INFORMED CONSENT: Special section

Editorial

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The new consent forms, issued by the Department of Health with a mandate for use from April 2002,[1] have led to a flurry of publications – like those in this[2–4] and previous[5–7] issues of the *Annals*. These explore what patients should be told about risks, and highlight variations and deficiencies in the recording of information patients are given. They raise issues about consent for surgery undertaken by trainees. Perhaps most important of all, some suggest the provision of good written information for patients which can be used as an adjunct to specific consent forms for common procedures. Until surgeons grasp this opportunity, the new consent forms are likely to remain a burden rather than a boon.

The intentions behind the new forms were beyond reproach. They provide a checklist of information patients ought to receive, together with a copy for the patient, in a format designed to be familiar to staff throughout the NHS. Importantly, the forms were produced with 'customisation' in mind, allowing individual hospitals and departments to include their own information about common procedures without the need for clinicians to write this down for each patient. However, the time scale was short and most hospitals simply handed the unmodified forms to clinicians with an instruction to use them. This means writing the 'intended benefits' and 'serious or frequently occurring risks' by hand on each form – both tedious and likely to be incomplete, so potentially exacerbating medicolegal difficulties, rather than preventing them.

The new forms were issued alongside important related documents. The Department of Health's *Reference Guide to Consent for Examination and Treatment*[8] is a remarkably thorough exposition of the legal aspects of consent but few clinicians have read this or the accompanying *Good Practice Guide*.[9] They explain that the new consent forms can contain pre-printed information about different procedures, including risks of anaesthesia (which have been succinctly described by The Royal College of Anaesthetists in their *Raising the Standards: Information for Patients*[10]).

Patients retain more and have a better chance to make informed decisions if they are given written information.[11] Surgeons not only serve their patients well but also simplify their own practices if they use good written information for all common operations. In the current climate of demand for information, patient choice and medicolegal threat, it seems incredible that patients should be offered common procedures without provision of good booklets about their condition, alternative treatments, recovery from surgery and risks. However, both anecdotal and published evidence suggests that this is common practice.[5]

Well-crafted booklets are the key to making the new consent forms 'user friendly' for both patients and surgeons. Each procedure-specific consent form can then include reference to a thorough information booklet which has been given to the patient (and archived for medicolegal use). Text from the booklet about risks of the procedure can then be printed on the consent form, either in full or preferably using headings (for example 'nerve damage; deep vein thrombosis; risks of a general anaesthetic' – exactly as in the booklet). The list and description of risks in each booklet should be thorough and should be agreed by all surgeons involved. They should include reference to **all** risks[12] which might be considered relevant by a 'reasonable man' or 'prudent patient' – the concept of telling patients only about 'minor complications with a > 10% risk and major complications with a > 1% risk' is no longer tenable.

Each pre-printed consent form should also contain a simple sentence about intended benefits (for example, 'to treat your varicose veins and any symptoms they are causing'). A 'generic' consent form can be used for individual patients or for uncommon or unique operations.

It is vital to remember that signing a form is just one stage in the process of consent. When considering the place of a signed form in the consent process it is worth remembering that:

- *Good records about discussions with patients in letters and written notes are at least as important as a signed form.*
- *A record of oral consent by the patient is entirely adequate if they cannot sign.*
- *When a patient lacks the capacity to consent, clear notes should be made about who else was involved in helping with decisions.*
- *Nobody else (including the next of kin) can sign a consent form on the patient's behalf: it is the duty of the responsible doctors to act in the patient's best interests.*
- *There is no requirement for any particular person to* hand *the consent form to a patient or to retrieve it from them, nor any need to witness it being signed.*

There is no 'right answer' about the ideal time and place for patients to sign consent forms: each unit needs to determine best local practice. All patients should receive written information when a procedure is first discussed and it may be appropriate to ask for consent forms to be signed in the out-patient clinic. For some procedures (*e.g.* endoscopy) both consent and the form may be dealt with 'on the day'. For complex major surgery, the form may best be dealt with on admission to hospital as a formality, after detailed counselling and documentation as an out-patient. It remains a mystery why consent forms are not regularly sent to patients by post, so that they can consider and sign them in the privacy of their homes.

Writing good patient information and dove-tailing this with consent forms takes time, effort and a degree of skill. Rather than 're-inventing the wheel' locally, professional societies, Royal Colleges or perhaps the National Institute for Clinical Excellence might take a lead, but they will need encouragement and commitment from clinicians. Surgeons who have found good solutions to the challenge of procedure specific consent forms might offer these as examples. I would be pleased to receive brief notification through the *Annals* office with a view to publication of ideas and contact details in a future issue.

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Improving risk disclosure during the consent process

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***Objectives*: To provide guidance about the risks which should be disclosed to patients and documented during the consent process.**
***Methods*: The Delphi Consensus Technique was used to decide what constitutes mandatory risk disclosure for three index procedures. Documentation of risk on consent forms was audited and compared to these locally agreed standards. A four stage strategy for change was undertaken following which practice was reviewed.**
***Results*: Mean mandatory risk documentation rose from 61.2% (95% CI: 58.1–64.4) pre-intervention, to 78.1% (95% CI: 72.6–83.6) post-intervention (ccc^2; $P < 0.001$).**
***Conclusions*: Although we demonstrated some benefit from this simple approach, the need for pragmatic means of achieving and sustaining complete discussion and documentation of risks across all surgical interventions based on universally accepted standards remains.**

Key words: Informed consent – Consent forms – Disclosure – Delphi technique – Consensus

Informed consent is becoming increasingly sophisticated and involves much more than a completed form.[1] The emphasis now focuses on facilitating adequately informed individual patient choice based on their personal values.[2] Comprehensive, relevant, and accurate risk disclosure is, therefore, essential. Towards this end, the Department of Health has recently produced a revised template for the standard consent form. The requirement for specific documentation of potential complications on the form represents a key change to previous versions.[3]

Discussion of every conceivable adverse outcome is impracticable. To date, practice has been based on precedents established in British law. Failure to mention a specific risk only constitutes negligent practice if 'a responsible body of professionals, in a similar situation, would have mentioned the risk'.[4] UK courts have since reserved the right to consider whether medical practice is reasonable.[5,6] Looking overseas, the 'responsible body of professionals' standard has been superseded by that of the 'reasonable patient'.[7,8] This correlates with an overall trend towards greater patient autonomy.[9] In future, only risk disclosure meeting a reasonable patient's needs may be adequate.

Currently in the UK, the problems are 2-fold. Agreed guidelines detailing what constitutes reasonable discussion of risk do not exist. A marked lack of consensus has been highlighted in various subspecialties.[10,11] Second, the discrepancy between what may be regarded as adequate risk disclosure, and actual practice has been previously highlighted.[11,12] Certainly, an heuristic assessment of current documentation led the authors to suspect that this shortfall in consenting practice also existed within their own department.

We set out to improve the quality of risk documentation in the new section of the revised consent form, to ensure that those conducting the process had been adequately prepared, and, in the absence of agreed national guidelines, provide a local professional consensus as to what constitutes a basic discussion of risk prior to surgery. The implicit secondary aim was to improve the quality of pre-operative counselling with regard to the discussion of potential complications.

Methods

The setting for the audit was a NHS teaching hospital serving a local population of approximately 400,000. The general surgical directorate employs 15 consultants, a further 12 middle grade doctors and 30 juniors. Practice was examined in relation to three index general surgical procedures – open appendicectomy, laparoscopic cholecystectomy and open inguinal hernia repair. The study comprised two separate components, a qualitative consensus of local opinion followed by an audit of change.

A local consensus was sought using The Delphi Process.[13] Each of the 15 consultants was interviewed independently to identify the risks they deemed to be relevant. All of these were subsequently presented to the interviewees as a cumulative list and each participant was asked which risks ought to be mandatory, preferred, or irrelevant. Those designated mandatory by 50% or more constituted a basic local standard for the purposes of measuring change. This synthesised list was offered to the consultant body for ratification prior to use.

An audit of change was undertaken. All index procedures occurring in a 2-month period were identified. The consent form for each was examined and the grade of the consenting doctor, along with the specific risks documented, was recorded.

Results of the first stage were analysed, shortfalls in practice identified, and improvement sought. A four-stage approach to engineering change was undertaken.

1. *All junior staff attended a plenary session outlining the requirements for a comprehensive consent process and the minimum spectrum of adverse events to be discussed for the index procedures.*
2. *All junior staff received written material as an aide memoir.*
3. *Similar aide memoirs were attached to every booklet of consent forms within the directorate.*
4. *Awareness of the problem was raised at a departmental audit meeting.*

Three months after the implementation of the above measures, a one month period was re-audited as before. Following the criticism that clinicians often discuss risk in the clinical setting and document this elsewhere, the case notes – including all correspondence and the daily clinical entries – were also examined. Any notation alluding to discussion of risk, or provision of written patient orientated information, was recorded.

Results

The results of the consensus of local consultant opinion are shown in Table 1. Over the initial 2-month audit period, 193 index procedures were performed for which 147 sets of notes and consent forms were reviewed; 50 appendicectomies, 70 open hernia repairs and 27 laparoscopic cholecystectomies.

The seniority of the clinician most frequently obtaining consent tended to vary by procedure. For example, 51% of herniorraphy patients were consented by a consultant compared with only 11% by a house officer. In contrast, 78% of laparoscopic cholecystectomy patients were consented by house officers with none consented by consultants (Fig. 1).

Table 1 Agreed mandatory risks to be discussed, for the purposes of assessing practice

Laparoscopic cholecystectomy	
	Bleeding
	Infection
	Retained stone
	Bile duct leak
	Biliary injury
	Conversion
Open hernia repair	
	Bleeding/haematoma
	Infection
	Recurrence
	Pain/chronic pain
For recurrent hernias	
	Testicular atrophy/orchidectomy
Open appendicectomy	
	Bleeding/haematoma
	Wound infection
	Pelvic collection
	Normal appendix

Risk documentation was universally poor. Only 2% of appendicectomy, 22% of herniorraphy and no laparoscopic cholecystectomy consent forms met even the rudimentary requirements established by the local consensus. In some cases risk documentation was entirely absent (Figs 2–4).

During the second period, 81 cases were identified for which 62 sets of case notes were retrieved; 30 appendicectomies, 24 open hernia repairs and 8 laparoscopic cholecystectomies.

Overall, there was a marked improvement with over 75% of consent forms for each procedure documenting a near complete (maximum of one omission) set of the basic risks. Most notably, three-quarters of the forms for laparoscopic cholecystectomy (all completed by house officers) demonstrated complete risk documentation (Figs 2–4). The mean percentage of basic risks documented rose from 61.2% (95% CI: 58.1–64.4) pre-intervention, to 78.1% (95% CI: 72.6–83.6) post-intervention. A χ^2 comparison of the proportion of risks documented between the two periods demonstrated a significant improvement ($P < 0.001$).

Finally, in only 4 of the 62 cases in the second audit was there any documentation, aside from the consent form itself, referring to risk disclosure or the provision of written information for the patient's perusal. In all four cases, specific risks were not detailed.

Discussion

Initial documentation in our department failed to meet even rudimentary standards, but minimal training, raising awareness, and providing convenient reminders significantly improved practice for three isolated procedures. To produce

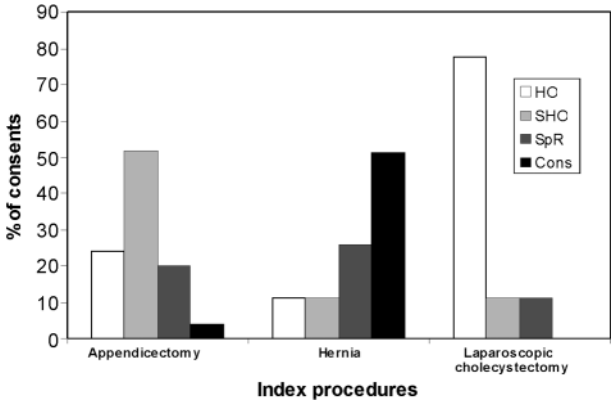

Figure 1 Percentage of consents obtained by each grade for the three index procedures.

this level of improvement across the board, two aspects of the process require consideration.

First, we must ensure that those persons seeking consent have received appropriate training. NHS guidelines recommend that those providing treatment, those capable of performing the procedure in question, or those specifically trained to seek consent for that procedure[14] should obtain consent. With junior doctors completing the majority of forms, training must be targeted accordingly; the benefits have been previously reported.[15] An alternative, given that the consent process is 'clinician-time-costly', may be to delegate the task to appropriately trained non-clinical staff. This may, however, result in a missed opportunity for cementing the doctor–patient partnership, a prerequisite for shared decision making.[16]

Second, comprehensive risk disclosure must be ensured. To achieve this, two provisions must be made – agreed guidelines as to what constitutes sufficient risk

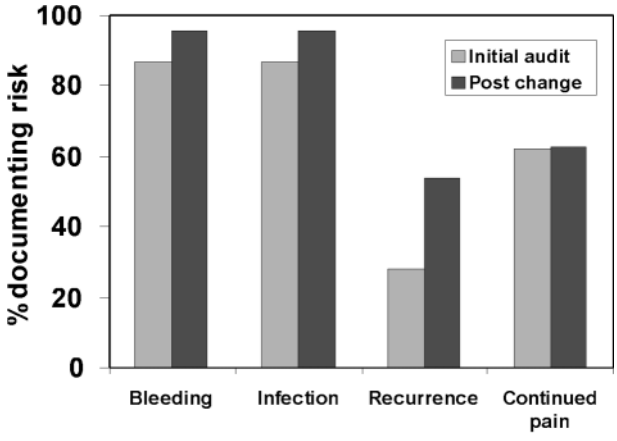

Figure 2 Percentage of mandatory risks documented for open herniorraphy, pre- and post-implementation of change.

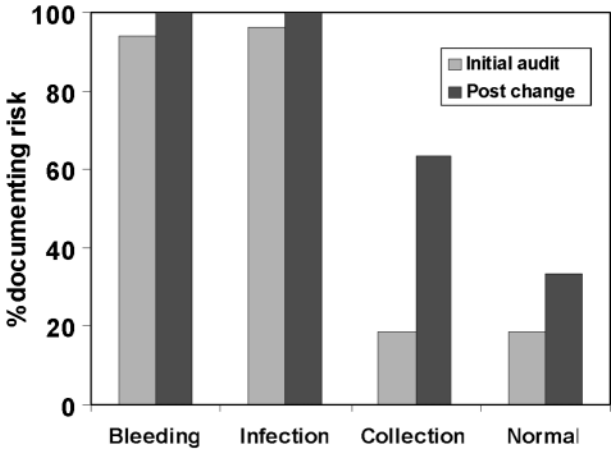

Figure 3 Percentage of mandatory risks documented for open appendicectomy, pre- and post-implementation of change.

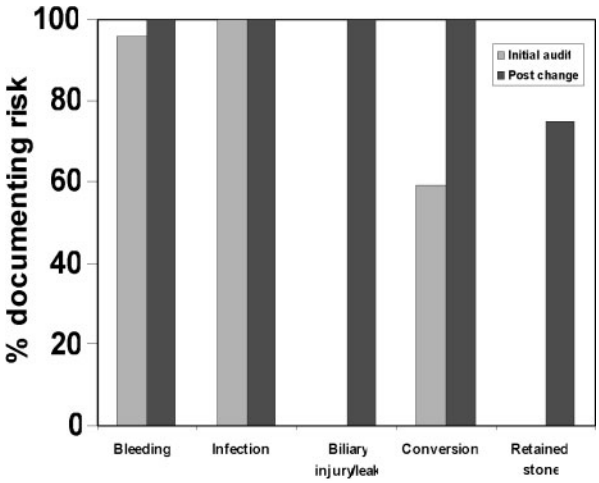

Figure 4 Percentage of mandatory risks documented for laparoscopic cholecystectomy, pre- and post-implementation of change.

discussion, and a pragmatic means of securing invariable comprehensive disclosure. The former may be achieved through a national consensus along similar lines to this study. In addition, other relevant stakeholders' opinion, those of the patients and the judiciary, should be involved, and the remit should be extended from compiling a basic list to one that satisfies the 'reasonable patient' standard. Addressing the latter is less straightforward though a number of solutions already exist.

Given the repertoire of procedures within each specialty and the number of possible adverse events associated with each one, repeated flawless comprehensive recall of complications, from memory alone, is unlikely. We have shown that for these selected procedures, aide memoirs result in fuller documentation. Although they demonstrate the potential benefits of written reference material, the extension of their use to all medical interventions seems impractical. Furthermore, in most hospitals (including our own), patient-centric information already exists in the form of information booklets which include an appropriate written disclosure of risk and are of proven benefit.[17] Their provision, along with documented patient acknowledgement of this, should become an obligatory component of the process and should be as much of a prerequisite for surgery as the patient's signature.

An alternative strategy is being trialled by the British Association of Urological Surgeons. Individual consent forms for all routine procedures, which include in their format a comprehensive listing of associated risks, are being provided as an alternative to the current generic forms.[18] Common to both this procedure-specific form and the patient information booklet is the use of written material to obviate the need for the memorising and recalling of all risks. Both do, however, rely on the inclusion of a reasonable listing of adverse events for their validity.

The lack of consensus regarding what constitutes a 'reasonable discussion of risk' in the opinion of a 'relevant professional body' has been highlighted. Similarly, in practice, without written prompts, documentation of this discussion having taken place is universally poor. The challenge remains to adopt universally pragmatic means of achieving and sustaining complete discussion and documentation of risks for all interventions. These being those accepted as meeting 'a reasonable patient's' expectations.

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'Will you be doing my operation doctor?' Patient attitudes to informed consent

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***Background*: As part of the consent process, it is part of a doctor's duty of care to reveal any material risk. Depending upon the level of supervision, whether the operating surgeon is a trainee may be such a risk, but in our experience this is not routinely discussed with patients pre-operatively. We set out to discover patients' attitudes to being operated on by trainee urological surgeons.**
***Patients and Methods*: A total of 101 completed questionnaires were received from patients (90 male, 11 female, mean age 72 years) undergoing transurethral resection of the prostate (TURP), transurethral resection of a bladder tumour (TURBT) or cystodiathermy on various aspects of their attitudes to being operated on by junior doctors as part of training.**
***Results*: The response rate was 77%. Of the respondents, 94 patients (91%) thought that junior doctors should perform surgery as part of their training. Only 11 of 73 (15%) said they would be happy for a junior doctor, competent to perform the procedure, to operate unsupervised. Of 98 patients, 80 (82%) thought they should be told if the operation was going to be performed by a junior doctor, and 85 (87%) that they should be told their name and designation.**
***Conclusions*: For consent to be 'informed', the experience and identity of the surgeon should be made known to patients. Most patients are happy to be operated on by a junior doctor under consultant supervision, but would want to be told and know their name and status.**

Key words: Consent – Surgery – Urology – Junior doctor

Informed consent is a legal requirement for all surgical procedures, and the basis of what informed consent should consist of is laid down not by medical authorities alone, but also legally, through case law. Case law in the UK is moving away from the Bolam principle in negligence claims[1] which holds that practitioners are not negligent if they act in accordance with practice accepted by a responsible body of medical opinion, to supporting what a reasonable patient might expect,[2] and in consent terms a reasonable patient would expect to be told of a material risk. A risk is material if 'in the circumstances of a particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it'.[3] The experience of a surgeon or, depending on the level of supervision whether the operating surgeon is a trainee, may represent a material risk. Guidelines from the General Medical Council[4] state information which patients might want to know may include whether doctors in training will be involved. Furthermore, it is clearly paramount that surgeons answer

all patients' questions concerning their surgery honestly. With the above facts established, what might be the reply to the patient's pre-operative question 'Will you be doing my operation doctor?' when asked of the consultant who knows that the registrar will be performing the procedure. Possible replies are shown in Table 1, but the only ethically and legally correct answer is the second one (providing that there will be supervision).[5] With this in mind, we set out to ascertain patients' attitudes to being operated on by trainee urologists.

Patients and Methods

A total of 132 questionnaires were given to patients undergoing transurethral resection of the prostate (TURP), transurethral resection of a bladder tumour (TURBT), or cystodiathermy in the postoperative period, and 101 completed questionnaires were returned (90 male; 11 female; mean age, 72 years; range, 48–91 years), giving a response rate of 77%. Of respondents, 44 patients underwent TURBT as the main procedure, 38 TURP, and 19 cystodiathermy. The questions are shown in Table 2.

Results

In all, 94 patients (91%) thought that junior doctors should perform surgery as part of their training. Only 11 (15% of the 73 who answered) said they would be happy for a competent junior doctor to operate unsupervised. Of 98 patients, 80 (82%) thought they should be told if the operation was going to be performed by a junior doctor, and 85 that they should be told their name and designation. If given the choice, 54 (57%) said they would wait and have a consultant operate but, in a separate question, 64 (74%) of patients also said that they would not mind a junior doctor operating on them unsupervised if it meant the operation could be done sooner.

Discussion

There is a clear ethical and legal duty to inform our patients fully prior to surgery. The right of patients to decide whether or not to undergo a procedure is protected in law, and doctors are expected to be aware of the legal principles set by relevant case law in this area.[4]

Table 1 Will you be doing my operation doctor?

Possible replies:

- The urology team is a team effort, with me, the consultant as 'team leader'. One of the team will perform your operation
- A supervised trainee will perform the procedure
- I will perform your operation with involvement of the trainee
- My morbidity and mortality rates when I assist trainees with this procedure are excellent when compared to national averages

Adapted from Jones and McCullough.[5]

Table 2 Postoperative questions asked and replies from patients

	Yes	No	No reply
Question 1			
(a) Do you think junior doctors should operate as part of their training	94	7	0
If YES, then			
(b) Would you be happy for a junior doctor to operate supervised by a consultant?	91	1	2
(c) Would you be happy for a junior doctor, capable of performing the operation, to operate unsupervised by a consultant?	11	62	21
Question 2			
Do you think you should be told if your operation is going to be performed by a junior doctor who is competent to perform the procedure?	80	18	3
Question 3			
Do you think you should be told of the name and designation of the surgeon who will perform your operation?	85	13	3
Question 4			
If having the consultant operate on you meant that your surgery might be delayed would you want to wait a bit longer so that the consultant could operate on you?	54	40	7
Question 5			
If having a junior doctor (one capable of performing the operation) operate on you meant that your operation could be done sooner would you want the junior doctor to perform your surgery?	64	23	14

With case law indicating that medical practitioners must disclose a material risk as part of the informed consent process, few would argue that a discussion of the experience of the operating surgeon, and whether they are a trainee and if so to what degree they will be supervised, is not relevant. This tenet was tested in the case of Dingle v. Belin,[6] where the patient and plaintiff Belin underwent a cholecystectomy. She had been assured prior to the operation that Dr Belin would perform the surgery and 'only use a resident to assist him as was absolutely necessary'. In the event, a fourth year resident, Dr Magnuson, performed the major part of the operation and a bile duct leak ensued, requiring further surgery and resulting in much pain and discomfort for the plaintiff. The case went to the appeal court, which held that in surgical procedures the surgeon must discuss and resolve with the patient the identity of which persons will be performing aspects of the surgery if the identity of those persons is important to the patient. The court emphasised that 'a physician who agrees to a specific allocation of responsibility …in order to obtain the consent of the patient to the procedure and then…proceeds in contravention of that allocation…has not obtained the informed consent of the patient'. Thus, if the patient asks as part of the informed consent process 'Will you be doing my operation doctor?', a complete and truthful answer must be given in order for the consent to be fully informed. The GMC guidelines on informed consent support this by saying 'you must respond honestly to any questions the patient raises'.[4]

The current NHS consent forms read 'I understand that you cannot give me a guarantee that a particular person will perform the procedure' as part of the statement which patients are asked to sign. However, this cannot absolve the doctor obtaining consent from an honest discussion with the patient about the identity and experience of the operating surgeon, particularly if the patient asks specifically about these points, as has been indicated by the GMC and developing case law.

The vast majority of patients agree that junior doctors need to operate as part of their training, and are happy to be operated on by junior doctors supervised by a consultant. However, they feel that they should be informed if a junior doctor will be performing their surgery, and be told their name and designation. These findings mirror those that have looked at patients' willingness to participate in clinical training of medical students.[7]

When patients were asked to balance their desire to be operated on by a consultant with the knowledge that they would have to wait longer to do so, 57% said they would wait and have a consultant operate, but, in a separate question, 74% of patients also stated that they would not mind a junior doctor operating on them if it meant the operation could be done sooner. Twenty-five patients indicated that they might want both options, and thus it would appear that patients want a choice, with their ultimate decision likely to depend upon the particular symptoms and prognosis in the individual case.

These results should not be extrapolated across all surgical disciplines. This patient group in question is elderly, predominantly male and their operations were not major, with many having undergone similar procedures previously. The findings may have been different if asked of patients undergoing more major surgery.

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Informed consent and surgeons in training: do patients consent to allow surgical trainees to operate on them?

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The issue of what defines informed consent is widely debated. General Medical Council guidelines specify that patients should have 'sufficient information before they can decide whether to give their consent'.[1] In addition to the risks, benefits, complications and alternative treatments available, we feel it is reasonable for the patient to be aware of who will perform their surgery, and this question should be raised prior to hospital admission. Our concern with this process was that if a high proportion of patients declined having a trainee performing their surgery, then this might impact on surgical training.

Patients and Methods

One hundred patients were asked if they would agree to 'a surgeon-in-training performing all or part of their surgery' before hospital admission in the form of a questionnaire. The results are shown in Figure 1.

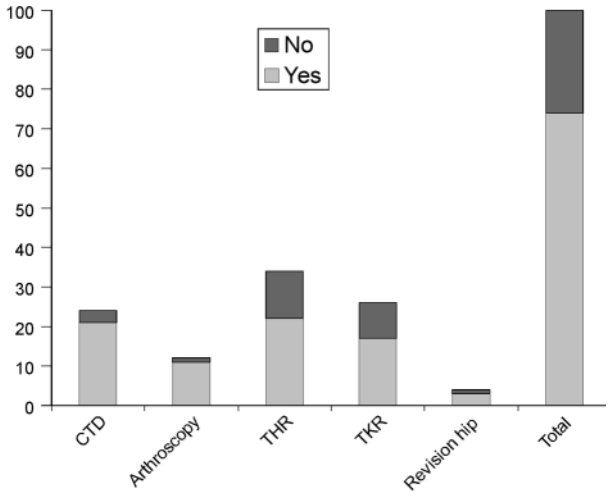

Figure 1 Numbers of patents prepared to allow trainees to do all or part of their operation. CTD, carpal tunnel decompression; THR, total hip replacement; TKR, total knee replacment.

Discussion

The most striking finding was the high proportion of patients prepared to allow trainees to perform part or all of their surgery (74%). This applied to smaller procedures, but also major cases with greater potential risks and complications.

An elective operating list should allow trainees to gain operative experience with patients aware of not only the risks, benefits and complications, but also who will be performing their operation. Detailed informed consent providing this information should not have an adverse impact on specialist registrar training.

References

1. General Medical Council. *Seeking Patients' Consent: The Ethical Considerations*. London: GMC, 2002.

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LETTERS

Response to paper by T Ibrahim, SM Ong, GJStC Taylor
The new consent form: is it any better?
*Ann R Coll Surg Engl 2004; **86**: 206–9*

Response 1

doi 10.1308/1478708041136

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We were interested to read this paper, having performed a similar audit on patients admitted with orthopaedic trauma. We had 50 patients in each group and examined the adequacy of consent with regard to the overall process and eight specific factors. The new form demonstrated an improvement in explanation of the diagnosis, risks, benefits, postoperative stay, and rehabilitation period. There was no benefit in the description of the operation or alternative treatments, information about the surgeon, or residual

impairment. There was a slight overall improvement with the new form, in terms of patients feeling adequately consented, feeling involved in their management, and recalling signing the form.

These studies provide evidence that documentation of benefits and risks in the additional space on the new form is associated with improved understanding, presumably as it enforces discussion. Specific documentation on the form of information pertaining to the remaining categories studied is therefore justified, and we believe, advised. These additions, with procedure-specific forms, and written, audio or visual aids, would form a comprehensive 'gold standard' consent process. The decision to be made by higher committees is whether to adopt these further changes on a national basis, accepting the inherent time and financial costs.

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Response 2

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We read this article, in which the authors compared the efficacy of the new consent form with the old on the quality of consent, with interest. We were particularly interested in the conclusion in which it is suggested that the use of supplemental material such as written, audio or video information will ensure that no aspects of consent are omitted. We have recently carried out an audit looking at the use of patient information booklets in the consent process. In 2000, we carried out a study at our institution to assess patients' understanding of information provided at the time of consent. We questioned 51 patients, who were to undergo primary or revision total knee or total hip arthroplasty, on their admission to the Robert Jones and Agnes Hunt Orthopaedic Hospital. The results revealed marked deficiencies in patient's comprehension as to what they had signed and why. As a direct result of this, patient information booklets were produced to help improve understanding and retention of information. In 2002, the same questionnaire was administered to a similar cohort of 50 patients undergoing primary and revision hip and knee arthroplasty at the same institution, all of whom had been provided with the information booklet. We found that patient information booklets made very little difference to the patients' understanding and retention of information and in some cases there was actually a deterioration in understanding. Following the results of our study, the use of patient information booklets at our institution is being reconsidered. We agree that a formatted consent form used in conjunction with supplemental material provides the patient with details of a procedure that can be kept for future reference. We disagree, however, with the claim that it necessarily improves the understanding of the procedure to be undertaken or that it will ensure no omissions of aspects of consent.

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Response 3

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We too have recently conducted a prospective study over a 2-month period at the Royal Glamorgan Hospital, South Wales, to establish the effectiveness and introduction of the new consent form. Unlike Taylor, we have not only considered the patients' views but also sought the views of doctors of all grades, with regard to the completeness of documentation of the forms and to address the increased time requirements for filling them in.

In our study, after the consent had been taken the forms were reviewed for completeness of documentation and a questionnaire was given both to the patient and doctors. Similar to Taylor, we found that the 'intended benefits' and what the operation entails better in the new forms. However, in our study, the risks of the actual operation in the new forms were very poorly filled out. Furthermore, it was found that the consultants' documentation was worse than any other grades, registrars being the best at completing the forms correctly. Despite this, patient satisfaction was the same be it consultant or junior doctor describing the operation. Lastly, most of the patients feel the white copy given to them was useful and the majority of patients were satisfied with the consenting process. It seems that the correct information is being imparted but the documentation is lacking. In our study, some patients felt that providing information leaflets would be of added benefit.

With regard to the doctors' point of view, the majority felt that the new forms were time consuming but better presented. There were a significant number of doctors

who were unsure as to when to fill in the confirmation of consent section and who is 'the responsible health professional'. In conclusion, we felt that patients and doctors were satisfied with the new consent forms and the process but some sections of the new consent form needed clarification. Attention still needs to be given to the accuracy of documentation as this has an impact on the medicolegal aspects of patient care.

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Response from the authors

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We were fully aware that the new consent form took more time than the old. However, we did not specifically measure this. Pollard *et al*. have highlighted the financial implication of this extra time. We feel that this time and money is well spent as it provides quality for the patient. It may well be recovered by decreased negligence claim costs.

Leaflets, booklets and audiovisual information supplied to patients have been shown in other studies[1] to improve quality of consent. However, this was not the case in the experience of McMurtrie *et al*. These controversial findings may mean this additional information is of no value or it may introduce a new variable. Time pressure may tempt clinicians to provide patients with leaflets, booklets and audiovisual information leaving the onus on the patient to understand this information without taking the time to explain it. McMurtrie *et al*. comment on patients' comprehension and retention of information. We believe retention and comprehension are two separate issues. Most articles use retention as a measurable surrogate for comprehension. Accurate measurement of comprehension is very difficult.

Mittapalli *et al*. have raised the issue of quality of documentation. We strongly agree that this is very important. However, they have not demonstrated in their letter that better documentation leads to improved quality of consent. The other point raised by Mittapalli *et al*. is the view of doctors on the new consent form. Despite the increased time to consent patients, doctors were still satisfied with the new consent form. However, any future changes in the consent form need to ensure it is not too burdensome.

Finally, we believe information on the expected postoperative course should be included in the new consent form. The postoperative course affects all patients, whereas complications affect only a very small percentage.

Reference

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