OPEN AND LAPAROSCOPIC INGUINAL HERNIA REPAIR: NORTH WEST CONSENTING PRACTICES

Audit Protocol

Prepared by: Project steering committee NWRC

07 April 2015
Version number: 1.1
AUDIT PROTOCOL

Full Name
Open and Laparoscopic Inguinal Hernia Repair: North West Consenting Practices

Short Name
Consent Audit

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Version 1.1
07 April 2015
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1. PROTOCOL SUMMARY

General Information

**Full Title:** Open And Laparoscopic Inguinal Hernia Repair: North West Consenting Practices

**Short Title:** Consent Audit

**Chief Investigators:** Miss C Slawinski, Mr N Heywood, Mr P Coe, Dr R Basson, Miss R Fish, Mr J Barker

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**Co-ordinating Group:** North West Research Collaborative

**Co-ordinating Centre:** Blackpool Teaching Hospitals NHS Foundation Trust

Study Information

**Indication:** To investigate the adequacy of written consent practices in the North West in relation to GMC and European Hernia Society guidelines for open and laparoscopic inguinal hernia repair.

**Design:** Retrospective observational audit

**Primary Outcome:** Adequacy of consenting practices for open and laparoscopic inguinal hernia repair

**Secondary Outcomes:** (1) Calculate the potential exposure of each trust to unconsented complications. (2) Compare written consent by grade of person consenting. (3) Compare written consent between centres.

**Study Timelines:**

- **Centre recruitment deadline:** 5pm Friday 1st May 2015
- **Audit dates:** May - June 2015
- **Data submission deadline:** 4pm Tuesday 30th June 2015
- **Data analysis:** July - August 2015
- **Results available:** September 2015
- **Abstract Submission:** MRAS 2015, ASIT 2016, European Hernia Society Meeting 2016
- **Paper submission:** January 2016
2. ABSTRACT

**Background:** Inguinal hernia repair is one of the mostly frequently performed general surgical operations; 65,000 procedures were performed in 2012/2013. Although serious complications are rare, litigation arising from this procedure has cost the NHS in excess of 7 million pounds sterling between 1995 and 2009, of which 10 per cent of claims were due to an issue with consent.¹ Previous UK publications have highlighted poor written consent practices which expose the NHS and Foundation Trusts to further litigation.² ³ Data on consent for these procedures in the North West of England are unknown.

**Aims:** The primary aim of this study is to audit the adequacy of written consent for open and laparoscopic inguinal hernia repair in the North West. Secondary outcomes are to (1) calculate the potential exposure of each trust to unconsented complications, (2) compare written consent by grade of surgeon and (3) compare written consent between centres.

**Audit Standards:** Audit standards are taken from GMC guidance which states, “you must tell patients if an investigation or treatment might result in a serious adverse outcome…You should also tell patients about less serious side effects or complications if they occur frequently”.⁴ The European Hernia Society Guidelines (EHSG) are used to determine frequently occurring and serious risks specific to open and laparoscopic inguinal hernia repair.⁵

**Methods:** A retrospective search of patients will be performed via clinical coding and the hospital theatre lists to identify all patients undergoing open and laparoscopic inguinal hernia repair between 01.08.2013 and 31.07.2014. A sample of these patients’ consent forms will be selected to be included in the study. Data will be collected from consent forms, anaesthetic records, and patient case files, and inputted into a standardised database, kept at each contributing site. Inclusion criteria are any elective open or laparoscopic inguinal hernia repair performed in patients aged 18 years or over.

**Results:** Results will be analysed to compare consenting practices by hospital and grade of person consenting. Accepted complication rates will be used to calculate a predicted number of patients that aren’t consented for a complication but are likely to suffer from that complication, and so calculate an individual hospital’s exposure.

**Discussion:** This study will assess adequacy of the current consent process and identify variation between centres in the North West, and grades of surgeons completing the consent form. Results will be fed back to all participating centres, together with suggestions for improvement in the written consent process.
3. INTRODUCTION

Inguinal hernia repairs are one of the mostly frequently performed general surgical operations, the majority of which are uneventful procedures. Complications such as chronic pain and testicular atrophy are well known risks, which may directly impact on patients’ quality of life, some of whom will attempt to claim clinical negligence against the operating surgeon or the health care trust. Since its inception in 1995, the National Health Service Litigation Authority (NHSLA) has received 37,528 claims and paid out £3,742,480,000 in surgery alone (excluding “below excess” claims handled by the Trusts). An analysis of NHSLA data between 1995 and 2009 revealed a total of 398 claims following groin hernia repair. 46.6% were successfully won by the claimant, amounting to £4,235,718 in damages and £3,122,492 in associated costs, with an average pay-out of £52,099 per claim. The most common reasons for litigation were testicular and cord structure injury (19.8%) and chronic pain (19.6%). Moreover, 10% of claims were related to consent issues. Similarly, an MDU analysis of 314 claims against general surgeon members, found that nine per cent of claims were related to lack of informed consent. And of the claims relating to inguinal hernia repair the most common complications were testicular atrophy (21%) and post-operative pain (24%).

Two studies in two separate UK centres have shown the inadequacy of consent in open inguinal hernia repairs, including consent for serious complications such as testicular atrophy (consented in 19 - 45.4%) or chronic pain (consented in 14 - 30%), with variability between grades of the consenting clinician. These two studies did not assess all complications related to inguinal hernia repair, as described in the EHSG. Additionally, consent adequacy for laparoscopic inguinal hernia repair has not been studied.

Consenting practices for open and laparoscopic inguinal hernia repair have not been previously assessed in the North West. We hypothesise that current practice is inadequate, potentially exposing NHS Trusts financially, and we do not know the extent of this risk. Additionally, this practice may vary according to the surgeon’s training level and may identify a training need for more junior trainees.
4. AIMS & OBJECTIVES

The overall aim of this audit is to assess current practice for written consent within NHS Trusts across the North West. We will do this by assessing the following outcomes:

**Primary outcome:**

(1) Adequacy of written consent forms for primary elective laparoscopic and open inguinal hernia repair. GMC guidance on consent and the complications identified by the EHSG have been used as audit standards.

**Secondary outcomes:**

(1) Calculate the potential exposure of each trust to unconsented complications

(2) Compare written consent by grade of person consenting

(3) Compare written consent between centres.

The results of this audit will be fed back to individual NHS Trusts in order to improve the consent process.
### 5. AUDIT STANDARDS

<table>
<thead>
<tr>
<th>Standard</th>
<th>Source</th>
<th>Target</th>
<th>Exceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>You must tell patients if an investigation or treatment might result in a serious adverse outcome, even if the likelihood is very small.</td>
<td>GMC⁴</td>
<td>100% for each risk</td>
<td>None</td>
</tr>
<tr>
<td>You should tell patients about less serious side effects or complications if they occur frequently (accepted practice is to consent for all complications with &gt;1% risk of occurrence)</td>
<td>GMC⁴</td>
<td>100% for each risk</td>
<td>None</td>
</tr>
<tr>
<td>Open inguinal hernia repair</td>
<td>EHSG⁵</td>
<td>100% for each risk</td>
<td>None</td>
</tr>
<tr>
<td>- Haematoma</td>
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<td></td>
<td></td>
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<tr>
<td>- Seroma</td>
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<td></td>
<td></td>
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<tr>
<td>- Bleeding</td>
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<td>- Wound infection</td>
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<tr>
<td>- Mesh infection</td>
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<tr>
<td>- Urinary retention</td>
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<tr>
<td>- Bladder injury</td>
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<td>- Bowel injury</td>
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<tr>
<td>- Vessel injury</td>
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<tr>
<td>- Testicular atrophy/ischaemic orchitis (male only).</td>
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<tr>
<td>- Damage to cord structures (vessels/nerves/vas) (male only).</td>
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<tr>
<td>- Pain</td>
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<td>- Chronic pain</td>
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<tr>
<td>- Numbness</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>- Recurrence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laparoscopic inguinal hernia repair</td>
<td>EHSG $^5$</td>
<td>100% for each risk</td>
<td>None</td>
</tr>
<tr>
<td>-----------------------------------------------------------------</td>
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<td>---------------------</td>
<td>------</td>
</tr>
<tr>
<td>• Haematoma</td>
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<tr>
<td>• Seroma</td>
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<td>• Bleeding</td>
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<td>• Wound infection</td>
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<tr>
<td>• Mesh infection</td>
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<tr>
<td>• Conversion to open</td>
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<tr>
<td>• Urinary retention</td>
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<td>• Bladder injury</td>
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<td>• Bowel injury</td>
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<tr>
<td>• Vessel injury</td>
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<tr>
<td>• Testicular atrophy/ischaemic orchitis (males only)</td>
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<tr>
<td>• Damage to cord structures (vessels/nerves/Vas) males only</td>
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<tr>
<td>• Bowel obstruction (TAPP technique)</td>
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<tr>
<td>• Port-site hernia</td>
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<tr>
<td>• Mesh rejection/migration</td>
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<tr>
<td>• Pain</td>
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<tr>
<td>• Chronic pain</td>
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<tr>
<td>• Numbness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Recurrence</td>
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<td></td>
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</tr>
</tbody>
</table>
6. DESIGN AND METHODS

Study Timelines:

(1) Registration Deadline: 1st May 2015.
(2) Study phase: May - June 2015
(3) Data Submission: 4pm Tuesday 30th June 2015
(4) Data Analysis: July – August 2015
(5) Results available: September 2015
(6) Abstract Submission: Manchester Regional Association of Surgeons 2015
    Association of Surgeons In Training 2016
    European Hernia Society Meeting 2016
(7) Paper Submission: January 2016

Study type
This study is a multi-centre, retrospective observational audit. A retrospective audit was selected in order to reduce the risk of bias associated with knowledge of the audit being undertaken prospectively.

Site eligibility and registration
Any NHS centre within Health Education North West that provides elective primary open and/or laparoscopic inguinal hernia repairs is eligible to participate in the audit and contribute patient data. Each site will be required to recruit a named consultant for local audit registration, in addition to trainee collaborators, for local data collection. The audit must be registered locally with each hospital’s clinical audit department. The hospital registration form (appendix B) must be returned by 5pm Friday 1st May 2015.

Each site must obtain permission for their data to be published anonymously, as indicated on the hospital registration form (appendix B).

Each site must provide a minimum of 50 data sets for laparoscopic and 50 data sets for open inguinal hernia repair, and a minimum of 50 data sets per collaborator. Centres performing fewer than 50 laparoscopic or open inguinal hernia repairs in the two year audit period, must inform the steering committee, but will still be included as eligible providing data is collected on all available cases.

Patient eligibility criteria
All patients undergoing elective primary open or laparoscopic inguinal hernia repair aged 18 years or over.
Patient identification
Patients will be identified via a retrospective search of clinical coding and theatre records for open and laparoscopic inguinal hernia repair performed between 01.08.2013 and 31.07.2014. A sample of patients from these two lists will be selected according to the following protocol:

- Each list (open and laparoscopic) of patients should then be ordered according to date of operation.
- Divide the total number of patients in the list by the number of patients required (according to the number of collaborators) to give a figure x.
- Select every x number of cases to request.
- For Example: If 200 open inguinal hernias are returned in the search and one collaborator is collecting all information and is required to collect 50 case notes: 200/50 = 4. Every 4th set of notes should then be requested.

Data collection
Data collection will be recorded according to a standardised data collection proforma (appendix D and E). To reduce the risk of inter-collaborator variability, we ask that all collaborators refer to the guidance for completion of data collection (appendix F).

Data will be collected from a number of sources:

1. Demographic/admission/operative data, (Case notes, anaesthetic records, operation notes)
2. Consent data (consent forms)

Hospital related variables will be collected via a questionnaire to be completed at the start of the study.

Data Input
It will be the responsibility of the local collaborators to ensure that data is entered into the standardised Microsoft Excel® spread sheet.

Confidentiality
It will be the responsibility of local collaborators to ensure that the data is held on a local computer and remains password protected. No patient identifiers must be submitted to the co-coordinating group.
Data submission
After completion of data collection, spread sheets will be submitted to the steering group via a secure NHS email. Any patient identifiers used for the purposes of data collection within the respective Trusts must be removed prior to submission of data.

Study outcomes:
Primary Outcome:
1. All serious or frequently occurring risks are stated on the consent form for open and laparoscopic inguinal hernia repair.

Secondary Outcomes:
1. Calculation of the potential exposure of each trust to un-consented complications.
2. Variation in consent between centres
3. Variation in consent between grades of surgeon

Data Analysis:
Data analysis will be performed by the steering committee, and each Trust will be provided with a summary of their individual results. All data will remain anonymous. Hospital data will be compared however, individual surgeons/hospitals/trusts will not be identified.
7. VARIABLES FOR DATA COLLECTION

1. Demographics
   a. Age
   b. Gender
   c. ASA grade

2. Admission details
   a. Length of hospital stay

3. Operation details
   a. Operation date
   b. Laterality of hernia repair (left, right, bilateral)
   c. Type of repair (Open, Trans Abdominal Pre-Peritoneal (TAPP), Total Extra-Peritoneal (TEP))
   d. Grade of surgeon operating
   e. Grade of most senior surgeon scrubbed

4. Consent details
   a. Grade of consenting clinician
   b. Benefits explained
   c. Risks included (see data collection proformas)
   d. Copy of consent form given to patient

5. Day case data
   a) Overnight stay?
   b) Reason for overnight stay?
8. AUTHORSHIP

A manuscript for publication will be produced by the steering group. Eligibility for authorship will be determined according to the NWRC Authorship policy,8 based on the International committee of medical journal editors’ guidance.9 This can be accessed at: http://nwresearch.org/documents-and-downloads/. Study collaborators from each hospital will be eligible to be listed as citable collaborators on “pubmed” providing that they have individually contributed to the data collection. To be eligible as a citable collaborator we require a minimum of 50 complete data sets per person. Failure to submit a completed data set (a minimum of 95% complete) may result in the data and the collaborators not being included in the study and authorship list.
10. REFERENCES


6. Factsheet 3: Claims information. Found at:

7. MDU Claims analysis general surgery. Nov 2012. Found at:

8. NWRC Authorship policy. Found at:

9. ICMJE. Defining the Role of Authors and Contributors. Found at
11. APPENDIX

Appendix A: how to register this audit

1. Identify a supervising consultant who will support the study and agrees to be named as the Supervising Consultant at your site.

2. Enlist trainee collaborators at your site who are willing to participate in data collection for the study (eligible to be on authorship list). Note that 50 complete data sets are required per local collaborator in order to be acknowledged as a citable collaborator, (please refer to section 8. Authorship).

3. Contact your audit department who will provide you with the information required to register the project and source patient data. Individual trust protocols must be followed locally to ensure appropriate registration and completion of audit projects.

4. Complete and submit the necessary audit proposal forms to the audit department (please ensure that audit departments are aware that this is part of a regional audit; data will be used for publication, Caldicott principles will be adhered to and no identifiable patient information will be submitted).

5. Once you have received approval from your audit department please send this to c.slawinski@nhs.net together with the registration form (see appendix B) by 5pm 30.04.2015 at the latest.
Appendix B: Consent Study Registration Form

<table>
<thead>
<tr>
<th>Consent Study</th>
<th>Collaborator Name</th>
<th>Grade/Specialty</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trust</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital Address</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultant Supervisor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trainee 1</td>
<td></td>
<td></td>
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<tr>
<td>Trainee 2</td>
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<td></td>
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<tr>
<td>Trainee 3</td>
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<td></td>
<td></td>
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<tr>
<td>Trainee 4</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I confirm that I have obtained local permission for publication of anonymised Trust results according to local Trust policies.

Signed: ________________________________

Print name: ________________________________ (Supervising Consultant)

Please complete and return this form to c.slawinski@nhs.net by 5pm Friday 1st May 2015, together with confirmation of local audit approval and the Hospital Data Questionnaire (appendix C).
## Appendix C: Hospital Data Questionnaire

<table>
<thead>
<tr>
<th>Hospital Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of hospital</strong></td>
<td></td>
</tr>
<tr>
<td>- University/Teaching Hospital</td>
<td></td>
</tr>
<tr>
<td>- District General Hospital</td>
<td></td>
</tr>
<tr>
<td>- Community hospital</td>
<td></td>
</tr>
<tr>
<td>- Other _____________________________</td>
<td></td>
</tr>
<tr>
<td><strong>Approximately how many open inguinal hernia repairs are performed each year?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Approximately how many laparoscopic inguinal hernia repairs are performed each year?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Is inguinal hernia repair routinely offered as a day case procedure?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>How many general surgeons of the following grades are there in your centre?</strong></td>
<td></td>
</tr>
<tr>
<td>- Associate Specialist</td>
<td></td>
</tr>
<tr>
<td>- Trust grade SpR</td>
<td></td>
</tr>
<tr>
<td>- ST13+</td>
<td></td>
</tr>
<tr>
<td>- CT1/2</td>
<td></td>
</tr>
<tr>
<td>- Trust grade ST1 or 2</td>
<td></td>
</tr>
<tr>
<td>- FY2</td>
<td></td>
</tr>
<tr>
<td>- FY1</td>
<td></td>
</tr>
</tbody>
</table>

Please complete and return this form to c.slawinski@nhs.net by 5pm 1st May 2015, together with the Consent Audit Registration Form and confirmation of local audit approval.
# Appendix D: OPEN INGUINAL HERNIA REPAIR DATA COLLECTION PROFORMA

## 1. Demographics

| a. Hospital number | __________ |
| b. Age at operation | ________ years |
| c. Gender | Male | Female |
| d. ASA grade | 1 | 2 | 3 | 4 |

## 2. Admission Details

| a. Length of hospital stay | ___________ days |

## 3. Operation Details

| a. Operation date | ____/____/____ |
| b. Laterality | Left | Right | Bilateral |
| c. Type of repair | Open | Primary |
| d. Grade of Surgeon Operating: | ____________ |
| e. Grade of most senior surgeon scrubbed: | ____________ |

## 4. Consent Details

| a. Grade of consenting clinician: | Consultant |
| | Associate specialist |
| | Trust registrar |
| | ST3 + Trainee |
| | CT1/2 or equivalent |
| | FY2 |
| | FY1 |
| b. Benefits explained | Yes | No |
| c. Reason stated | ____________________________________________________ |

Consented for the following?

| d. Haematoma | Yes | No |
| e. Seroma | Yes | No |
| f. Bleeding | Yes | No |
| g. Wound infection | Yes | No |
| h. Mesh infection | Yes | No |
i. Urinary retention Yes No
j. Bladder injury Yes No
k. Bowel injury Yes No
l. Vessel injury Yes No
m. Testicular atrophy/ischaemic orchitis Yes No
n. Damage to cord structures (vessels/nerves/vas - male) Yes No
o. Pain Yes No
p. Chronic pain Yes No
q. Numbness Yes No
r. Recurrence Yes No
s. Other

“Copy of consent form accepted by patient”
t. Has been marked as: Yes No Not marked
u. Is the patient copy filed in the notes? Yes No

5. Day-case data
a. Overnight stay? Yes No
b. Reason for overnight stay? ________________________________

Consent Study Audit Protocol v1.1  Date 07.04.15  21
Appendix E: LAPAROSCOPIC INGUINAL HERNIA REPAIR
DATA COLLECTION PROFORMA

1. Demographics
   a. Hospital number __________
   b. Age at operation __________years
   c. Gender Male Female
   d. ASA grade 1 2 3 4

2. Admission Details
   a. Length of hospital stay __________days

3. Operation Details
   a. Operation date ____/___/____
   b. Laterality Left Right Bilateral
   c. Type of repair TAPP TEP Primary
   d. Grade of Surgeon Operating: __________
   e. Grade of most senior surgeon scrubbed: __________

4. Consent Details
   a. Grade of consenting clinician: Consultant
      Associate specialist
      Trust SpR
      ST3 + Trainee
      CT1/2
      Trust ST1/ST2
      FY2
      FY1
   b. Benefits explained Yes No
   c. Reason Stated ________________________________

Consented for the following?
   d. Haematoma Yes No
   e. Seroma Yes No
   f. Bleeding Yes No
   g. Wound infection Yes No
h. Mesh infection  
  i. Conversion to open  
  j. Urinary retention  
  k. Bladder injury  
  l. Bowel injury  
  m. Vessel injury  
  n. Testicular atrophy/ischaemic orchitis  
  o. Damage to cord structures (Vessels/nerves/vas - male)  
  p. Bowel obstruction (TAPP technique)  
  q. Port-site hernia  
  r. Mesh rejection/migration  
  s. Pain  
  t. Chronic pain  
  u. Numbness  
  v. Recurrence  
  w. Other  

“Copy of consent form accepted by patient”  
  x. Has been marked as:  
  y. Is the patient copy filed in the notes?  

5. Day-case data  
  a. Overnight stay?  
  b. Reason for overnight stay?  

Consent Study Audit Protocol v1.1  Date 07.04.15
Appendix F: Guidance for completing data collection

Open Inguinal hernia Repair

Question 1 a-d: Complete hospital number, age at operation, gender and ASA grade.

Question 2 a-c: Complete admission and discharge dates and calculate length of stay in days.

Question 3 a-e: Complete operation date, laterality of procedure, type of repair, grade of surgeon operating and grade of most senior surgeon scrubbed. If the grade of surgeon is unknown to you please ask a senior.

Question 4 a: complete grade of consenting clinician, if the grade of surgeon is unknown to you please ask a senior.

Question 4 b: Accept haematoma, or collection of blood or equivalent.

Question 4c: Accept seroma, or collection of serous fluid, or equivalent.

Question 4d: Accept bleeding, blood loss, or equivalent.

Question 4e: Accept infection, wound infection

Question 4f: must specify mesh infection,

Question 4g: accept urinary retention, or equivalent

Question 4h: accept bladder injury, or equivalent (not damage to organs)

Question 4i: Accept bowel injury, or visceral injury, or equivalent (not damage to organs)

Question 4j: Accept vascular/vessel injury (not damage to structures)

Question 4k: Accept testicular atrophy or ischaemic orchitis or loss of blood to testicle, or equivalent.

Question 4l: Accept damage to cord, or damage to cord vessels, nerves, vas.

Question 4m: Accept pain , discomfort, or equivalent

Question 4n: Must specify chronic pain.

Question 4o: Accept numbness, altered sensation

Question 4p: Accept recurrence, or equivalent

Question 4q: please state any additional risks consented for not included in the above.

Question 5a-b: Did the patient stay overnight? What was the reason for the stay?
**Laparoscopic Inguinal hernia Repair**

Question 1 a-d: Complete hospital number, age at operation, gender and ASA grade.

Question 2 a-c: Complete admission and discharge dates and calculate length of stay in days.

Question 3 a-e: Complete operation date, laterality of procedure, type of repair, grade of surgeon operating and grade of most senior surgeon scrubbed. If the grade of surgeon is unknown to you please ask a senior.

Question 4 a: Complete grade of consenting clinician, if the grade of surgeon is unknown to you please ask a senior.

Question 4b-c: are the benefits clearly explained and what is the reason stated?

Question 4 d: Accept haematoma, or collection of blood or equivalent.

Question 4e: Accept seroma, or collection of serous fluid, or equivalent.

Question 4f: Accept bleeding, blood loss, or equivalent.

Question 4g: Accept infection, wound infection.

Question 4h: Must specify **mesh** infection.

Question 4i: Conversion to open, ± open, or equivalent.

Question 4j: Accept urinary retention, or equivalent.

Question 4k: Accept bladder injury, or equivalent (not damage to organs/structures).

Question 4l: Accept bowel injury, or visceral injury, or equivalent (not damage to organs/structures).

Question 4m: Accept vascular/vessel injury (not damage to structures) or equivalent.

Question 4n: Accept testicular atrophy or ischaemic orchitis or loss of blood to testicle, or equivalent.

Question 4o: Accept damage to cord, or damage to cord vessels, nerves, vas, or equivalent.

Question 4p: Accept bowel obstruction/blockage, or adhesions, or equivalent.

Question: 4q: Accept port-site hernia, key-hole hernia, or equivalent.

Question 4r: Accept mesh migration/movement/rejection, or equivalent.

Question 4s: Accept pain, discomfort, or equivalent.

Question 4t: Must specify **chronic** pain.

Question 4u: Accept numbness, altered sensation or equivalent.
Question 4v: Accept recurrence, or equivalent.

Question 4w: please state any additional risks consented for not included in the above.

Question 4x-y: What has the section “copy of consent from accepted by patient?” been marked as? And is the patient copy of the consent form filed in the notes.

Question 5a-b: Did the patient stay overnight? What was the reason for the stay?