giving copies of the consent to patients prior to the planned elective procedure with additional written information, will allow them to re-evaluate their decision and make more informed choices under less stressful circumstances. This may help building rapport with the clinical team at the time of admission (12).

The results of this study led to several changes being made within the trust. We have developed a presentation to be given to all new doctors starting at the trust with the intention of giving appropriate training on the process of consenting of patients and how related documentation should be completed. We have also increased the availability of patient information leaflets on common procedures, by placing them in clinics and wards. Staff awareness regarding importance of securely filing consent forms and the process of confirming consent in those patients consented in advance was increased.

To determine whether these interventions improved our adherence to consenting guidelines we completed a re-audit exercise. This involved the random selection of 110 adult patient medical records who were undergoing procedures at our hospital. We examined the notes in the same way making note of whether the GMC guidelines for consenting were adhered to.

Table 1 compares the results from the initial study of consent forms to those selected after introduction of our interventions.

This table demonstrates that there has been a statistically significant change in 3 of the standards set by the GMC guidance.

The limitations of our study include not measuring the information given verbally during the consent process and not assessing the impact of complete documentation of consent form on patient recall. Other studies acknowledged that detailed documentation does not equate to an adequate consent process (13).

Table 1 - RESULTS COMPARED FROM THE INITIAL STUDY OF CONSENT FORMS TO THOSE SELECTED AFTER INTRODUCTION OF OUR INTERVENTIONS.

Standard Assessed	Initial	Repeat	p-value
Consent used	100	100	1
Intended benefits of procedure legible?	83	92	0.085
Risks legible?	98	98	1
Extra procedures recorded?	43	45	0.886
Consent form securely filed	55	47	0.3221
Leaflet given to patient	13	37	0.0001
Type of anaesthesia recorded	90	90	1
Health professional signed form	100	100	1
Health professional name legible	81	89	0.1649
Health professional contact recorded	5	24	0.0002
Patient signed	100	100	1
Health professional signed consent >2 days <18wks	26	20	0.401
Advanced consents confirmed	90	83	0.2139
Copy of consent given to patient	35	38	0.7691

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