



# GROIN HERNIA GUIDELINES

May 2013

Association of Surgeons of Great Britain and Ireland

*ISSUES IN PROFESSIONAL PRACTICE*

Groin Hernia Guidelines



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Association of Surgeons of Great Britain and Ireland

## ISSUES IN PROFESSIONAL PRACTICE

# GROIN HERNIA GUIDELINES

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Groin Hernia Surgery Guidance Development Group  
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### PUBLICATION DATE

May 2013

### REVIEW DATE

May 2016

### PUBLISHED BY

Association of Surgeons of Great Britain and Ireland  
35-43 Lincoln's Inn Fields, London, WC2A 3PE

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Association of Surgeons of Great Britain and Ireland

**ISSUES IN PROFESSIONAL PRACTICE**

Groin Hernia Guidelines

## FOREWORD

*Issues in Professional Practice* (IIPP) is an occasional series of booklets published by the Association of Surgeons of Great Britain and Ireland to offer guidance on a wide range of areas which impact on the daily professional lives of surgeons. Some topics focus on clinical issues, some cover management and service delivery, whilst others feature broader aspects of surgical working life such as education, leadership and the law.

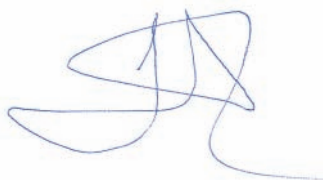
Inguinal hernia repair is one of the most common surgical procedures, and how effectively this is done in a healthcare system has a substantial social and economic impact. Although every surgeon is sure he/she can repair a hernia, information from the few national databases which exist in Europe have demonstrated how disappointing the results of groin (inguinal and femoral) hernia in general surgical practice are, and how widely they differ from the outcomes reported in the literature by enthusiastic experts.

Open or laparoscopic repair, local or general anaesthetic, day-case or short stay, what outcomes should be measured, and even whether every inguinal hernia should be repaired, are all issues that are currently being hotly debated. Thus, it was felt that this was an appropriate time to produce this IIPP. It is derived from a Guidance Document on Groin Hernias, requested by the Department of Health to assist Commissioners and local service providers in planning an appropriate "Hernia Service".

The authors have highlighted the important issues to be addressed in groin hernia surgery, and have presented objective, evidence-based guidance that will be useful to surgeons of all levels. Where evidence is lacking, this has been indicated. Indeed, the lack of good quality high-level evidence in a number of important areas is surprising, and suggestions for further research are listed at the end of the booklet.

The Association hopes that this publication, and others in the series (all accessible at: [www.asgbi.org.uk/publications](http://www.asgbi.org.uk/publications)), will provide concise advice and guidance on major current issues and grow into a helpful and accessible resource to support your professional practice.

Suggestions for any potential topics for future booklets in the *Issues in Professional Practice* series would be welcome.



**Professor John Primrose**  
**President**

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**ACKNOWLEDGEMENTS**

Additional support was received from Joanne Cripps, Erana Sitterie, Bazian and the East Midlands Observatory.

**ABBREVIATIONS**

|              |  |
|--------------|--|
| <b>ASGBI</b> | Association of Surgeons of Great Britain and Ireland |
| <b>BHS</b>   | British Hernia Society                               |
| <b>CI</b>    | Confidence interval                                  |
| <b>CQUIN</b> | Commissioning for Quality and Innovation             |
| <b>CT</b>    | Computerised tomography                              |
| <b>EL</b>    | Evidence level                                       |
| <b>EHS</b>   | European Hernia Society                              |
| <b>GDG</b>   | Guidelines Development Group                         |
| <b>MRI</b>   | Magnetic resonance imaging                           |
| <b>NICE</b>  | National Institute for Clinical Excellence           |
| <b>NHS</b>   | National Health Service                              |
| <b>OR</b>    | Odds ratio   |
| <b>RCT</b>   | Randomised control trial                             |
| <b>RR</b>    | Relative risk  |
| <b>SD</b>    | Standard deviation                                   |
| <b>SIGN</b>  | Scottish Intercollegiate Guidelines Network          |
| <b>UK</b>    | United Kingdom                                       |
| <b>USS</b>   | Ultrasound scan                                      |
| <b>WMD</b>   | Weighted mean difference                             |

# 1. INTRODUCTION

Inguinal hernia repairs are amongst the most commonly performed general surgical operations <sup>[1]</sup>. In the National Health Service (NHS), patients and surgeons have the choice between various techniques and materials, and currently it is left to the surgeon and healthcare policy makers to decide which to use. There is no national system of audit or follow-up, and the overall low reported recurrence rate following inguinal hernia repair makes it difficult to determine which procedure is best. Moreover, it is no longer sufficient to judge outcome solely in terms of hernia recurrence. Wound complications, length of hospital stay, chronic pain, patient experience, quality of life and cost should also be recorded <sup>[2]</sup>.

## 1.1 AIM OF THIS DOCUMENT

This document has been produced to present currently available best evidence in the management of groin hernia, in order to provide a resource for clinicians and other interested parties involved with delivering a high quality, cost-effective, evidence-based hernia service across Great Britain and Ireland, that meets the needs of the local population and takes into account patient experience. This document does not deal with other abdominal wall hernias, such as epigastric hernia, umbilical hernia and incisional hernia.

## 1.2 WHO HAS DEVELOPED THE GUIDELINE

This document was prepared by a health-care professional group convened by the Royal College of Surgeons of England and the British Hernia Society. The surgeons are practitioners of both open and laparoscopic repair and have a special interest in hernia surgery. Staff from the Royal College of Surgeons of England and information specialist Bazian provided methodological support for the guideline development process, helped with systematic searches and the retrieval and appraisal of the evidence.

## 1.3 GUIDELINE DEVELOPMENT METHODOLOGY

The guidelines have been developed in accordance with the Surgical Speciality Associations and the Royal College of Surgeons of England Commissioning Guidance Process Manual

([http://www.rcseng.ac.uk/surgeons/working/docs/commissioning-guidance-process-manual/at\\_download/file](http://www.rcseng.ac.uk/surgeons/working/docs/commissioning-guidance-process-manual/at_download/file)) and the AGREE II criteria ([www.agreetrust.org](http://www.agreetrust.org)).

### Literature search strategy

The aim of the literature review was to identify and synthesise relevant published evidence. Relevant guidelines produced by other development groups were identified using Internet resources, including the National Guideline Clearinghouse, Scottish Intercollegiate



Guideline Network (SIGN) and Turning Research into Practice (TRIP). The reference lists in these guidelines were checked against subsequent searches to identify missing evidence.

Evidence to answer the clinical questions formulated and agreed by the GDG, was identified using biomedical databases via the PUBMED platform. Searches were performed using relevant medical subject headings and free-text terms. No language restrictions were applied to the searches. Both generic and specially developed search filters were employed when necessary. Databases searched were MEDLINE (1966 onwards), EMBASE (1980 onwards), Cochrane Central Register of Controlled Trials (4th Quarter 2004), Cochrane Database of Systematic Reviews (4th Quarter 2004), Database of Abstracts of Review of Effects (4th Quarter 2004), and Cumulative Index to Nursing & Allied Health Literature (1982 onwards).

Searches to identify economic studies were undertaken using the above databases, as well as the Health Economic Evaluations Database and the National Health Service Economic Evaluations Database.

There was no systematic attempt to search grey literature (conferences, abstracts, theses and unpublished trials). Hand searching of journals not indexed on the biomedical databases was not carried out.

A preliminary scrutiny of titles and abstracts was undertaken, and full copies of publications that addressed the clinical questions were obtained. Following a critical appraisal of each publication, studies that did not report relevant outcomes or were not relevant to a particular clinical question were excluded.

Searches were re-run at the end of the guideline development process, thereby including evidence published and included in the literature databases up to October 2012. Any evidence published after this date was not considered for inclusion. This date should be considered for the starting point for searching for new evidence for future updates to this guidance document.

### Synthesis of clinical effectiveness evidence

Evidence relating to clinical effectiveness was reviewed using established guides<sup>13-51</sup>, and classified using the established hierarchical system shown in **Table 1**. This system reflects the susceptibility to bias that is inherent in particular study designs. The type of clinical question dictates the highest level of evidence that may be sought. In assessing the quality of the evidence, each paper receives a quality rating coded as ‘++’, ‘+’ or ‘-’. For issues of therapy or treatment, the highest possible level of evidence (EL) is a well-conducted systematic review or meta-analysis of RCTs (EL = 1++) or an individual RCT (EL = 1+). Studies of poor quality are rated as ‘-’. Usually, studies rated as ‘-’ should not be used as a basis for making a recommendation, but they can be used to inform recommendations. For issues of prognoses, the highest possible level of evidence is a cohort study (EL = 2-).



| Level | Source of evidence  |
|-------|---|
| 1++   | <ul style="list-style-type: none"> <li>High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias.</li> </ul>   |
| 1+    | <ul style="list-style-type: none"> <li>Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias.</li> </ul>  |
| 1-    | <ul style="list-style-type: none"> <li>Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias.</li> </ul>  |
| 2++   | <ul style="list-style-type: none"> <li>High-quality systematic reviews of case-control or cohort studies.</li> <li>High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal.</li> </ul> |
| 2+    | <ul style="list-style-type: none"> <li>Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal.</li> </ul>  |
| 2-    | <ul style="list-style-type: none"> <li>Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal.</li> </ul>  |
| 3     | <ul style="list-style-type: none"> <li>Non-analytical studies (for example, case reports, case series).</li> </ul>  |
| 4     | <ul style="list-style-type: none"> <li>Expert opinion, formal consensus.</li> </ul>   |

**Table 1: Levels of evidence for intervention studies** <sup>161</sup>

For each clinical question, the highest available level of evidence was selected. Where appropriate, studies of a weaker design were not included, for example, if a systematic review, meta-analysis or RCT existed in relation to a question. Where systematic reviews, meta-analyses and RCTs did not exist, other appropriate experimental or observational studies were sought. For diagnostic tests, test evaluation studies examining the performance of the test were used if the efficacy of the test was required, but where an evaluation of the effectiveness of the test in the clinical management of patients and the outcome of disease was required, evidence from RCTs or cohort studies was used.

For this guideline, the selection criteria for including studies as a source of evidence were based on the comparability of the study population and repair technique to that of the UK, as determined to be appropriate by the Guideline Development Group.

Evidence was synthesised qualitatively by summarising the content of identified papers in evidence tables and agreeing brief statements that accurately reflected the evidence.

Summary results and data are presented in the high quality care pathway. More detailed results and data are presented in the accompanying evidence section. Where possible, dichotomous outcomes are presented as relative risks (RRs) with 95% confidence

intervals (CIs), and continuous outcomes are presented as mean differences with 95% CIs or standard deviations (SDs). Meta-analyses based on dichotomous outcomes are presented as pooled odds ratios (ORs) with 95% CIs, and meta-analyses based on continuous outcomes are presented as weighted mean differences (WMDs) with 95% CIs.

### Health economics

The aim of the economic input to the guideline was to inform the GDG of potential economic issues related to service provision in the management of inguinal hernias, and to assess the cost-effectiveness of different methods. For this purpose, a systematic review of the economic literature was undertaken, together with a cost-effectiveness analysis based on a decision-analytic economic model that was developed for this guideline.

The search strategies adopted for the systematic review were designed to identify any economic study related to inguinal hernia. Abstracts of all papers identified were reviewed by the health economists and were excluded if they did not relate to the economic questions being considered in the guideline. The relevant papers were retrieved and critically appraised. Potentially relevant references in the bibliographies of the reviewed papers were also identified and reviewed. All papers reviewed were assessed by the health economists against standard quality criteria for economic evaluation.

The decision-analytic model was developed by the health economists with the support of the GDG, who provided guidance on the data needed to populate the model and on the assumptions required to make appropriate comparisons.

### Forming and grading recommendations

| Class    | Evidence  |
|----------|---|
| <b>A</b> | <ul style="list-style-type: none"> <li>• At least one meta-analysis, systematic review, RCT that is rated as 1++, and is directly applicable to the target population, or:</li> <li>• A systematic review of RCTs or a body of evidence that consists principally of studies rated as 1+, is directly applicable to the target population and demonstrates overall consistency of results, or:</li> <li>• Evidence drawn from a NICE technology appraisal.</li> </ul> |
| <b>B</b> | <ul style="list-style-type: none"> <li>• A body of evidence that includes studies rated as 2++, is directly applicable to the target population and demonstrates overall consistency of results, or:</li> <li>• Extrapolated evidence from studies rated as 1++ or 1+.</li> </ul>   |
| <b>C</b> | <ul style="list-style-type: none"> <li>• A body of evidence that includes studies rated as 2+, is directly applicable to the target population and demonstrates overall consistency of results, or:</li> <li>• Extrapolated evidence from studies rated as 2++.</li> </ul>  |

|                |   |
|----------------|---|
| <b>D</b>       | <ul style="list-style-type: none"> <li>• Evidence level 3 or 4, or:</li> <li>• Extrapolated evidence from studies rated as 2+, or:</li> <li>• Formal consensus.</li> </ul>        |
| <b>D (GPP)</b> | <ul style="list-style-type: none"> <li>• A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group.</li> </ul> |

**Table 2: Classification of recommendations** <sup>161</sup>

For each clinical question, recommendations were derived using, and explicitly linked to, the evidence that supported them. Initially, guideline recommendations were based on an informal consensus. Consensus was achieved at formal GDG meetings to finalise the agreement of recommendations and audit criteria. In cases where high-level evidence exists advocating a particular approach, investigation or technique ahead of another/others, it has been recommended. Areas of uncertainty have been flagged as priorities for further research. In these areas, and other domains where there is no clinical difference in outcomes, the most cost-effective approach (based on resource cost) has been recommended.

Each recommendation was graded according to the level of evidence upon which it was based using the established system shown in **Table 2**. For issues of therapy or treatment, the best possible level of evidence (a systematic review or meta-analysis or an individual RCT) would equate to a grade A recommendation. For issues of prognosis, the best possible level of evidence (a cohort study) would equate to a grade B recommendation. However, this should not be interpreted as an inferior grade of recommendation because it represents the highest level of relevant evidence.

### **Outcome measures used in the guideline**

For this guideline, the effectiveness of a particular approach to investigation and management of inguinal hernia has been assessed against a number of outcomes, which were agreed by the GDG on the basis of their relevance to patients and professionals. These outcomes are recurrence, chronic pain, infection and other adverse outcomes, length of hospital stay, patient experience and quality of life. Specific consideration was given to the effectiveness and use of these methods in specific groups patients, such as patients with ASA grade 3 or 4, patients with recurrent hernia, bilateral hernias, women, obese patients and those deemed at risk of chronic pain.

## 2. HIGH VALUE CARE PATHWAY

### 2.1 PRIMARY CARE

Which patients should be referred to secondary care, and which patients do not require referral?

|  |                |
|--|----------------|
| Patients with occult/asymptomatic/minimally symptomatic primary or recurrent inguinal hernias <b>AND</b> who have significant co-morbidity (ASA 3 or 4) <b>AND</b> who do not want to have surgical repair (after appropriate information provided) can be managed conservatively at primary care level. | <b>B</b>       |
| All other patients should be referred to a secondary care provider.  | <b>B</b>       |
| Hernia trusses should not be routinely used.   | <b>D (GPP)</b> |

What speed of referral should be requested?

|  |                |
|--|----------------|
| Men with reducible symptomatic inguinal hernias and those with occult/asymptomatic/minimally symptomatic hernias (who do not fulfil the criteria for conservative management at primary care level) should be referred as a ' <b>routine referral</b> '. | <b>D (GPP)</b> |
| Men with symptomatic hernias that have a history of being irreducible or that are currently irreducible or only partially reducible should be referred as an ' <b>urgent referral</b> '.   | <b>D (GPP)</b> |
| Women with groin hernias should be referred as an ' <b>urgent referral</b> '.  | <b>D (GPP)</b> |
| Patients with suspected strangulated or obstructed inguinal hernia should be referred as an ' <b>emergency referral</b> '.   | <b>D (GPP)</b> |

To which secondary care provider should patients be referred?

|  |                |
|--|----------------|
| Patients with primary inguinal hernias meeting referral criteria can be referred <b>generically</b> to an appropriate secondary care provider.   | <b>D (GPP)</b> |
| Patients with bilateral inguinal hernias (which do not fulfil the criteria for conservative management at primary care level) should be referred to a surgeon who performs <b>both</b> open and laparoscopic repair.   | <b>D (GPP)</b> |
| Patients with recurrent inguinal hernias meeting referral criteria should be referred to a surgeon who performs <b>both</b> open and laparoscopic repair and, where possible, to the <b>named surgeon</b> who performed the first repair (providing the patient does not request otherwise). | <b>D (GPP)</b> |

Patients with multiple recurrent (more than one recurrence) inguinal hernias should be referred to a **named surgeon** who has **sub-specialty interest** in hernia repair **and** performs **both** open and laparoscopic repair.

D (GPP)

### Should diagnostic imaging be arranged at primary care level?

Diagnostic imaging should not be arranged at primary care level

D (GPP)

### Should there be routine primary care follow up for those not referred to secondary care, or deemed unsuitable for surgery by secondary care?

There should be no **routine** follow up for those not referred to secondary care or deemed unsuitable for surgery by secondary care.

D (GPP)

### What patient information and advice should be given at primary care level?

All patients (other than those meeting criteria for emergency admissions) should be provided with a patient information leaflet on groin hernia.

D (GPP)

Patient information should correlate with the advice given in this document and should be updated in accordance with updates to the commissioning guidelines (every 3 years).

D (GPP)

Production of a high quality national patient information leaflet on groin hernia should be prioritised for availability coinciding with publication of the commissioning guidelines.

D (GPP)

### How should postoperative complications be recorded?

There is no robust way of collecting accurate outcome data within the current NHS framework. A specialist nurse may facilitate this process. In the future, a national hernia registry may help to address this issue.

D (GPP)



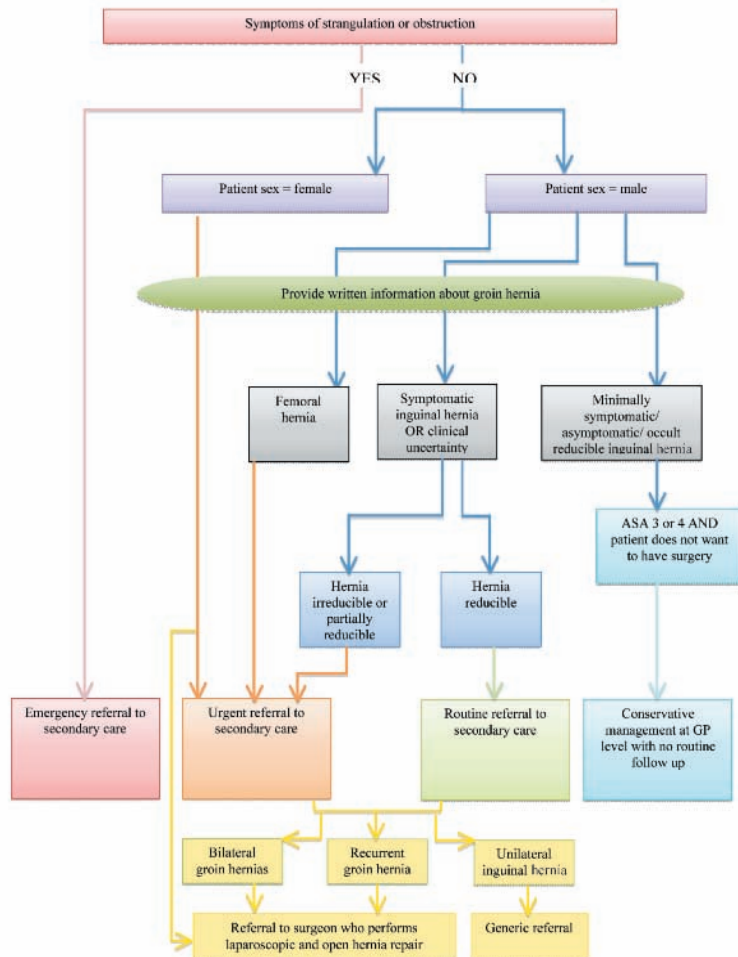


Figure 1: Recommended algorithm for primary care

## 2.2 SECONDARY CARE

### When should medical imaging be used in the investigation and management of patients referred with suspected groin hernias?

The diagnosis of an inguinal hernia is clinical, based on history and examination – the presence of a groin swelling.

C

Medical imaging should be considered in patients in whom there is diagnostic uncertainty, or to exclude other pathology.

D



### What type of medical imaging should be used?

|   |   |
|---|---|
| USS is recommended as the first line investigation. Herniography is rarely performed, but can be utilised if local expertise is available as an alternative to USS. | C |
| MRI should be considered if USS is negative and groin pain persists.  | C |

### Which patients with a groin hernia require an operation?

|   |   |
|---|---|
| Surgical repair should be offered to patients with a symptomatic inguinal hernia. Patients with asymptomatic hernias can be managed conservatively, but there is a likelihood of requiring surgery in the future. | B |
| Surgical repair is recommended for patients with a femoral hernia.  | B |

### How should patients be assessed pre-operatively?

|  |   |
|--|---|
| All patients should be pre-assessed in keeping with NHS and NICE guidelines.   | B |
| A well-structured pre-operative assessment reduces per patient cost.   | B |
| There is no clear guideline highlighting the best timing of pre-assessment, but it has been suggested that it is as early as possible after decision to operate is made, in order to allow investigations and results to be processed in a timely fashion. | D |

### What are the indications for day case surgery versus planned inpatient stay?

|   |         |
|---|---------|
| All patients should be considered for day case surgery. The pre-assessment process and surgical infrastructure are important in ensuring appropriate selection and effective day case services. | B       |
| A small number of individuals require inpatient stay for co-morbidity, social reasons or for complex inguinal hernias.  | D (GPP) |

### What are the indications for perioperative antibiotics use?

|   |   |
|---|---|
| There is no indication for the routine use of antibiotic prophylaxis in elective open or laparoscopic groin hernia repair in low-risk patients. | B |
| In the presence of risk factors for wound infection, the use of antibiotic prophylaxis should be considered.                                    | C |

**Do certain patient sub-groups significantly benefit from either open or laparoscopic surgery?**

|   |                |
|---|----------------|
| The laparoscopic approach may be beneficial in patients at risk of chronic pain (younger patients, other chronic pain problems, pre-operative presentation of severe groin pain with only a small hernia on palpation).   | <b>D (GPP)</b> |
| The open approach under LA may be beneficial in older patients or those with significant co-morbidity.  | <b>D (GPP)</b> |
| In the management of unilateral primary inguinal hernias (general population), there is conflicting information on whether laparoscopic repair reduces the incidence of chronic pain and improves other outcomes. The majority of meta analyses conclude that the incidence and severity of pain (both acute and chronic) are lower after laparoscopic repair compared to open repair, but there are limitations in the studies used. See below for bilateral and recurrent inguinal hernias. | <b>B</b>       |
| The resource cost at the time of surgery is higher for laparoscopic surgery (TEP and TAPP) compared to open surgery.  | <b>D</b>       |

**Is there benefit of one laparoscopic approach over another (i.e. TAPP vs TEP)?**

|  |                |
|--|----------------|
| There is no evidence supporting TEP ahead of TAPP or vice versa.   | <b>C</b>       |
| TAPP may be beneficial if there is diagnostic uncertainty in cases of groin/lower abdominal pain, since it can be used to grossly assess intra-abdominal structures. | <b>D (GPP)</b> |

**Do certain patient sub-groups significantly benefit from either local anaesthetic versus general anaesthetic?**

|   |          |
|---|----------|
| Local anaesthesia is recommended for groin hernia repair in elderly patients, and patients with co-morbidities. | <b>C</b> |
|---|----------|

**What prosthetic material(s) (meshes) should be used?**

|   |          |
|---|----------|
| All adult inguinal hernias should be repaired using flat mesh (or non-mesh Shouldice repair, if experience is available). | <b>A</b> |
| There is no clinical advantage of plugs compared with flat mesh for open inguinal hernia repair.                          | <b>A</b> |
| A cost-effective 'lightweight' (large pore) mesh should be used.  | <b>A</b> |

The use of a large mesh for laparoscopic inguinal hernia repair is supported by the literature, albeit with a low level of evidence, which makes it impossible to recommend an optimal size. However, it seems reasonable to suggest that the mesh should overlap the hernia defect by at least 3 cm in all directions, and we recommend a mesh of at least 15 x 10 cm. It should be emphasised that, in laparoscopic repair, dissection of the preperitoneal space has to be adequate for the size of mesh, to ensure that the mesh lies flat against the abdominal wall.

**B**

There is insufficient evidence to make a recommendation on the use of mesh for femoral hernia repair.

**D (GPP)**

### What post-operative analgesia and instructions should be given?

Local anaesthetic infiltration of the wound after hernia repair provides extra pain control and limits the use of analgesics. Opiates should be avoided.

**B**

It is recommended that limitations are not placed on patients following an inguinal hernia operation and patients are, therefore, free to resume activities. “Do what you feel you can do.” Probably a limitation on heavy weight lifting for 2 to 3 weeks is enough.

**C**

A median return to work should be expected in 7 days for uncomplicated inguinal hernia surgery, whether open or laparoscopic.

**C**

Patients should be able to drive 7 days after hernia repair, but should be advised to inform their insurance company.

**D (GPP)**

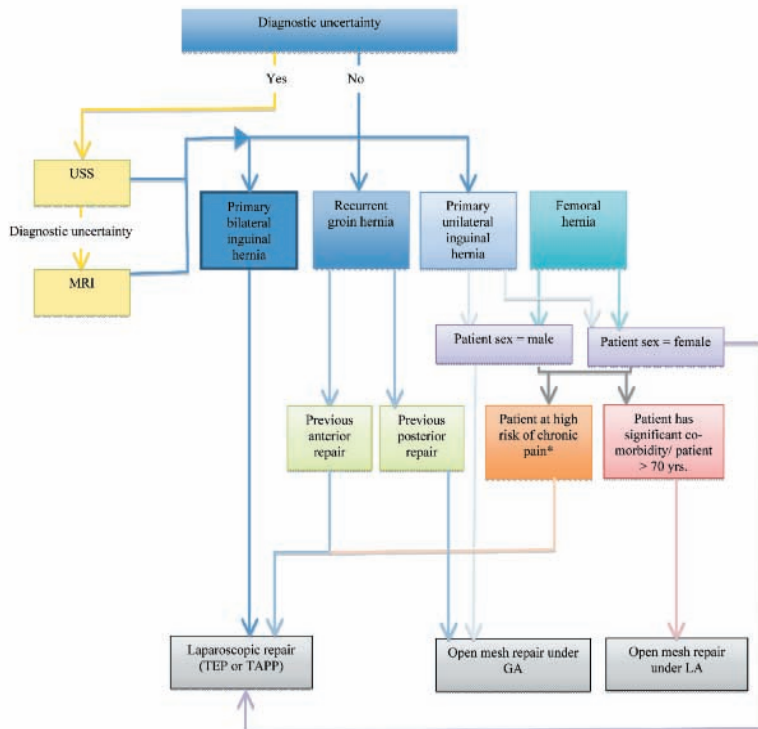
Patients should be provided with written information regarding dressings/wound care. Patients should be informed of potential complications from the surgery and, in particular, ‘red flag’ symptoms that require review. These include; severe abdominal groin or testicle pain, loss of appetite, increasing nausea or vomiting, fever or flu like symptoms, calf pain or increasing breathlessness.

**D (GPP)**

### Should there be routine follow up?

There is no data to support elective follow up.

**D (GPP)**



\*Younger/ active patients, predominant symptom of pain, history of chronic pain

Figure 2: Recommended algorithm for secondary care

### 2.3 SPECIAL GROUPS

#### Groin hernias in women

|   |          |
|---|----------|
| Groin hernias in women should be repaired laparoscopically. | <b>B</b> |
|---|----------|

#### Recurrent groin hernias

|  |          |
|--|----------|
| The technique used in the index hernia repair should be taken into account when choosing the technique for repair of recurrence. If the initial approach was an open anterior repair, then the recurrent operation should be a laparoscopic repair and vice versa. | <b>B</b> |
| There is no evidence to promote one laparoscopic approach ahead of another (TEP or TAPP), and the choice should be dependent on surgeon expertise and preference.  | <b>B</b> |

|  |                |
|--|----------------|
| It has been suggested that primary repairs, such as Kugel patch, Prolene Hernia System, and plugs, that place mesh in the preperitoneal space, make subsequent laparoscopic repair more difficult. Similarly, patients who have had previous preperitoneal dissection, such as for a prostatectomy, or operations involving the iliac vessels or a preperitoneally located transplanted kidney, may make laparoscopic repair technically difficult. In these groups open anterior repair is recommended. | <b>C</b>       |
| Patients with severe cardiac or pulmonary diseases may be better treated with open repair with local anaesthesia, and open preperitoneal repair should be considered.  | <b>C</b>       |
| Patients who are anticoagulated or are at risk for bleeding may be better suited to open repair.   | <b>D (GPP)</b> |
| Recurrent hernias in women should be repaired laparoscopically because the repair may represent a femoral hernia.  | <b>D (GPP)</b> |

**Bilateral groin hernias**

|  |                |
|--|----------------|
| Bilateral inguinal hernias should be repaired laparoscopically from a cost-utility and patient perspective.                            | <b>D (GPP)</b> |
| Current evidence does not show significant difference in outcomes after open versus laparoscopic repair of bilateral inguinal hernias. | <b>B</b>       |
| We could not find evidence for a particular approach to groin hernia repair in morbidly obese patients.                                | <b>D (GPP)</b> |

**Groin hernias in the morbidly obese**

|   |                |
|---|----------------|
| Obesity appears to reduce the risk of groin hernia development, rather than increase it.                | <b>C</b>       |
| We could not find evidence for a particular approach to groin hernia repair in morbidly obese patients. | <b>D (GPP)</b> |

### 3. EVIDENCE BASE FOR HIGH VALUE CARE PATHWAY

#### 3.1 PRIMARY CARE

##### Which patients should be referred to secondary care?

##### Evidence base:

- A multicentre RCT conducted at five North American centres included 720 men (364 watchful waiting, 356 surgical repair) followed up for 2 to 4.5 years. One watchful-waiting patient (0.3%) experienced acute hernia ‘incarceration’ without strangulation within 2 years, and a second had acute ‘incarceration’ with bowel obstruction at 4 years; there was a frequency of 1.8/1000 patient-years inclusive of patients followed for as long as 4.5 years <sup>17</sup>.
- In further analysis of the data from the RCT, patient characteristics (of 336 patients randomised to watchful waiting) were used to predict 2 outcomes, namely crossover to surgery or the development of hernia pain limiting activities and/or crossover to surgery. At 2 years, 72 patients crossed over to surgery, with pain with strenuous activities (OR, 1.3 per 10-mm visual analogue scale pain scale), chronic constipation (OR, 4.9), prostatism (OR, 2.9), being married (OR, 2.3), and good health [OR, 3.0 American Society of Anaesthesiologists Class (ASA) 1 or 2], predicting crossover. An additional 28 patients developed pain, limiting their activities, with pain during strenuous activities (OR, 1.3 per 10-mm visual analogue scale) and chronic constipation (OR, 4.5), predicting the combined outcome of pain limiting activities and/or crossover to surgery. Higher levels of activity reduced the risk (OR, 0.95) of this combined outcome <sup>18</sup>.
- Another study examined costs, QALY, and cost-effectiveness at 2 years of follow-up. Costs were assessed by applying Medicare reimbursement rates to patients’ healthcare use. Quality of life was assessed using the Short Form-36, version 2, and health-related quality-of-life survey. Of the 724 men randomly assigned, 641 were available for the economic analysis: 317 were randomly assigned to tension free repair (TFR) and 324 to watchful waiting. At 2 years, TFR patients had \$1831 higher mean costs than watchful waiting patients [CI, \$409 to \$3044], with 0.031 higher QALY [CI, 0.001 to 0.058]. The cost per additional QALY for TFR patients was \$59,065 [CI, \$1356 to \$322,765]. The probability that TFR was cost-effective at the \$50,000 per QALY level was 40%. At 2 years, watchful waiting was a cost-effective treatment option for men with minimal or no hernia symptoms <sup>19</sup>.
- To quantify the risk of obstruction in groin hernia, the cumulative probability of strangulation in relation to the length of history has been calculated for inguinal and femoral hernias in a study of 476 patients (439 inguinal, 37 femoral). There were 34 strangulations



(22 inguinal, 12 femoral). After 3 months, the cumulative probability of strangulation for inguinal hernias was 2.8%, rising to 4.5% after 2 years. For femoral hernias the cumulative probability of strangulation was 22% at 3 months and 45% at 21 months <sup>[10]</sup>.

- In a prospective study involving 699 patients with inguinal hernia, the cumulative probability of increased pain with time was found to be almost 90% at 10 years, and the cumulative probability of irreducibility increased from 6.5% [CI, 4% to 9%] at 12 months and to 30% [CI, 18% to 42%] at 10 years. Leisure activities were affected in 29% of patients, although only 13% of patients had to take time off work because of hernia-related symptoms. Only 2 patients (0.3%) required resection of ischemic bowel or omentum <sup>[11]</sup>.
- In a British RCT, 160 men aged 55 years or more with a painless inguinal hernia were randomised to observation or operation between 2001 and 2003. After a median follow-up of 7.5 (range 6.2 to 8.2) years, 42 men had died (19 in the observation and 23 in the operation group); 46 of the 80 men randomised to observation had conversion to operation. The estimated conversion rate (using the Kaplan-Meier method) for the observation group was 16 (95 per cent confidence interval 9 to 26) per cent at 1 year, 54 (42 to 66) per cent 5 years and 72 (59 to 84) per cent at 7.5 years. The main reason for conversion was pain in 33 men, and two presented with an acute hernia. Sixteen men developed a new primary contralateral inguinal hernia, and three had recurrent hernias. There have been 90 inguinal hernia repairs in the 80 patients randomised to surgery compared with 56 in those randomised to observation <sup>[12]</sup>.
- Two independent systematic reviews both concluded that watchful waiting is safe, but most patients will develop symptoms (mainly pain) over time and will require an operation <sup>[13, 14]</sup>.

### **What speed of referral should be requested?**

#### **Evidence base:**

- There are no guidelines or studies specifically addressing the timeframe for referral for groin hernia. The recommendations are based on symptoms and the increased risk.
- The mortality risk following elective inguinal hernia repair is low, even at older age. It is, in all series, less than 1% and in a Swedish register study not raised above that of the background population <sup>[15]</sup>. In a Danish study among 26,304 patients, the mortality following elective inguinal hernia repair was 0.02% under the age of 60 years and 0.48% above 60 years of age <sup>[16]</sup>.
- In contrast, an emergency operation carries a substantial mortality risk <sup>[15-21]</sup>. In the Danish study, the mortality was 7%, and in the Swedish database, it was increased seven-fold after emergency operations and 20-fold if bowel resection was undertaken <sup>[15, 16]</sup>.

- Women have a higher mortality risk than men, due to a greater risk for emergency procedure irrespective of hernia anatomy and a greater proportion of femoral hernia. After a femoral hernia operation, the mortality risk was increased seven-fold for both men and women [15].
- Most of the evidence assessing the use of hernia trusses is more than 20 years old. One study reported on 85 patients who were treated before operation with a truss for periods ranging from one month to 42 years [22]. This was a retrospective review with no untreated controls, and the subjects had all been selected for treatment with elective surgery. Almost all of the patients used an elastic truss. Almost a third (24 patients) experienced complete relief from hernia discomfort and a further third (29) reported some improvement in their symptoms. The remaining 26% (22 patients) had a variety of difficulties, including the discomfort of the truss exceeding that of the hernia itself in 9 patients; the hernia became incarcerated in 6; one patient suffered ipsilateral testicular atrophy, and in the remaining 7 the truss was considered ineffective. No prospective controlled studies of the use of trusses have been reported.

### Which secondary care provider should patients be referred to?

#### Evidence base:

- Patients with recurrent or bilateral hernias should be offered a laparoscopic repair as an option (see these sections). In an effort to avoid multiple referrals, these patients should be referred to a surgeon who performs both open and laparoscopic repair.
- The Royal College of Surgeons of England recommends continuity of care where possible [23], stating that it improves communication and overall patient experience. Therefore, recurrent hernias should be referred back to the surgeon who performed the original surgery, providing they meet the criteria in bullet point one.

### Should there be any diagnostic imaging requested at primary care level?

#### Evidence base:

- As discussed in the '*Secondary care: What diagnostic imaging should be used*' section of this document, the sensitivity, specificity and accuracy of medical imaging to diagnose impalpable (occult) groin hernias is variable and depends on local expertise. In many cases, it is not necessary. In order to reduce unnecessary investigations (both from a patient and cost perspective), the request for imaging to aid in the diagnosis of groin hernia should be performed at secondary care level only.

## Should there be routine primary care follow up for those not referred to secondary care or deemed unsuitable for surgery by secondary care?

### Evidence base:

- The recommendations of this guidance are that most patients should be referred to secondary care, based on the high crossover to surgery with watchful waiting <sup>[12]</sup>. The small group of patients not referred should be provided with verbal and written information regarding symptoms that require further review but do not need routine follow up.
- Similarly, patients deemed not suitable for surgery by secondary care should be provided with verbal and written information regarding symptoms that require further review but do not need routine follow up.

## What patient information and advice should be given at primary care level?

### Evidence base:

- We were unable to identify any studies relating to patient information in direct relation to groin hernia repair. However, guidance from the Department of Health in 2004 and the QS15 Quality standard for patient experience in adult NHS services published by NICE, recommend that adequate patient information ensures that:  
*“the quality of consent for treatment is improved, people take a more active role in managing their health, and health professionals are better supported to provide a level of healthcare and choice that they can take great pride in and that people increasingly expect. Easy, equitable access to high quality information lays the foundation for such partnerships to flourish”* <sup>[24, 25]</sup>.
- The provision of patient information improves patients’ experience, makes better use of waiting times and reduces DNAs (‘did not attend’), encourages self-care and helps people to manage their long term conditions <sup>[25]</sup>. Good patient information ensures that patients are fully aware of the next step in their pathway and are able to plan ahead.
- Written information should be evidence-based and produced in such a way that it is available in formats that are legible and understandable <sup>[24]</sup>. Health literacy is fundamental to patient engagement. If individuals do not have the capacity to obtain, process and understand basic health information, they will not be able to look after themselves effectively or make appropriate health decisions <sup>[26 - 29]</sup>.
- The Strategy set down by Department of Health <sup>[24]</sup> explains that patients should have:
  - Access to accurate, high quality, comprehensive information delivered in the way they want.
  - Their personal information needs to be considered and discussed at every contact with health care professionals.

- As much support as they want to access and understand information.
- The empowerment to ask questions and be involved as far as they want in making decision about, for example, the benefits and risks of action, and how any risks can be mitigated.
- A link to a suggested national patient information leaflet on groin hernia appears in *Section 6.1* of this document.

### 3.2 SECONDARY CARE

#### When should medical imaging be used in the investigation and management of groin hernias?

##### Evidence base:

- The vast majority of groin hernias present with a palpable or visible swelling in the groin <sup>130</sup>. The diagnosis is usually apparent on clinical grounds, and further investigation is not usually necessary.
- Diagnostic uncertainty exists when a patient has discomfort or pain in the groin and either has no lump or swelling on examination, or has equivocal physical signs. In these cases, special investigations may be warranted to decide whether the patient has a groin hernia, or whether the symptoms have another cause, i.e. to exclude other pathology.
- Two questions need to be answered in the patient with groin pain and diagnostic uncertainty. These are: **a)** does the patient have an inguinal hernia, and, if not, **b)** is there another cause for the pain that requires treatment. The situation is complicated by the fact that inguinal hernias are common, often asymptomatic, and the findings of a hernia after radiological investigation does not necessarily mean that the hernia is the cause of the current symptoms.
- Because the consequences of acting on a false positive finding is an unnecessary operation, from the clinical and practical point of view one of the most important aspect of the investigation is that it should have a high positive predictive value. In other words, what is important to the clinician is how reliable is the report that says the patient has an inguinal hernia. Secondly, if the initial investigation is negative for hernia, should further investigations be carried out to determine the cause of the symptoms?

#### What type of medical imaging should be used?

##### Evidence base:

- In detecting ‘occult’ hernias, there is wide variation in the published literature for sensitivity, specificity, positive and negative predictive values, and accuracy.

## *Ultrasound (USS)*

- USS is safe, non-invasive, readily available and relatively inexpensive. It is a dynamic investigation, so that the patient can be asked to strain or cough during the scan to emphasise the protrusion. It is, however, operator dependent, depending very much on the skill and experience of the person carrying out the investigation. **Light et al** (2011) retrospectively reviewed the notes of 297 patients who had had an USS for groin pain and a suspected inguinal hernia. 167 scans were 'positive for hernia' - and 85 patients were found to have a hernia at operation - a positive predictive value of 50%.
- They concluded that USS is only useful in conjunction with clinical judgment. Interestingly, 51 of these patients with a positive scan were not operated on, possibly because the surgeon did not trust the ultrasound report.
- A recent meta-analysis of USS ('sonography') in the diagnosis of inguinal hernias found 9 articles that matched their inclusion criteria. Pooled data showed a sensitivity of ultrasound of 87.3%, a specificity of 85.5%, and a positive predictive value of 73.6% i.e. a patient with a positive ultrasound report has a 73.6% chance of having an inguinal hernia <sup>[31]</sup>.
- **Robinson et al** carried out a prospective study of 59 consecutive patients with 'symptoms of a hernia but normal or equivocal clinical examination findings'. All patients underwent both USS and herniography by experienced radiologists blinded to the clinical findings. Both USS and herniography had 100% specificity (no false positives). The sensitivity of USS was higher than herniography (95% vs. 70%) <sup>[32]</sup>.
- A retrospective analysis of 52 patients by **Alam et al** in which the radiologist was 'blinded' to the side of groin pain resulted in a sensitivity for hernia detection of just 33% <sup>[33]</sup>. This study has been criticised for using a suboptimal USS technique with inappropriate lower frequency transducers.
- The majority of reports have concluded that ultrasound can only act as a guide, and the decision whether or not to operate should be based on clinical judgment.

## *Herniography*

- A recent systematic review of the use of radiology in the diagnosis of occult hernia reviewed 23 studies that matched the inclusion criteria. Using pooled data, the review concluded that herniography was the most accurate imaging modality for occult inguinal hernias, and should be considered as the initial investigation for occult inguinal hernia <sup>[31]</sup>. These recommendations were given despite the fact that its sensitivity and specificity were only marginally better than USS. In addition, herniography is invasive and not painless. It carries the risks of visceral puncture, abdominal wall haematoma, allergic reaction to contrast media and radiation exposure <sup>[34, 35]</sup>.



- While the efficacy of herniography for detecting occult hernia may be good in the context of a trial or study when carried out by enthusiastic experienced radiologists, it is likely that complications will be more common when it is used by the “occasional” herniographer. Because of the risk of serious complications, unless the radiologist has specific expertise and experience in herniography, it should be only be used when ultrasound is negative, but there is a high index of suspicion regarding a potential hernia [33].

### *CT scanning*

- CT is inappropriate as an initial investigation for possible occult inguinal hernia. It is associated with high radiation exposure and is relatively expensive. Its sensitivity and specificity for detecting occult hernias is no better than USS or herniography, and although it can identify other pathology, so can plain x-ray and MRI scan [31, 36].

### *MRI scans*

- There have been no studies that have evaluated MRI scanning in the diagnosis of occult inguinal hernia. MRI does have a role in diagnosing other causes of groin pain in the absence of an inguinal hernia. It should, therefore, be used in patients with unexplained groin pain and a negative ultrasound investigation, and/or a negative herniogram [37, 38].

## **How should patients be assessed pre-operatively?**

### **Evidence base:**

- We were unable to identify any studies relating to pre-operative assessment (POA) in direct relation to groin hernia repair. However, the NHS Institute for Innovation and Improvement [39] and NICE [40] states that POA is an essential part of the planned care pathway and that it enhances the quality of care in a number of ways:
- If a patient is fully informed, they will be less stressed and recover more quickly.
- A health check ensures good medical health before anaesthesia and surgery.
- Planning admission and discharge individually ensures that patient and carers know what to expect, thus facilitating earlier post-operative care at home.
- Cancellations due to patient ill-health or DNAs are reduced.
- Admission on the day of surgery and early discharge are more likely.
- Evidence-based guidelines have been issued to rationalise the use of pre-operative tests [40 - 43], and the use of such guidelines has been reported to lead to a reduction, rather than increase, in the number of pre-operative tests, with no impairment of patient safety and significant reduction in per patient cost [44 - 49]. NICE guidance has been produced in order to guide patient-appropriate pre-operative investigation [40].



- Pre-operative assessment reduces surgical cancellation rates and, consequently, appears to improve theatre list efficiency. A large Norwegian case control study assessed cancellation rates and theatre utilisation before and after the introduction of pre-assessment clinics. The mean cancellation rate was reduced from 8.5% to 4.9% (95% CI for mean reduction 2.6–4.5,  $p < 0.001$ ). The reduction in the cancellation rate was sustained over a period of 26 months after the interventions. The median number of operations performed per month increased by 17% ( $p = 0.04$ )<sup>150</sup>.
- Pre-operative assessment appears to work best if it is built in to the patient pathway with a clear infrastructure developed<sup>139–42, 50</sup>.
- GPs should ensure that patients understand their responsibilities, and potential pathway steps and timescales, when being referred and of the need to be contactable and available for appointments when referred. The Primary Care Trust is responsible for ensuring robust communication links are in place to feed back information to GPs<sup>139, 40, 42, 44</sup>.
- The use of non-medically trained staff to screen patients for pre-assessment has been successfully implemented in a number of studies<sup>151–55</sup>. This includes the use of telephone pre-assessment, face-to-face nurse led pre-assessment and anaesthetist assessment decided on a case by case basis according to a predefined protocol. Guidelines suggest how such a pathway can be implemented<sup>156</sup>.
- There is no clear evidence of the ideal timeframe for POA. The majority of guidelines and reviews recommend that assessment be carried out as early as possible after booking of the procedure (and that two weeks prior to operation is too late)<sup>139, 40, 42, 49</sup>. This allows any necessary investigation, and subsequent results, to be managed in a timely fashion.

### **What are the indications for day case surgery versus planned inpatient stay?**

#### **Evidence base:**

- As early as 1955, the advantages of inguinal hernia repair as day surgery were already described in the literature: quicker mobilisation, patient-friendly and lower costs<sup>157</sup>.
- In subsequent years, retrospective series have been published<sup>158, 59</sup>, as well as two small RCTs, in which day surgery was compared with inpatient treatment<sup>160, 61</sup>. A further RCT compared how much patients valued different treatments<sup>162</sup>. These historical studies showed that day surgery is as safe and effective as in-patient stay, and less costly. In two of the three studies, patients were at least as content with day surgery as with hospital stay<sup>161, 62</sup>.
- In a large American cohort study, the costs of an inguinal hernia repair in a clinical setting were found to be 56% higher than those for day surgery<sup>163</sup>. Also, in Germany, this day case surgery has been reported to generate lower costs<sup>164</sup>.

- In addition to the few RCTs, there are a multitude of cohort studies concerning patients successfully operated on as day surgery, under general, regional and local anaesthetics, and with both suture techniques as well as open tension-free repairs and laparoscopic techniques. A large study conducted in Denmark noted the hospital readmission rate of 0.8% <sup>164, 651</sup>. Although a tension-free repair under local anaesthetic seems to be the most suitable operation, the published series showed that other surgical and anaesthetic techniques could also be effectively used as day surgery.
- When day surgery was in its infancy, there was a strict selection of patients with a low risk of complications (ASA I–II, age limit, anticipated length of operation less than one hour, low BMI, etc.). Such strict selection is becoming less common and, in principle, an inguinal hernia repair as day surgery can be considered for virtually every patient who has satisfactory care at home <sup>166-681</sup>.
- In this consideration, pre-assessment is extremely important <sup>1681</sup>. A number of factors will either encourage or discourage day surgery. These include hospital, physician and patient related factors <sup>1301</sup>. In a hospital with considerable experience in day surgery and a good infrastructure, such as the presence of a pre-assessment consultation and a day surgery department, a large percentage of inguinal hernia treatments will take place as day surgery. The same applies to surgical factors, such as short operating times with a low percentage of complications, and anaesthetic factors, such as effective control of post-operative pain and nausea, all of which facilitate early safe discharge.
- On a worldwide basis, there is a clear increase in the percentage of inguinal hernia repairs that are being carried out as day surgery <sup>167, 691</sup>. There is considerable variation between different countries, which cannot be explained solely by the degree of acceptability of day surgery among patients and surgeons but, to a significant extent, is also determined by the healthcare financing system <sup>1301</sup>.

### Should perioperative antibiotics be used?

#### Evidence base:

- Antibiotic prophylaxis in inguinal hernia surgery is controversial. In inguinal hernia repair the risk of SSI (surgical site infection) is between zero and 14.4% <sup>130, 70 - 821</sup>. Repair of inguinal hernia is a high volume operation. Antibiotic prophylaxis may reduce wound infection rates with an impact on patients' satisfaction, wound care, and sick leave, but it also involves risks of toxicity, allergic side effects, bacterial resistance, and higher costs <sup>1831</sup>.
- In contrast to superficial SSI, mesh infections occur relatively infrequently. However, they are of considerable clinical importance because of their associated morbidity. Following inguinal hernia repair, the rates of mesh infection range from 0.3% to 2% <sup>184-861</sup>.
- A total of five systematic reviews or meta-analyses comparing antibiotic prophylaxis versus placebo were identified. Three

different systematic reviews and meta-analyses were performed in 2005, 2006, and 2007 <sup>187-891</sup>. The two most recent meta-analyses reached contradictory conclusions despite analysing the same data; this was mainly due to the statistical methods used <sup>187, 891</sup>.

- A recent Cochrane review, of 17 studies assessing the use of prophylactic antibiotics, reported that the overall infection rates were 3.1% and 4.5% in the prophylaxis and control groups, respectively (OR 0.64, 95% CI 0.50-0.82) <sup>1901</sup>. This is a non-significant reduction with a number needed to treat of 68. The review concluded that the routine use of antibiotics cannot be recommended; however, it may be appropriate in high risk settings <sup>1901</sup>.
- For the prevention of a mesh infection, data is available on 2,103 patients. The deep infection rate is 0.3% in the prophylaxis group and 0.6% in the placebo group (OR 0.50, 95% CI: 0.12–2.09). The reduction is not significant, and the number needed to treat is 352 to prevent one mesh infection <sup>1301</sup>.
- The Swedish National Inguinal Hernia Register recorded the wound infections between 1992 and 2006. The incidence was 1.4% in 28,220 patients recorded to have received antibiotic prophylaxis. The infection rate also was 1.4% in the non-prophylactic group, consisting of 104,354 patients <sup>1911</sup>. There is no specific analysis on the laparoscopic patients, representing approximately 8% of the patients who underwent surgery.
- **Pessaux et al** <sup>1921</sup>, converted predictive risk factors for infection, such as age older than 75 years, obesity, and urinary catheter, into a global infection complication score. Low-risk patients had an infection rate of 2.7% and high-risk patients of 14.3% ( $p < 0.001$ ) <sup>1921</sup>.
- No studies specifically addressing antibiotic prophylaxis in femoral hernia repair were identified.

### **Do certain patient subgroups significantly benefit from either open or laparoscopic surgery?**

#### **Evidence Base:**

- Systematic reviews and meta-analyses of laparoscopic versus open surgery for inguinal hernia have generally reported that the laparoscopic group suffered less acute pain, less chronic pain and less severe chronic pain, less post surgery numbness in the groin, less infection and a quicker return to work <sup>193-971</sup>. In some reviews, the rate of visceral injury and damage to the inferior epigastric vessels rate were higher in the laparoscopic group <sup>193, 971</sup>. Overall, there were similar recurrence rates between the two groups <sup>193-961</sup>. However, all of these reviews used data from the same pool of clinical trials. None of these trials included open LA inguinal hernia repair, and the McCormack review found significant heterogeneity among RCTs in the length of hospital stay <sup>1981</sup>. There were greater differences in the mean length of stay between different hospitals than between different operative techniques <sup>1981</sup>. Furthermore, in

some cases the surgery was performed by laparoscopic experts exclusively, raising the question of publication bias.

- In other studies the incidence of (severe) chronic pain between open and laparoscopic repair seems to equalise with time. Only numbness seems to persist in the open group <sup>199, 1001</sup>.
- A recently published comparative effectiveness review <sup>1971</sup> included 37 studies and concluded that the laparoscopic approach reduced time to return to daily activity (difference of 3.9 days, CI 2.2 – 5.6), time to return to work (difference of 4.6 days, CI 3.1 – 6.1), long term pain (OR 0.61, CI 0.48 – 78), haematoma (OR 0.7, CI 0.55 – 88) and infection (OR 0.59, CI 0.33- 71) rates. In contrast, two outcomes favoured open surgery, namely recurrence (RR 1.43, CI 1.2 – 1.8) and inferior epigastric vessel injury. There was no difference in length of stay. However, the 37 compared various mesh-based open vs laparoscopic procedures (the Lichtenstein method, the mesh plug method, TEP, and TAPP). Consequently, the findings from the meta-analyses (e.g. effect sizes) might not apply to comparisons of specific procedures (e.g. the Lichtenstein method vs TEP). Meanwhile, in 34 of the 37 studies reviewed, the trials were performed in the 1990s or early 2000s. This body of evidence may not necessarily reflect the comparative performance of the procedures that are performed currently. Twenty-one of the 37 studies reviewed provided information on surgeons' prior experience for the surgeries being compared. Surgeons' level of experience was reported as "experienced", "highly experienced", "with moderate experience", or by the number of prior cases. When the term "experienced" was used, the meaning of the term was rarely defined (e.g. by the number of prior cases or years of practice). Sixteen of the 37 studies reviewed did not report data on surgeons' experience at all. Given the limitation in data reported, the authors were unable to judge what implication surgeons' experience may have in the applicability of the evidence. Patient enrolment criteria and reported baseline characteristics varied significantly across the 37 studies. Almost half of the studies reviewed excluded female patients or patients unfit for general anaesthesia. Some studies excluded patients with bilateral or irreducible hernias. The setting of the 37 studies varied significantly, ranging from outpatient surgical clinics to community hospitals to academic medical centres. Based on the data reported, it is unclear how the clinical settings of the studies might affect the applicability of the evidence.
- There appears to be benefit for the laparoscopic approach for recurrent hernias (where a previous anterior repair was performed), bilateral hernias and groin hernias in women (see these sections).
- The laparoscopic approach has been reported to take longer <sup>11 - 41</sup>, however the clinical implication of an operation taking between 7 and 15 minutes longer <sup>11 - 41</sup> are unclear.
- Laparoscopic surgery has been reported to be more expensive than open surgery, when equipment costs are calculated <sup>130, 1011</sup>. However,

there is a lack of good quality economic evaluation comparing the two approaches. The most thorough economic evaluation reported that, for the management of unilateral hernias, the base-case analysis and most of the sensitivity analysis suggest that open flat mesh is the least costly option, but provides less quality adjusted life years (QALYs) than TEP or TAPP <sup>196</sup>. The same review concluded that TEP is likely to dominate TAPP (on average TEP is estimated to be less costly and more effective). The results of the base-case analysis and much of the sensitivity analysis suggest that the mean incremental cost per QALY for TEP compared with open mesh is less than £10,000 and that there is approximately an 80% chance that TEP is the most cost-effective intervention should society's maximum willingness to pay for an additional QALY be £20,000.

- Several series have suggested that laparoscopic hernia surgery is more problematic when performed by inexperienced laparoscopic surgeons <sup>1102-1071</sup>. However, as discussed in the clinical effectiveness report <sup>197</sup>, there are variations in reporting, which make it impossible to estimate the length of the learning curve. Key problems exist in interpreting the data in three areas: the possibility of a time confound (that earlier patients had been followed for longer and had more time to have recurrences), procedural evolutions (that details of the procedure often changed over time, making it difficult to pinpoint the effect of technical improvements and increasing expertise), and selective outcome reporting (that the studies reporting this association may have chosen to do so because of the nature of the data).
- Not all patients are suitable for a laparoscopic approach. The TAPP approach requires access to the peritoneal cavity, and previous abdominal surgery or disease may have resulted in adhesions that have obliterated this space. The TEP approach requires the pre-peritoneal space to be opened up, and again, previous surgery, radiotherapy and/or disease may make the creation of this space impossible <sup>196</sup>.
- There are many reports published with variable experiences of TEP repairs performed under regional anaesthesia (1,724 repairs under spinal <sup>1108, 1091</sup> and 82 under epidural <sup>1110, 1111</sup>). All of the studies concluded that laparoscopic TEP repair under spinal/epidural anaesthesia appears to be safe, technically feasible, and an acceptable alternative to GA. However, the studies included ASA 1 and 2 patients only, who are not representative of the high-risk patients in which such an approach may be desirable.
- An important question is whether laparoscopic surgery has significant benefit in certain patient groups. A recent study <sup>1112</sup> demonstrated a benefit in terms of chronic post surgery pain with a laparoscopic approach in patients with a high pre-operative Activity Assessment Score and/or a high pre-operative pain response to tonic heat stimulation. While such scoring is not in routine use, in general young male patients appear to be at higher risk of chronic pain and,



perhaps, a laparoscopic approach should be considered as the procedure of choice in such a group, if there is no contra-indication to either approach.

- In older patients, the implied benefits of laparoscopic repair may not be as significant. Only one low quality retrospective study has compared laparoscopic with open surgery in older patients <sup>[113]</sup>. The authors compared open vs laparoscopic inguinal hernia repair in patients over the age of 80 years <sup>[113]</sup>. The study had poorly matched groups in terms of numbers (31 laparoscopic repairs vs 84 open repairs) and did not include open repair under LA. The authors reported that patient satisfaction was higher in the laparoscopic group, but there was no difference in other outcomes.

### **Is there benefit of one laparoscopic approach over another (i.e. TAPP vs TEP)?**

#### **Evidence Base:**

- There are two RCTs directly comparing TAPP and TEP inguinal hernia repairs <sup>[114, 115]</sup>. The two studies had conflicting results, and the number of patients randomised to the two techniques was very small. A further 6 studies have assessed TEP vs TAPP in conjunction with comparing other procedures (e.g. Lichtenstein or plug repair) <sup>[116-121]</sup>. Significant heterogeneity between the studies, and small study numbers, makes it difficult to draw any conclusions on outcomes based on these studies <sup>[97]</sup>. Similarly the Cochrane database review 2005 <sup>[107]</sup> concluded that there are insufficient data to draw any significant conclusions regarding what is better TAPP or TEP.
- From a pragmatic viewpoint, TAPP can be used to grossly assess intra-abdominal structures if there is diagnostic uncertainty in cases of groin/lower abdominal pain. However, there are no studies that specifically evaluate this.

### **Do certain patient sub-groups significantly benefit from either local anaesthetic versus general anaesthetic?**

#### **Evidence base:**

- The advantages claimed for the use of LA include increased safety for patients, better post-operative pain control, less urinary difficulties, a shorter recovery period, and reduced cost when compared with hernia repair performed under GA. Day-case rates may also be improved. Nevertheless, there have been no large randomised clinical trials comparing LA and GA for hernia repair. In addition, differences in safety between LA and GA hernia repair are difficult to assess, as mortality and serious cardiovascular events are so low following elective groin hernia repair.



- In an RCT of 276 patients having an inguinal hernia repair under LA or GA, no major differences in patient outcome were found <sup>[122]</sup>. All operations in this study took place on an in-patient basis and not in a dedicated day unit, and it was noted that GA hernia repair cost 4% more than the same operation under LA. Outcome measures in this study were broad, not patient-centred, and the mean hospital stay was 3 days. The authors concluded that the decision to use LA or GA should be at the discretion of the individual surgeon in consultation with the patient.
- A retrospective analysis of 577 inguinal hernia repairs performed in a district general hospital found that the day-case rates were significantly higher under LA compared to GA (82.6% versus 42.6%;  $P < 0.05$ ) <sup>[123]</sup>. The outcome measures were early and late post-operative complications and patient satisfaction. It was noted that patients operated under LA had lower post-operative analgesic requirements and lower incidence of urinary retention compared with the GA group ( $P < 0.05$ ).
- In virtually all studies, there is a higher incidence of urinary retention in patients undergoing groin hernia repair under GA compared with LA <sup>[124, 125]</sup>. This may lead to unplanned hospital stay and a higher rate of unplanned prostatectomy, with associated additional morbidity.
- A prospective nation-wide study of 29,033 elective groin hernia repairs, registered in the Danish Hernia Database, found that in patients more than 65 years of age, medical complications were more frequent after regional anaesthesia (RA) (1.17%), compared with GA (0.59%) ( $P=0.003$ ) and urological complications were more frequent after RA (0.87%) compared with LA (0.09%) ( $P=0.006$ ) <sup>[126]</sup>. Seventeen prostatectomies were required because of post-operative urinary retention after GA or RA, but none after LA.
- In a multi-centre randomised trial in Sweden, comparing cost of hernia repair under LA, RA or GA, LA was found to have significant cost advantages over RA and GA ( $P < 0.001$ ) <sup>[127]</sup>. The mean in-patient stay was 3.1 hours (LA) vs 6.2hrs (GA), and unplanned admission occurred in 7% (LA) vs 22% (GA). The advantage was also significant for total hospital and total healthcare costs; 1675 for LA vs 2000 for GA and RA. ( $P < 0.001$ ). The LA patients also returned to normal activity in a shorter time compared with GA patients (9 days vs 14 days respectively).
- It has been suggested that GA may have a significant effect on psychomotor skills, attention, and memory in the post-anaesthesia period, and that this effect may be long-term and related to cerebral ischemia <sup>[128]</sup>.
- Anaesthetic risk is higher in elderly patients with significant co-morbid disease. As a consequence, the routine use of LA for groin hernia repair is likely to allow more elderly patients and those with co-morbidities to have their hernia repaired safely <sup>[129]</sup>.

## What prosthetic material(s) (meshes) should be used?

### Evidence Base:

#### *Mesh vs Suture*

- The use of synthetic mesh substantially reduces the risk of groin hernia recurrence irrespective of the placement method (open or laparoscopic) <sup>[130 - 133]</sup>. Mesh repair appears to reduce the chance of persisting pain rather than increase it <sup>[134]</sup>.

#### *How do meshes work?*

- The process of fibrosis in mesh structures is associated with the progressive ingrowth of fibrous tissue <sup>[135-137]</sup>. Animal studies have shown that tissue ingrowth begins early (within two weeks) and increases in strength over time (up to 12 weeks) <sup>[135, 138 - 140]</sup>. The extent and velocity of ingrowth, which is part of the inflammatory response, depends on the properties of the mesh <sup>[137, 140 - 142]</sup>. Ingrowth of collagen provides long-term adhesive strength <sup>[142]</sup>. Whilst this produces a strong mechanical barrier, florid ingrowth can also be detrimental. Examination and measurement of the abdominal wall after implantation of mesh in humans was performed by **Welty et al** using 3D stereography and ultrasound <sup>[143]</sup>. Patients with 'heavyweight' monofilament meshes (which have been shown to promote fibrosis) had higher levels of paraesthesia and pain than those with 'lightweight' monofilament meshes (which result in less fibrosis). The abdominal wall stiffness was increased in all patients, but the extent of stiffness increased with mesh weight and decreased with pore size. This has been supported by several animal models, which have shown decreased compliance with extensive mesh ingrowth <sup>[144-146]</sup>. In some patients, chronic inflammation and progressive fibrosis may result in the mesh shrinking after implantation and this can result in hernia recurrence <sup>[147, 148]</sup>.

#### *'Lightweight' vs 'heavyweight' meshes*

- Despite recent attempts <sup>[149 - 153]</sup>, there is currently no universally accepted and widely used classification for hernia meshes.
- Regardless of this, meshes are frequently categorised as 'lightweight' or 'heavyweight'.
- The term 'lightweight' is not simply descriptive of the product being low in weight, nor can it be simply be defined by a cut-off value of weight per square metre, filament or specific pore size <sup>[154]</sup>. 'Lightweight' typically refers to meshes with a larger pore size, resulting in smaller surface area. The lower amount of material present in lightweight material should, theoretically, lead to decreased foreign body reaction and fibrosis <sup>[155, 156]</sup>.
- In recent attempts to classify meshes and provide a cut-off, 'lightweight' meshes have been suggested to be <70g/m<sup>2</sup> and 'heavyweight' meshes >70g/m<sup>2</sup> <sup>[152]</sup>. An alternative classification, discusses 'lightweight' or 'large pore' meshes as having >60% porosity <sup>[151]</sup>. However, the porosity is not usually stated by the

manufacturers, and these values are not precisely defined limits but rather represent 'educated' guesses from the authors.

- It has been suggested that the increased flexibility of 'lightweight' meshes should result in a better activity profile post surgery <sup>1157</sup>. However, concerns have been raised over the strength of 'lightweight' meshes in the repair of large hernia defects and the risk of sutures tearing out of the mesh <sup>1158</sup>.
- In previous RCTs comparing 'lightweight' mesh with standard 'heavyweight' mesh, two indicated that the use of 'lightweight' mesh was associated with significantly less pain on exercise after six months <sup>1159</sup>, and less pain of any severity at 12 months in the 'lightweight' group <sup>1158</sup>. Moreover, a meta-analysis including eight prospective RCTs of good quality, found no significant difference concerning severe pain (OR 0.99%; 95% CI, 0.48 – 2.02;  $P = 0.97$ ), however the incidence of any pain and the foreign body sensation was significantly lower in the 'lightweight' group (OR 0.65; 95% CI 0.5 – 0.84;  $P = 0.001$ ) <sup>1160</sup>. A more recent meta analysis including a total of 2231 hernias from 11 RCTs, reported less post-operative chronic pain (odds ratio [OR] = 0.64, 95% confidence interval (CI) = 0.51-0.82;  $P < 0.05$ ) and less sensation of a foreign body (OR = 0.56; 95% CI = 0.40-0.78;  $P < 0.05$ ) with 'lightweight' mesh <sup>1161</sup>. In the same study, there was no significant difference in post-operative recurrence, seroma, haematoma, wound infection, urine retention, and testicular atrophy.

#### ***Currently marketed meshes***

- There are currently more than 200 commercial meshes on the market, each with major and minor variations in polymer and structure, aimed at producing the most desirable biological response and improved outcomes <sup>1162</sup>. Since most manufacturers make similar claims about the superiority of their product, it is left to the surgeon and healthcare policy makers to decide which material to use.
- Synthetic meshes vary in their chemical composition (polymer type, addition of coating agents or additives), physical properties (filament weave, pore size, mesh weight and density) and mechanical properties (tensile strength, bursting force) <sup>1162</sup>.
- Several variations of each mesh exist, e.g. addition of titanium for strength reinforcement, addition of Dexon® for improved handling. Invariably these modifications cost more, without high-level evidence of improved clinical outcome.

#### ***What should the mesh be made of?***

- Most synthetic meshes are constructed from a base polymer of polypropylene, polyester or ePTFE. More recently, other plastic polymers, namely cPTFE and PVDF, have been used.
- Monofilament polypropylene and polyester meshes appear to produce comparable results <sup>1163-1165</sup>. ePTFE meshes were designed for intraperitoneal placement, and their high cost is not justified in

extraperitoneal repair. In addition, in the clinical setting, several studies have shown that ePTFE is more susceptible to infection than other biomaterials <sup>[166-170]</sup>, and that when infection occurs, most ePTFE implants will need to be removed <sup>[171, 172]</sup>.

- Experimental studies have demonstrated that multifilament materials are associated with increased bacterial adhesion *in vitro* and *in vivo* <sup>[173-175]</sup>. This is presumably due to the increased surface area.
- Irrespective of structural differences, mesh materials should be able to withstand the tensile stresses placed on the abdominal wall, which are in the order of 16N/cm for hernia repair and 32N/cm for complete abdominal wall reconstruction (although this may be as high as 42.5N/cm in obese patients) <sup>[155, 176]</sup>.
- The older generation of ‘heavyweight’ mesh greatly exceed these required tensile strength values. Virtually all meshes tested *in vitro* are able to withstand this pressure, even the ‘lightweight’ meshes (e.g. Vypro® burst pressure = 360 mmHg <sup>[177]</sup>). Exceptions are ‘ultra-lightweight’ meshes, such as TiMesh® ExtraLight (16g/m<sup>2</sup>), which has a tensile strength of only 12N/cm <sup>[178]</sup>.

#### **Plug vs patch**

- A total of 2912 patients, enrolled into eight RCTs, were included in a meta-analysis of plug versus Lichtenstein open inguinal hernia repair. Pooled data showed similar results according to all the compared post-operative complications and return to daily activity. In another meta-analysis comparing mesh plug, Prolene® Hernia System and Lichtenstein for open inguinal hernia repair, ten RCTs with 2708 patients were included. There was no significant difference in recurrence when comparing Lichtenstein’s operation to mesh plug repair or Prolene® Hernia System repair (risk ratio: 0.71; 95% confidence intervals: 0.32-1.56), (risk ratio: 2.19; 95% confidence intervals: 0.63-7.62), respectively <sup>[179]</sup>. A recent clinical effectiveness report <sup>[97]</sup> evaluated 21 studies comparing Lichtenstein open mesh with various plug techniques and concluded a shorter return to work with Lichtenstein repair but, overall, there was no other significant difference in terms of outcomes.

#### **Mesh size**

- Mesh size may have a greater impact on recurrence than surgical technique <sup>[180]</sup>. A small mesh has been shown to be an independent risk factor for recurrence compared with a large one, irrespective of the type of mesh, i.e. ‘light’ or ‘heavyweight’ <sup>[181]</sup>.
- We found no RCTs that specifically compared mesh sizes, but several studies on surgical techniques used different sizes of mesh. Data extracted from a recent meta-analysis of open versus laparoscopic hernia repairs provide some information about this issue <sup>[182]</sup>. A significant trend toward reduced recurrence rates with increasing mesh size was noted (a “large” mesh was most often 10 x 15 cm<sup>2</sup> size). Indeed, use of a small mesh almost doubled the risk for recurrence <sup>[182]</sup>.

- A large, retrospective series that included 3,017 patients who underwent TAPP inguinal herniorrhaphies showed a 5% recurrence rate using an 11 x 6 cm<sup>2</sup> mesh in 325 repairs and a 0.16% recurrence rate using a 15 x 10 cm mesh in 3,205 repairs [183].
- There are two large randomised studies from Sweden; one compared TAPP with Shouldice with a 5-year follow up of 920 patients, and showed a recurrence rate of 6.6% when using a mesh size of 7 x 12 cm [184], and the other compared TEP with Lichtenstein with 5-year clinical examination of 1370 patients when using a mesh size of 12 x 15 cm and showed a recurrence rate of 3–5% [185].
- Animal data have suggested that a minimum of 3 cm mesh overlap is essential to prevent mesh protrusion through the hernia defect resulting in recurrence [186].
- It should be emphasised that, in laparoscopic repair, dissection of the preperitoneal space has to be adequate for the size of mesh to ensure that the mesh lies flat against the abdominal wall [181, 187, 188].

### What postoperative analgesia and instructions should be given?

#### Evidence base:

- Post-operative pain is best treated with a combination of local anaesthesia [189, 190] and peripherally acting agents (paracetamol, NSAID or their combination), while opioids should be avoided due to side effects, primarily nausea, sedation and urinary retention [191].
- Wound infiltration with a local anaesthetic results in less postoperative pain than the administration of placebos [189, 190].
- Recently, **Bay-Nielsen** and colleagues examined convalescence after Lichtenstein repair in a case-control study using data from the Danish hernia database [192]. The median length of absence from work was 7 days (sedentary work 4.5 days, strenuous work 14 days). The study found that a single day of convalescence was feasible without increasing recurrences. Pain was the most common cause of a delay in returning to work (60%), followed by wound problems (20%).
- It is generally accepted that there is variation in patients returning back to work based on age, social class, occupation, income and evidence of depression [193].
- In a single prospective trial, two post-operative regimes (after Bassini technique) were compared with each other using a recurrence within 1 year as an end point [194]. The resumption of heavy work after 3 weeks was compared with that after about 10 weeks, and has no influence on the recurrence rate. In another study, patients undergoing Lichtenstein hernia repair under LA, were advised to take one-day convalescence for light/moderate work and three weeks for strenuous physical activity. Results revealed that >75% of patients were doing their own shopping without assistance



within 6 days. Patients resumed work after an average of 6 days, and resumed heavy work 4 days after the proposed resting period was over <sup>[195]</sup>.

- The advice on when to drive after groin hernia surgery, given to patients by general surgeons in the United Kingdom, seems to be inconsistent, varying from the day of surgery to two months after surgery <sup>[196, 197]</sup>. Even surgeons and day units that rely on published data give variable advice. Many day units do not provide written information on driving after hernia repair, or fail to document what information has been given.
- In 1975, the reaction times in patients pre and post inguinal hernia repair was measured using a brake pedal simulator. Although only a small number of subjects were assessed, the mean time to return to pre-operative reaction levels was 7.5 days <sup>[198]</sup>. A further study showed that, after seven days, the normal response time was achieved in 82% of cases following an endoscopic repair, in 64% of cases after Lichtenstein operation and in 33% of cases after Bassini technique <sup>[199]</sup>. In the Lichtenstein clinic, the opinion is that driving can be resumed straight away <sup>[200]</sup>.
- We were unable to identify any studies specifically addressing convalescence in femoral hernia repair.

### 3.3 SPECIAL GROUPS

#### Groin hernias in women

##### Evidence base:

- Very little is published on groin hernias in women, and most of our knowledge in this area comes from the large Swedish hernia registry, where 6895 women with inguinal hernias were followed prospectively <sup>[201]</sup>. In 267 repairs for recurrent hernias, 41.6% of women, diagnosed with a direct or indirect inguinal hernia at the primary operation, were found to have a femoral hernia at the time of reoperation. In a multivariate analysis of relative risks for reoperation, the risk was reduced when TAPP laparoscopic repair was performed at the time of primary repair. After adjusting for all other factors (e.g. mode of admission, reoperation, suture material, hernia type, methods of repair, postoperative complications, methods of anaesthesia), women were found to have a higher risk of reoperation for recurrence than men. This study points to considerable differences that need to be taken into consideration when addressing recurrent hernias in women as compared with men.

#### Recurrent groin hernias

##### Evidence Base:

- The National Institute for Health and Clinical Excellence (NICE), advocates the use of laparoscopic repair for recurrent inguinal



hernias <sup>12021</sup>. The NICE guidance places significant emphasis on the surgeon's experience in laparoscopic repair, and stipulates that this is a key factor if laparoscopy is to be considered the preferred technique for recurrent hernia. There was no consensus on a preferred method of laparoscopic repair (TAPP or TEP), and no trials specify a minimum degree of laparoscopic experience to eliminate the learning curve.

- In addition to emphasising the importance of operator experience, the guidelines of the European Hernia Society state that the technique used in the index hernia repair should be taken into account when choosing the technique for repair of recurrence <sup>1301</sup>. Specifically the choice of repair for the recurrent hernia will depend on the initial repair used. Initial repairs can include primary conventional tissue repair; primary anterior mesh repair, such as Lichtenstein onlay patch <sup>12031</sup>; plug and patch <sup>12041</sup>; Prolene Hernia System (Ethicon®) <sup>12051</sup>; or primary posterior mesh repair, such as open posterior mesh repair (e.g. Read, Rives, Stoppa, Kugel) <sup>1206-2081</sup> or a laparoscopic repair. It has been suggested that primary repairs, such as Kugel patch, Prolene Hernia System, and plugs, that place mesh in the preperitoneal space, make subsequent laparoscopic repair more difficult <sup>12091</sup>.
- If the initial repair was a mesh repair, then the recurrent repair should preferably employ an approach in the space in which the tissue planes have not been violated previously <sup>12091</sup>.
- A low quality and underpowered prospective RCT included 99 patients undergoing surgery for recurrent inguinal hernia who were prospectively randomised into having either open or laparoscopic mesh repair <sup>12101</sup>. There were three recurrences in the Lichtenstein group and none in the TEP group (6.4% versus 0.0%, respectively), but this difference was not statistically significant. Chronic pain was more prevalent in the Lichtenstein group compared with the TEP group (13 [27.7%] versus 4 [8.2%] patients, respectively,  $P = 0.02$ ). Post-operatively, the Lichtenstein group needed more pain medication than the TEP group (4.4 versus 3.0 doses, respectively,  $P = 0.02$ ) and returned to work later (17.9 versus 14.8 days, respectively,  $P = 0.05$ ). Similarly, in a large Danish observational study including 2117 recurrent inguinal hernias, the cumulative reoperation rate after primary Lichtenstein repair was substantially reduced after laparoscopic operation for recurrence (1.3%), compared with open repairs for recurrence (11.3%) <sup>12111</sup>.
- Other small series have also demonstrated the efficacy of both laparoscopic TAPP and TEP for recurrent inguinal hernias. However, these studies do not mention the method of original repair <sup>1212, 2131</sup>.
- There are no multi-centre prospective randomised studies comparing TEP and TAPP repairs for recurrent inguinal hernia. Most non-randomised studies find equivalent rates of recurrence and complications between TEP and TAPP repair <sup>12141</sup>. A Cochrane

review looking at TAPP versus TEP for inguinal hernia repair, suggests that TAPP is associated with higher rates of port-site hernias and visceral injuries, and there appear to be more conversions with TEP <sup>[98]</sup>. Vascular injuries and deep or mesh infections were found to be rare, with no obvious difference between the groups <sup>[215]</sup>. A number of studies have looked at TAPP repair for recurrence after TEP or TAPP, these studies have shown excellent results, but were done by experts <sup>[183, 215, 216]</sup>.

- In contrast, a meta-analysis including four RCTs of medium quality, demonstrated that laparoscopic repair of recurrent inguinal hernia did not offer a significant benefit over open tension-free mesh repair in the major outcome measures of preventing future recurrence and chronic pain <sup>[217]</sup>. However, in the same analysis, laparoscopic surgery offered benefits in secondary outcome measures by reducing short-term post-operative pain, shortening the time to return to work after operation and reducing the incidence of superficial wound infections, but there was a significantly longer operating time in the laparoscopic group. These findings have been supported by other prospective and observational studies <sup>[98, 180, 183, 218 - 221]</sup>.
- Patients with severe cardiac or pulmonary diseases may be better treated with open repair with local anaesthesia <sup>[222]</sup>.
- The extensive preperitoneal space is usually created by blunt dissection in the case of TEP and by peeling the peritoneum in the case of TAPP, so patients who are anticoagulated, or are at risk for bleeding, may be better suited to open repair <sup>[209]</sup>. It is also more difficult to create the preperitoneal space if the patient had previous preperitoneal dissection, such as for a prostatectomy, or operations involving the iliac vessels or a preperitoneally located transplanted kidney <sup>[209]</sup>. For these patients, the advantage of laparoscopic repair may be outweighed by the disadvantage of technical difficulty in creating the preperitoneal space to place the mesh. Similarly, patients with large scrotal hernias or ascites may be also better treated with open hernia repair <sup>[209]</sup>. However, there is no data to support these recommendations.

### Bilateral groin hernias

#### Evidence Base:

- For bilateral hernias, three meta-analyses comparing laparoscopic versus open surgery are based on a small number of RCTs <sup>[98, 217, 223]</sup>; there is limited evidence showing no significant difference in persisting pain (TEP vs open mesh) or recurrence (TEP and TAPP vs open mesh); there is limited evidence to suggest that laparoscopic repair reduces the time taken to return to normal activities compared with open-mesh repair, however local anaesthetic repair is not included in this assessment.
- In an RCT comparing TAPP versus Lichtenstein for bilateral and recurrent hernias, three-quarters of the patients with a recurrence

after laparoscopic repair had bilateral hernias treated with one large mesh (30 x 8 cm) <sup>[219]</sup>. Thus, in bilateral hernias, a sufficiently large mesh should be used or two different meshes (e.g. 15 x 10 cm on both sides) <sup>[224]</sup>.

- The laparoscopic approach may provide better posterior inguinal wall exposure, enabling easier bilateral reinforcement <sup>[225]</sup> and allow a quicker recovery time than open surgery <sup>[224, 226]</sup>. No studies have shown the true efficacy of TEP vs TAPP for bilateral hernias, thus a recommendation for one or the other method cannot be given and depends on the skill and personal preference of the surgeon involved <sup>[98]</sup>. Well-designed prospective, randomised, controlled studies are imperative for more clarity and more reliable recommendations.
- An unexpected contralateral hernia is reported in 10–25% of primary laparoscopic inguinal hernia repairs <sup>[227-230]</sup>. Up to 28.6% of these patients will progress to a symptomatic hernia within 1 year <sup>[230]</sup>. It is likely that these occult contralateral hernias would not be recognised with open surgery.

### Groin hernias in the morbidly obese

#### Evidence Base:

- We found no RCTs addressing the issue of groin hernia repair in the morbidly obese patients.
- A Swedish prospective cohort study investigated whether overweight and obesity in middle age could significantly predict future groin hernia in men <sup>[231]</sup>. The study included 7483 men aged 47 to 55 years who were followed-up from baseline (1970-1973) for a maximum of 34 years. A total of 1017 men (13.6%) were diagnosed with groin hernia. An inverse relationship was found between body mass index (BMI) and risk of groin hernia. With each BMI unit (3-4 kg), the relative risk for groin hernia decreased by 4% ( $P < 0.0001$ ). Compared with men of normal weight, obese men had a 43% lower risk ( $P = 0.0008$ , 95% confidence interval 21%-59%).

## 4. PROCEDURES EXPLORER

### 4.1 NHS OPCS 4 CODES

Number of results found = 14

| OPCS4.2 Code | OPCS4.2 Code | OPCS4.2 Code | OPCS4.2 Code | OPCS4.2 Code | Description   |
|--------------|--------------|--------------|--------------|--------------|---|
| T19.8        | T19.8        | T19.8        | T19.8        | T19.8        | Other specified simple excision of inguinal hernial sac.                |
| T19.9        | T19.9        | T19.9        | T19.9        | T19.9        | Unspecified simple excision of inguinal hernial sac.                    |
| T20.1        | T20.1        | T20.1        | T20.1        | T20.1        | Primary repair of inguinal hernia using insert of natural material.     |
| T20.2        | T20.2        | T20.2        | T20.2        | T20.2        | Primary repair of inguinal hernia using insert of prosthetic material.  |
| T20.3        | T20.3        | T20.3        | T20.3        | T20.3        | Primary repair of inguinal hernia using sutures.                        |
| T20.4        | T20.4        | T20.4        | T20.4        | T20.4        | Primary repair of inguinal hernia and reduction of sliding hernia.      |
| T20.8        | T20.8        | T20.8        | T20.8        | T20.8        | Other specified primary repair of inguinal hernia.                      |
| T20.9        | T20.9        | T20.9        | T20.9        | T20.9        | Unspecified primary repair of inguinal hernia.                          |
| T21.1        | T21.1        | T21.1        | T21.1        | T21.1        | Repair of recurrent inguinal hernia using insert of natural material.   |
| T21.2        | T21.2        | T21.2        | T21.2        | T21.2        | Repair of recurrent inguinal hernia using insert of prosthetic material |
| T21.3        | T21.3        | T21.3        | T21.3        | T21.3        | Repair of recurrent inguinal hernia using sutures.                      |
| T21.4        | T21.4        | T21.4        | T21.4        | T21.4        | Removal of prosthetic material from previous repair of inguinal hernia. |
| T21.8        | T21.8        | T21.8        | T21.8        | T21.8        | Other specified repair of recurrent inguinal hernia.                    |
| T21.9        | T21.9        | T21.9        | T21.9        | T21.9        | Unspecified repair of recurrent inguinal hernia.                        |

## 4.2 ICD-10 CODES

Number of results found = 7

| ICD 10 Code | Description  |
|-------------|--|
| K40         | Unilateral or unspecified inguinal hernia, with obstruction, without gangrene. |
| K40.0       | Bilateral inguinal hernia, with obstruction, without gangrene.                 |
| K40.1       | Bilateral inguinal hernia, with gangrene.                                      |
| K40.2       | Bilateral inguinal hernia, without obstruction or gangrene.                    |
| K40.3       | Unilateral or unspecified inguinal hernia, with obstruction, without gangrene. |
| K40.4       | Unilateral or unspecified inguinal hernia, with gangrene.                      |
| K40.9       | Unilateral or unspecified inguinal hernia, without obstruction or gangrene.    |

Association of Surgeons of Great Britain and Ireland

**ISSUES IN PROFESSIONAL PRACTICE**

Groin Hernia Guidelines

## 5. LEVERS FOR IMPLEMENTATION

### 5.1 AUDIT AND PEER REVIEW MEASURES

Within the current framework of the NHS, the collection of good, accurate and precise outcome data is difficult. A large surgical registry would prove an ideal data collection mechanism, and would have to be carefully implemented in order to accurately record the relevant information. In addition, the registry would have to be easy to use in the NHS framework as well as becoming part of the natural data collection process for each patient. Many randomised trials have investigated important questions, but their modest sizes limit their ability to detect rare events, such as hernia recurrence, which generally will require much larger sample sizes to permit clear inferences. Registry data require sophisticated analytic techniques, such as propensity scores or instrumental variables, to reduce the impact of confounding reports as a result of selection bias.

Only audit and peer review measures have been included which are achievable within the NHS framework and do not significantly influence the healthcare practitioner's workload. Secondary care providers must ensure that adequate outcome data is recorded at a local level in order to demonstrate the efficacy of their service. Particular emphasis should be placed on patient-based outcomes and compliance with best evidence as outlined in this guidance document. This list does not include currently collected HES data.

| Standard                        | Description  |
|---------------------------------|--|
| Cancellation rates              | Operations cancelled by the hospital within 48-hours of surgery.   |
| High compliance with PROMs data | Providers should aim to collect Patient Reported Outcomes Measures (PROMs) for all patients and compliance should be checked against hospital exit data. |

### 5.2 QUALITY SPECIFICATION/CQUIN

Healthcare providers adhering to this guidance and achieving the audit and peer review measures should be rewarded with C/QUINs as outlined below.

| Measure  | Description       | Data specification                                       |
|--|-------------------|--|
| Day case rates                                 | 70% day case rate | HES data   |
| 7 day Readmission rates                        | <5%               | HES data   |
| 30 day Readmission rates                       | <5%               | HES data   |
| Reoperation (same side) within 12 months       | <5%               | HES data   |
| Laparoscopic rates for recurrent groin hernia  | ≥40%*             | HES data   |
| Laparoscopic rates for bilateral groin hernia  | ≥40%*             | HES data   |
| Compliance rates with completion of PROMs data | ≥75%              | PROMs compliance rate from data collection organisations |

\* These are below the recommend best practice levels; however, they represent a realistic goal for providers.



## 6. DIRECTORY

### 6.1 PATIENT INFORMATION

| Name  | Publisher              | Link  |
|---|------------------------|---|
| National patient information leaflet on groin hernia (produced in conjunction with the commissioning guidance). | British Hernia Society | The document is currently being finalised and will be available at: <a href="http://www.britishherniasociety.org/links/">http://www.britishherniasociety.org/links/</a> |

### 6.2 CLINICAL INFORMATION

| Name   | Publisher                                  | Link  |
|--|--|---|
| European Hernia Society guidelines on the treatment of inguinal hernia in adult patients.                                      | Hernia                                     | <a href="http://download.springer.com/static/pdf/620/art%253A10.1007%252Fs10029-009-0529-7.pdf?auth66=1363805022_d9137efaa66a9ef2ca38a8438e5d0c3d&amp;ext=.pdf">http://download.springer.com/static/pdf/620/art%253A10.1007%252Fs10029-009-0529-7.pdf?auth66=1363805022_d9137efaa66a9ef2ca38a8438e5d0c3d&amp;ext=.pdf</a> |
| Guidelines for laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal Hernia [International Endohernia Society (IEHS)] | Surgical endoscopy                         | <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3160575/pdf/464_2011_Article_1799.pdf">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3160575/pdf/464_2011_Article_1799.pdf</a>   |
| Laparoscopic surgery for inguinal hernia repair: systematic review of effectiveness and economic evaluation                    | Health Technology Assessment               | <a href="http://www.hta.ac.uk/pdf/xecs/summ914.pdf">http://www.hta.ac.uk/pdf/xecs/summ914.pdf</a>   |
| Surgical Options for Inguinal Hernia: Comparative Effectiveness Review   | Agency for healthcare research and quality | <a href="http://www.effectivehealthcare.ahrq.gov/ehc/products/244/1176/CER70_Inguinal-Hernia_FinalReport_20120816.pdf">http://www.effectivehealthcare.ahrq.gov/ehc/products/244/1176/CER70_Inguinal-Hernia_FinalReport_20120816.pdf</a>   |

### 6.3 NHS EVIDENCE CASE STUDIES

| Name                                | Publisher               | Link  |
|-------------------------------------|-------------------------|---|
| Pre-Operative Assessment Guidelines | Royal Cornwall Hospital | <a href="http://www.rcht.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/Clinical/Anaesthetics/PreOperativeAssessmentGuidelines.pdf">http://www.rcht.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/Clinical/Anaesthetics/PreOperativeAssessmentGuidelines.pdf</a> |

## 7. BENEFITS AND RISKS

The benefits of adopting this guidance are to ensure evidence-based practice for groin hernia surgery and to reduce regional variation in the quality of service provided. This should allow access to effective management, improve access to patient information and improve the overall patient experience. Adoption of the recommendations made in this guidance should reduce unnecessary referrals; ensure that imaging and peri-operative investigations and the surgical procedure are appropriate.

The risk of adoption of the guidance is that the current local framework may not have the resources or the infrastructure in place to deliver a complete service, including laparoscopic and open groin hernia repair. This may require additional resource, to establish a specialist provider in order to develop the hernia service. Alternatively, patients may have to travel further for treatment to a centre which can offer the services suggested.

## 8. FURTHER INFORMATION

### 8.1 RESEARCH RECOMMENDATIONS

We identified several gaps in available evidence in the course of conducting this guidance. The following areas should be addressed:

1. A RCT of laparoscopic *vs* open inguinal hernia repair in patients with pre-operative risk factors for developing chronic pain.
2. A cohort study (with well matched groups) comparing laparoscopic and open LA inguinal hernia repair in patients > 70 years.
3. Laparoscopic *vs* open surgery for femoral hernia repair.
4. Mesh *vs* suture open femoral hernia repair.
5. Use of MRI in occult hernia.

### 8.2 OTHER RECOMMENDATIONS

For the next update of this document in April 2016, the following areas should be addressed:

1. Hernias in <18 year olds.
2. Measuring outcome data.
3. Establishment of compulsory national hernia registry.

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Groin Hernia Guidelines



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