



## Written consent – a prospective audit of practices for ENT patients

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### ABSTRACT

**INTRODUCTION** It is very important that patients are given sufficient time to consider the implications of surgical treatment.

**PATIENTS AND METHODS** The authors audited the consenting practices for patients undergoing surgery in a busy ENT unit.

**RESULTS** The first cycle demonstrated that 15% of patients were providing written consent for surgery on the same day as their operation. Subsequent to a simple change in departmental policy, this was reduced to 2%. The medicolegal implications of this audit are discussed with reference to current recommendations.

**CONCLUSIONS** This simple policy change not only protects the hospital trust from potential litigation but also provides a smooth journey for the patients from diagnosis to making the decision to operate and finally to undergoing surgery.

### KEYWORDS

Audit – Consent

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Recently, there has been a number of medicolegal cases in which the plaintiffs have argued that they were not given sufficient time to consider the consequences of procedures that they had just consented to have performed. The case of *Chester vs Afshar*, amongst others, has popularised the importance of giving patients sufficient time to consider carefully the full implications of their proposed surgery.<sup>1</sup> We have noticed that, in our ENT department, a proportion of patients are consented for their surgery on the same day as their surgery. In the event of an unfavourable surgical outcome, this practice may well substantiate the patients' case for compensation.

The aims of this study were to: (i) audit the number and types of patients that are being consented for surgery on the same day as their operations; (ii) introduce a mechanism to prevent this practice; and (iii) re-audit the number and types of patients that are being consented for surgery on the same day as their operations. The gold standard would be to ensure that all patients have been consented for their surgery prior to the day of surgery.

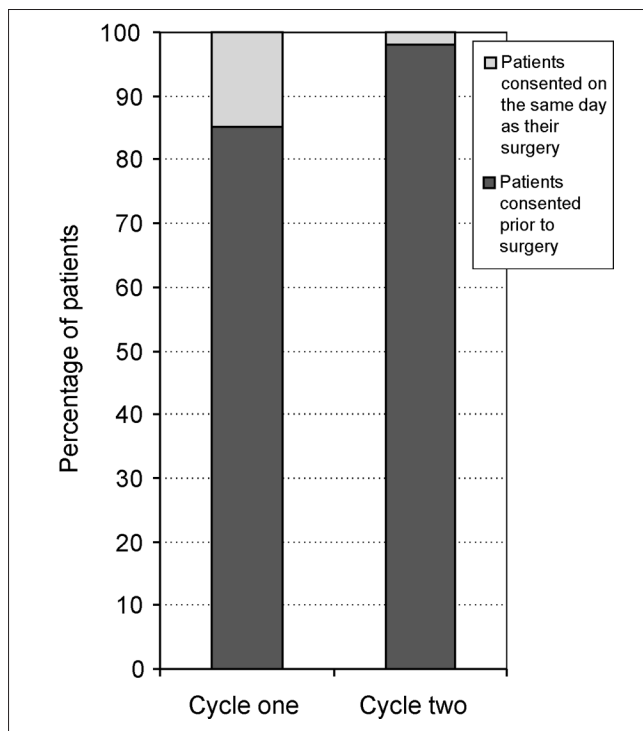
### Patients and Methods

This was a blinded prospective audit of patients without a valid consent form on the day of surgery. The information

was gathered by an ENT senior house officer (SHO) who was not involved with the consenting procedure. The rest of the departmental staff comprising 3 consultants, 3 registrars, 2 staff grades, 2 research fellows and an SHO remained unaware of the fact that the audit was taking place. Upon commencing the audit, the standard practice was for the patients to be consented in clinic at the time of listing for the operation and then to be seen in a pre-assessment clinic 1 week prior to surgery.

One-hundred, consecutive, patient case-notes were reviewed on the morning of surgery to determine whether consent prior to arrival for their elective operation had been obtained. Patients admitted for emergency operations were excluded from the audit. If consent was lacking, then a reason for the absence of consent was sought and noted solely from information available in the case notes.

The results were analysed and a new policy was introduced so that patients would not be able to progress from the pre-operative assessment clinic without a valid consent form being completed. This was initiated across adult and paediatric nurse-led pre-assessment clinics; if a consent form was not satisfactorily completed, the nurse running the clinic would contact an appropriate doctor to consent the patient at that time. Patients not attending a pre-assessment clinic for routine surgery had their operations



**Figure 1** The percentage of patients consented on the same day as their surgery both before and after the change in departmental admission policy.

postponed and were invited again to attend the clinic. This new policy was allowed to run for 6 weeks before a further 100 patients were audited using the same methods to complete the audit cycle.

## Results

### Cycle one

A total of 108 consecutive patients were audited over a 3-week period. Sixteen patients (14.8%) were consented on the same day as their surgery.

### Cycle two

A total of 105 consecutive patients were audited over a 3-week period. Two patients (1.9%) were consented on the same day as their surgery.

A comparison of these two cycles is shown in Figure 1.

### Reasons for lack of prior consent

Table 1 summarises the reasons for lack of a valid consent form prior to the day of admission for surgery.

## Discussion

It is important that patients have adequate time to consider the indications and implications of any potential operation.

Reason for lack of consent	Patients (n)
<b>CYCLE ONE</b>	
• No valid reason available from notes	13
• Consent form incorrectly completed	1
• Patient sent for cardiology review and added to list without another clinic review	1
• Joint operation with maxillofacial surgeons, not seen in ENT clinic	1
• <b>Total</b>	<b>16</b>
<b>CYCLE TWO</b>	
• Patient seen by community ENT specialist; therefore, not seen in pre-assessment	2
• <b>Total</b>	<b>2</b>

The process of informed consent is a continuous process and rushing a patient to give consent has ethical as well as medicolegal consequences. The UK General Medical Council (GMC) code of good medical practice states:<sup>2</sup> ‘in obtaining informed consent you should allow patients sufficient time to reflect, before and after making a decision, especially where the information is complex or the severity of risk is great. Where patients have difficulty understanding information or there is a lot of information to absorb it may be appropriate to provide it in manageable amounts over a period of time or to repeat it.’

There have been a number of medicolegal cases in which judgement has been in favour of the patient when it has been argued that insufficient time has been provided for adequate digestion and reflection of the relevant implications of surgical treatment. The case of Chester vs Afshar is often used to highlight this issue.<sup>1</sup> This case involved a patient with lumbar disc protrusion who was operated on electively 3 days after initial consultation by the surgeon. The patient ultimately ended up with cauda equina syndrome and proceeded to sue the surgeon on grounds of negligence. Cauda equina was considered as a recognised risk of the surgery but the patient was not informed of this risk pre-operatively. The patient admitted that, having known of this, she would still have undergone surgery. However, she claimed that she would have sought a second opinion had she had more time to do so. After an involved legal process, the award of compensation to the patient was finally ordered in the House of Lords.

There is no reason why patients cannot be consented in good time for routine elective surgery. There are a number of criticisms regarding consenting patients on the same day as their surgery. Patients are a lot less used to the hospital

environment and the whole process of being admitted for surgery is stressful and emotionally taxing. Often, patients have been waiting for their surgery for many months so the prospect of postponing their operation to consider further risks of surgery now presented in ‘black and white’ during the taking of consent is often difficult. Patients may feel further pressure to sign a consent form without discussing the risk presented with other family members, the original attending surgeon or family doctor. Once patients are gowned and sitting in bed awaiting their surgery, they are put in a position where they may feel it is more difficult to ‘back-out’ of their proposed operation. All these factors contribute to cause unease and, on occasions where the outcome of surgery has subsequently been unfavourable, can encourage patients to take legal measures in compensation.

Initially, we found that nearly 15% of our patients were being consented on the day of their surgery. In the majority of cases, no reason was given for the lack of consent at the time of listing and it was assumed that the consenting process was overlooked in the out-patient clinic. One patient required medical assessment before listing and was not seen again in the out-patient clinic for consenting: in another case, the consent form was completed incorrectly. The second cycle demonstrated how easily matters could be amended in the pre-operative assessment clinic to allow appropriately informed consent with time prior to the operation for the patients to assess the information they had been given. The results from the second cycle revealed a dramatic improvement from our change of policy but two patients were still consented on the day of their surgery. These had both been seen and pre-assessed by a community GP specialist in ENT. Although these patients should have

been consented by the ENT specialist in the community, he was not informed of the policy change or of the audit’s existence after the first cycle. We have since discussed the consenting procedure with him.

The new policy achieved its aims, as nearly all patients were consented prior to arrival for their surgery. As a result of the first audit cycle, there was some concern regarding such a strict policy that postponed patients who did not attend a pre-assessment clinic. The pre-assessment clinic has many roles including that of making provision for ensuring patients are medically fit and appropriate for their surgery. Despite concerns over long-waiting times and the strains on current operating lists, it is our duty to protect the well-being of the patient. We made sure that patients were informed regarding the consequences of not attending a pre-operative assessment clinic and confirmed that the operation was non-urgent before their postponement.

## Conclusions

It is important that patients are consented with enough time prior to surgery to allow them to digest and reflect upon information that has been provided. We have introduced a simple policy change that not only protects the hospital trust from potential litigation, but also provides a smooth journey for the patients from diagnosis to making the decision to operate and finally to undergo surgery.

## References

1. Case of *Chester vs Afshar*, House of Lords. 2003–2004.
2. General Medical Council. *GMC Guide to Good Medical Practice*. London: GMC, 2001.