

# Consent for Hernia Repair: Are we achieving informed consent?

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**Keywords:** *Hernia repair; Consent*

*Although inguinal hernia repair is one of the most common elective day case surgical procedures, there is evidence suggesting considerable variation in the quality and content of the information discussed with the patient.*

*We aimed to evaluate trends in adherence to consent guidelines, establish what clinicians include when consenting for inguinal hernia repair and examine patient recall of this information; using this data to suggest ways of improving the consent process.*

*A proforma was devised for data collection that included patient's age, grade of the surgeon obtaining consent, documented indications for surgery and associated risks, and patient recall of this discussion pre or post-operatively. In addition, if the patient received an information leaflet, it was asked whether this was found useful and would patients like an alternative form of information?*

*More than one third of consent forms had no documented benefit/indication for hernia repair, 63% of which were completed by consultants. Only 10% had evidence of consent discussed in the notes other than the consent form. 58% of all patients recalled no benefit/indication for surgery as having been discussed. Consultant grades were more likely to document chronic groin pain as a complication compared to junior grades. Less than half of all patients consented for chronic pain or testicular atrophy recalled these as potential complications.*

*Consistent with the literature, there is a wide variation in the consenting process for inguinal hernia repair within the department and patient recall is poor. By establishing and addressing the causes of this problem, we can aim to improve the quality of consent.*

## **Introduction**

The standards for obtaining valid consent for patient treatment are established by the GMC's "Consent Guidance: Patients and Doctors making decisions together"<sup>1</sup>. For an informed decision the discussion between doctor and patient must include the nature of the operation (the intended benefits/indications), and the potential risks/complications. This is clearly set out in the format of the standard consent form for adults. However, there is no set standard for what the clinician should be including in their discussion when consenting a patient specifically for inguinal hernia repair. Although inguinal hernia repair is one of the most common elective surgical procedures, there is evidence to suggest considerable variation in the quality and content of the information discussed with the patient. Consequently, patients may not be receiving adequate information for consent to be valid<sup>2-3</sup>.

Part of this variation may be attributed to the fact that what one clinician believes is of importance naturally differs from the other depending on their clinical experience. This may be reflected by research that demonstrates that specific information given when consenting patients, often depends on the grade of the

clinician, for example a study into the variations in quality of consent found that consultants were more likely to mention the complication of chronic pain than SpRs/SHOs (60% vs 35% SpRs and 7% SHOs), whereas juniors were more likely to mention the risk of recurrence (60% vs 88% SpRs and 93% SHOs)<sup>2</sup>.

To add to the problem, the level of information an individual wishes to receive, invariably differs from the next, and this must be respected by the clinician<sup>4</sup>. However, there is evidence to suggest that increased awareness of the operation and its potential complications does not increase anxiety levels<sup>5,6</sup>. Conversely, patients who are not fully aware of the peri and post-operative risks may experience greater levels of anxiety during their recovery period when unexpected complications occur<sup>7</sup>. This is particularly true of chronic groin pain after hernia repair, which can be debilitating<sup>8-10</sup>.

Effective information transfer is necessary for the patient to be able to come to a decision regarding their treatment.

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This requires the clinician to provide clear information in a way the patient can understand, and is aided by the provision of information in other formats such as a leaflet that the patient can read in their own time to recall their discussion with the clinician<sup>4</sup>. As well as protecting the patient’s autonomy and confidence in the clinician, it should not be forgotten that valid consent is essential in protecting the clinician from litigation should they fail to communicate the necessary information<sup>2,3</sup>.

We therefore set out to audit the standards of consent for inguinal hernia repair, with our primary aims to provide evidence of trends and adherence to guidelines for valid consent (as set out by the GMC Guidelines for Consent), i.e. the number of completed consent forms, with the standard set at 100%. We also aimed to establish what specifically patients are consented for when undergoing inguinal hernia repair. We devised a proforma (Appendix 1) that included the established benefits/indications for inguinal hernia repair and the most common and serious risks/complications of the operation, to which we set our standard against. We aimed to examine information transfer from clinician to patient by looking at patient understanding and recall following discussion with the clinician regarding the repair of their hernia.

**Patients and methods**

A prospective patient questionnaire and completion of a data collection sheet was conducted over the months of November 2009 to March 2010 at New Cross Hospital, Wolverhampton. Thirty-one male patients were included in the study. Selection was achieved by inclusion of any patient that I was able to see during the working day. These patients were seen immediately after their pre-operative assessment clinic, or pre or post-operatively.

Since the pre-operative assessment clinics at the Trust are run by pre-registered house officers, “first stage” of consent is generally obtained at the original outpatient clinic, and the “second stage” is achieved on the day of the procedure.

Data was collected from patient notes and the standard adult consent form:

- A) Patient demographics (age), the operation consented for and the grade of the clinician taking consent;
- B) Information documented as having been discussed with the patient;
- C) A discussion with the patient regarding what they understood/could recall regarding the operation and its risks/complications (without prompting).

The patient was also asked if they had received a patient information leaflet, if they found this useful and whether they would like any further information in a different format.

**Results**

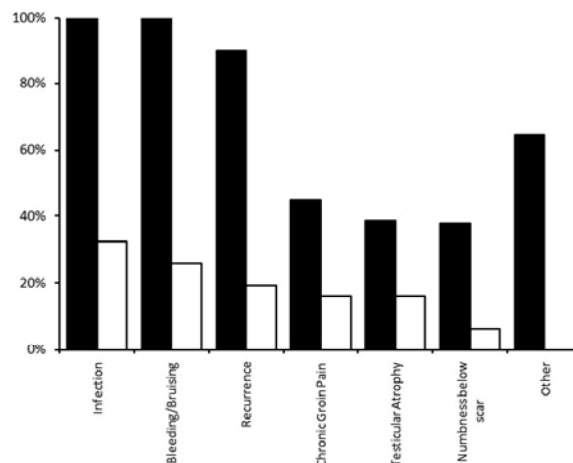
The average age of the patients included in the study was 65.5 years. Grades of clinicians obtaining consent included 21 (67%) SpRs, 8 (25%) consultants and 2 (6%) CT2s.

More than one third of consent forms had no documented benefit/indication for hernia repair, the majority of which had been completed by a consultant grade, while 57% of patients recalled no benefits/indications for their surgery (Table 1). 10% had evidence of discussion of consent in a place other than the consent form, such as in the clinic notes or clinic letter.

**Table 1** Benefits and Indications for Hernia Repair documented as discussed and then remembered by the patient.

Benefit	Documented (%)	Remembered by patient (%)
Relief of pain/discomfort	6 (19.4%)	4 (12.9%)
Prevention of bowel obstruction/strangulation	10 (32.3%)	6 (19.4%)
Both	3 (9.7%)	3 (9.7%)

The risks/complications from the proforma, documented as having been discussed with the patient together with recall rates are shown in Figure 2. Other risks cited were – thrombo-embolic, bowel/bladder injury, urinary retention, scar and anaesthetic risk (64.5%). Less than half of patients were made aware of the risk of chronic groin pain or testicular atrophy. 5 of the 8 consultants consenting documented chronic groin pain as a discussed complication and only 3/8 documented testicular atrophy. Less than one third of patients recalled infection or bruising as potential complications.



**Figure 2** Documented evidence that a complication had been recorded/discussed (■), and patient recall (□) of such discussion.

**Figure 1** Audit Proforma.

Hernia repair: Audit of Valid Consent – New Cross Hospital, Wolverhampton		
Patient details:	Age	Male/Female
<b>Section A: Procedure details</b>		
<i>Details of procedure to be performed:</i>		
Date of procedure: ___ / ___ / ___		
Grade of clinician taking consent: SHO/ SpR/ Consultant		
<b>Section B: Information documented in the notes as having been discussed with the patient</b>		
<b>Why is hernia repair indicated?</b>	Yes	No
• Pain /discomfort		
• Strangulation/bowel obstruction		
<b>Risks associated with the procedure?</b>		
• Infection		
• Bruising		
• Chronic groin pain		
• Testicular atrophy/ischaemia		
• Recurrence		
• Numbness/parasthesia below scar		
• Other		
<b>Section C: What the patient understands:</b>		
<b>Why are they having their hernia repaired?</b>	Yes	No
• Pain/discomfort		
• Strangulation/bowel obstruction		
<b>Risks associated with the procedure?</b>		
• Infection		
• Bruising		
• Chronic groin pain		
• Testicular atrophy/ischaemia		
• Recurrence		
• Numbness/parasthesia below scar		
<i>Did you receive a trust information leaflet?</i>		
<i>If yes - Was the leaflet useful?</i>		
<i>If no - Would you like to be provided with a leaflet?</i>		
<i>Would you find a CD explaining your hernia repair useful?</i>		

Patients were also asked about the patient information leaflet provided by the Trust. Sixteen patients report having received a patient information leaflet, of which fifteen found it useful. Almost one third of all patients believe another source of information such as a DVD would be useful to aid their understanding of their operation; why they were having it and what risks were involved.

**Discussion**

This audit demonstrates the large variation in the consenting process for inguinal hernia repair, which is consistent with the current literature. The fact that 38% of consent forms had no documentation of intended benefits/indications and that the majority of patients were unable to explain why they were having an operation, emphasises the extremes of this variation.

Although common risks/complications such as infection and bruising are mentioned in 100% of cases, one in ten patients were not told about the possibility of recurrence, a complication that we would also expect to be documented in 100% of cases. We found that less than half the patients had been consented for chronic pain, a common complication that has been found to have a severe impact on the patient’s quality of life<sup>8-10</sup>. In reference to litigation, one study showed that patients who did develop chronic groin pain, were more likely to report that they had not

been told of this complication prior to their operation, emphasising the need for clear, accurate documentation of what has been discussed with the patient<sup>6</sup>. Similarly, testicular atrophy, although rare, clearly has the potential to have a serious effect on the patient, should they be one of the unfortunate few to suffer from this.

This variety in the information discussed with the patient and documented by the clinician may be due to several factors, including time constraints, or the clinician’s individual perception or personal experience of the possible risks and complications. Since only 8/31 clinicians consenting were of consultant grade, it is hard to speculate whether there is indeed a trend in the grade of doctors and the information provided when consenting. However, it should be noted that the consent taken by the CT2 grade, included both indications and 5/6 of the potential complications from the proforma.

A major limitation of the study is the small patient sample, which may not reflect the larger population. However, in contrast to previous studies with larger numbers, our audit recorded patient recall of aspects of consent alongside clinicians’ documentation. For example, despite 100% being consented for infection and bleeding, less than one third of patients recalled these as potential complications. This clarifies statements from the literature that the current method of transfer of information from clinician to patient is insufficient to provide valid consent.

Confounding factors that may influence the data on patient recall include the mean age of the patient cohort (65.5 years); with an effect on level of memory and the paternalistic doctor-patient relationship often adopted by the previous generation. Literacy levels of the patient cohort should also be taken into account.

Only 16/31 patients were provided with an information leaflet, highlighting the failure of this part of the consent process that clearly needs addressing. We found, of the patients that did not receive an information leaflet, fewer were able to recall indications for their surgery compared to those who had receive an information leaflet. However, only one third of the latter group were able to recall the reason for their surgery, and 8/16 were unable to recall any risks/complications of the operation. This demonstrates that although information leaflets provide a vital role in reinforcing issues discussed with the clinician, they are not providing sufficient reinforcement for the majority of patients.

Despite these limitations, our findings clearly demonstrate that serious complications of surgery are not being discussed with the patient and patient recall is poor. In order to improve the quality of valid consent, certain aspects of the process need addressing. Firstly, the clinician needs to spend an adequate amount of time in their clinic discussing the reasons for the patient’s operation and the associated risks, clearly documenting their discussion in the clinic notes as well as the consent form. It is vital

that affirmation of consent is achieved following this initial consultation. Pre-printed procedure specific consent forms may be of benefit, providing an aide memoire for clinicians as well a copy of the discussion for the patient that they can read at their leisure, a way of reinforcing information for patients<sup>41-43</sup>.

Secondly, we must ensure every patient receives an information leaflet. This may be improved by availability of leaflets at both the first outpatient clinic and the pre-operative assessment. However, as we found, in order for improvement of information transfer from clinician to patient, an alternative format of information, such as a DVD may be of use. This audio-visual means of communicating information has been found in previous studies to optimise patient understanding and therefore improve the validity of consent<sup>44,45</sup>.

Future aims from this audit are to provide patients with the information required for valid consent for inguinal hernia repair in the format of a DVD alongside the standard Trust information leaflet, subsequently re-auditing to observe any improvement of patient understanding and recall.

We are forever advocating patient empowerment. So why aren't we encouraging our patients to understand the basics of their problem, how an operation can help and what can go wrong?

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