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Health Technology Assessment of Scheduled Procedures

Referral thresholds for adult patients with groin (inguinal or femoral) hernia

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Safer Better Care

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Table of Contents

| | |
|--|-----------|
| ABOUT THE HEALTH INFORMATION AND QUALITY AUTHORITY | 3 |
| 1 GROIN HERNIA | 6 |
| 1.1 Scope of this health technology assessment..... | 6 |
| 1.2 Background..... | 6 |
| 1.3 Surgical procedure, potential complications and alternative treatments | 7 |
| 1.4 Current practice in Ireland..... | 9 |
| 2 CLINICAL REFERRAL/TREATMENT THRESHOLD | 12 |
| 2.1 Review of the literature | 12 |
| 2.2 Clinical evidence | 13 |
| 2.3 Cost-effectiveness evidence | 18 |
| 2.4 Budget impact and resource implications | 20 |
| 2.5 Advice on clinical referral/treatment threshold | 22 |
| 3 DISCUSSION..... | 23 |
| 4 REFERENCES..... | 25 |
| APPENDICES | 29 |
| Appendix 1.1 – HIPE ICD-10AM/ACHI list of intervention codes for hernia repair procedures | 29 |
| Appendix 1.2 – Primary care flow diagram | 30 |
| Appendix 1.3 – Flowchart of suggested treatment algorithm for elective inguinal and femoral hernia repair in adults..... | 31 |
| Appendix 1.4 - Examples of CCG and PCT Thresholds, UK..... | 32 |
| Appendix 1.5 - Evidence table summarising the data extracted from the cost-effectiveness literature | 35 |

1 Groin hernia

1.1 Scope of this health technology assessment

This health technology assessment (HTA) evaluates the appropriateness and potential impact of introducing clinical referral or treatment thresholds for people suspected of requiring groin hernia (inguinal or femoral) repair in Ireland. The effectiveness of this surgery may be limited unless undertaken within strict clinical criteria. This report is one of a series of HTAs of scheduled procedures. Details of the background to the request and general methodology are provided in the separate 'Background and Methods' document.⁽¹⁾

The scope of this HTA is to investigate clinical referral and diagnostic thresholds that can be used in the assessment, diagnosis and referral of adults who are potentially suffering from a groin hernia in Ireland. Inputs from an expert advisory group along with a review of the clinical and cost-effectiveness literature were used to inform the criteria. Additionally, the budget impact and resource implications were assessed, as appropriate.

1.2 Background

A hernia is an abnormal protrusion of an organ or part of an organ through an abnormal opening in the wall of its containing cavity. Herniae involving the external abdominal wall are the most common form, and include inguinal, femoral and umbilical types.

Herniae may be described as reducible, incarcerated or strangulated. A reducible hernia is one in which the contents of the hernial sac can be easily pushed back into the abdomen while conversely an incarcerated (irreducible) hernia cannot be placed back into the abdominal cavity proper. In general, the longer a hernia remains, and the larger it becomes, the harder it is to reduce.⁽²⁾ A strangulated hernia occurs when the vascular supply to the contents of the already incarcerated hernial sac (usually bowel or fat or omentum) is compromised, resulting in ischaemia or gangrenous bowel; this is a surgical emergency.

Groin herniae may be inguinal or femoral; the former involves herniation through the inguinal canal while the latter occurs as a consequence of herniation along the path of the femoral canal. It is estimated that 20 million inguinal herniae are repaired worldwide every year, with the lifetime risk being 27% for men and 3% for women.⁽³⁾ A 2013 Danish study by Burcharth et al. reported on all groin hernia repairs undertaken in Denmark over the five years to the end of 2010 (n=46,717).⁽⁴⁾ Surgery in men accounted for 88.6% of procedures. Inguinal herniae comprised 97%

of groin hernia repairs (90.2% males, 9.8% females) and femoral herniae 3% of groin hernia repairs (29.8% males, 70.2% females). Patients between 0–5 years and 75–80 years constituted the two dominant groups for inguinal hernia repair. In contrast, the age-specific prevalence of femoral hernia repair increased steadily throughout life, peaking at age 80–90 years in both men and women.⁽⁴⁾

Inguinal herniae are more common in males, with a male:female ratio of 12:1. They are slightly more common on the right side of the body. The vast majority of inguinal herniae present with a palpable or visible swelling in the groin.⁽⁵⁾ The diagnosis is usually apparent on clinical grounds, and further investigation is generally unnecessary. Less than 5% present as an emergency.⁽⁶⁾

Inguinal herniae typically develop slowly, but can be exacerbated by any condition which raises pressure within the abdomen, for example, obesity, constipation, straining at micturition or chronic coughing. Continued heavy lifting is thought to have a similar effect.⁽²⁾ Smoking is recognised as a risk factor. An inguinal hernia may be asymptomatic or can result in a variety of symptoms, including:

- Groin pain with a positive cough impulse.
- Intermittent episodes of difficulty reducing the hernia.
- Increasing size of the hernia and an associated bulge in the groin or scrotum.
- Tenderness over the site of herniation.

Femoral herniae account for 20% of herniae in women and 5% in men. In men, inguinal hernia is 40 times more common than femoral hernia, but in women inguinal hernia is only twice as common.⁽²⁾ Femoral herniae are usually acquired as a result of raised pressure within the abdominal cavity (for example, pregnancy or obesity). Of importance, strangulation is the initial presentation in 40% of femoral hernia.

It should be noted that this HTA does not pertain to the entity known as Gilmore's groin or 'sportsman's hernia' or pubalgia, in which a syndrome of chronic groin pain is associated with a dilated superficial inguinal ring.⁽⁷⁾

1.3 Surgical procedure, potential complications and alternative treatments

Diagnosis of hernia can be made on clinical grounds in the majority of cases.⁽⁸⁾ In general terms, once a diagnosis of femoral hernia is made, these patients should be referred for review in secondary care. Inguinal herniae, meanwhile, may be managed conservatively with a pressure truss, but recent UK commissioning guidance has suggested that these are both ineffective and uncomfortable, and hence will only be suitable in very limited circumstances. Specific referral practices are discussed in section two.

Inguinal herniae may be repaired using open or laparoscopic techniques. The latter approach may be beneficial in patients with bilateral herniae or for those at risk of chronic pain (for example, younger patients, those with other chronic pain problems, patients who present pre-operatively with severe groin pain with only a small hernia on palpation). The abdominal wall defect may be closed with sutures or with mesh, with the latter having the reported advantages of: being easy to learn, decreased postoperative pain and low recurrence rates.⁽²⁾ Day case surgery should be considered in all surgical candidates. A small number of individuals require inpatient stay for comorbidity, social reasons or for complex inguinal hernias. Local anaesthesia is recommended for groin hernia repair in elderly patients, and patients with comorbidities.

A Finnish study of 55,000 inguinal hernia repairs between 2003 and 2007 reported an overall complication rate of 4.5 per 1,000 hernia procedures; distribution of complications included chronic pain (32%), infections (22%), bleeding complications (13%), urologic complications (12%), recurrence (8%), intestinal complications (7%), and miscellaneous disorders (6%).⁽⁹⁾

The mortality risk following elective inguinal hernia repair is low, even in older age. It is much less than 1% and is generally not raised above that of the background population.⁽¹⁰⁾ Large studies have shown that for elective hernia repair, the mortality rate was 0.02% and 0.48% for those aged less than and greater than 60 years of age, respectively.⁽¹¹⁾ Of note, in an emergency repair, the mortality rate rises to 7% and there is a 20-fold increase in mortality if bowel resection is undertaken.^(10;11)

The surgical approach to repair of a femoral hernia varies depending on the individual patient's health status and the presumed status of the contents of the hernial sac (whether the contents are compromised or not). Again, an open or laparoscopic approach can be employed. The principal of the surgery is to dissect out the borders of the hernial sac, open and examine the contents of this sac, reduce the contents (or excise if they are compromised), and then to close the hernial defect (which caused the problem in the first instance). Closure is generally with non-absorbable sutures; mesh may or may not be employed. A 2013 study of 885 patients (690 female, 78.0%) who underwent femoral hernia repair between 1997 and 2007 in the UK reported that 406 (45.9%) did so as an emergency; compared with zero percent mortality within 30 days of surgery for elective repair, emergency repair was associated with a mortality rate of 1.7%. Adverse events were more common among patients operated on as emergency, with 94 (23.2%) having a small bowel resection compared with one (0.2%) who had elective surgery.⁽⁶⁾

1.4 Current practice in Ireland

Potential candidates for inguinal or femoral hernia repair are generally referred by their general practitioner (GP) or by another hospital specialist to a general surgeon. Referral or treatment thresholds (similar to those discussed in Section 2 below) may be used by GPs and surgeons in Ireland to identify eligible candidates for referral or treatment. However, it is unclear if such thresholds are being used, or how consistently they are being applied.

Hernia repair is a routine scheduled surgical procedure within the publicly-funded healthcare system in Ireland. The Hospital In-Patient Enquiry (HIPE) system was employed during this HTA to assess activity levels in relation to hernia repair. This procedure may be coded as the principal procedure or as a secondary procedure. For consistency and completeness, data are reported to include the principal and secondary procedures (that is 'all procedures') with all data presented on this basis. The International Classification of Diseases (ICD) intervention codes used to retrieve this data are listed in Appendix 1.1.

The HIPE system reports that there were approximately 3,164 adults (greater than or equal to (\geq)18 years of age) who underwent hernia (inguinal or femoral) repair in 2012. Of these, 2,923 (92.4%) patients were admitted for their procedure on an elective (planned surgery) basis; 199 procedures were done as an emergency, with 42 performed during an elective or emergency readmission. Of the 199 procedures performed as an emergency, at least 69% were for an inguinal hernia, with at least 21% performed for a femoral hernia.

These data capture procedures provided as hospital day case and inpatient procedures, as in the other HTA reports in this series. Of the 2,923 procedures carried out in the pure elective setting, 1,473 (50.4%) were reported as being done on a day case basis. The National Clinical Programme in Surgery has set out targets for the percentage of procedures that should be performed as day cases in its document, 'model of care in elective surgery'.⁽¹²⁾ This identifies day case targets of 95% for unilateral laparoscopic repair of an inguinal hernia and 90% for unilateral repair of an inguinal hernia. Analysis of hernia repairs performed in public hospitals in Ireland in 2012 reveals that the overall day case rate for patients undergoing unilateral laparoscopic repair of an inguinal hernia, where it was coded as the principal procedure, was 52.3% (hospital range 0-100%), while that for patients undergoing unilateral repair of an inguinal hernia, where it was coded as the principal procedure was 50.9% (hospital range 1.1%-100%).

A total of 1,450 elective procedures were carried out on an inpatient basis, with an average length of stay (ALOS) of 1.9 days. It is noted that the average length of stay for patients undergoing elective groin hernia repair in public hospitals decreased from 2.8 days in 2005 to 1.9 days in 2012 (Figure 1.1). Given the variation in day case rates noted above, it may be that those institutions with shorter average lengths of stay have concomitantly lower day case rates. The average age of patients (≥ 18 years of age) undergoing elective groin hernia repair in 2012 was 56 years.

The 2,923 elective hernia repairs recorded within the HIPE system in 2012 were performed across 37 different hospital sites (range 7-147 procedures per hospital). These institutions are categorised according to their hospital groups in Table 1.1. Any variation in practice may be explained by differing catchment sizes or the availability of a particular surgical service, hospital size or specialisation.

Table 1.1 HIPE data for elective hernia repair per HSE hospital group* (2012)⁽¹³⁾

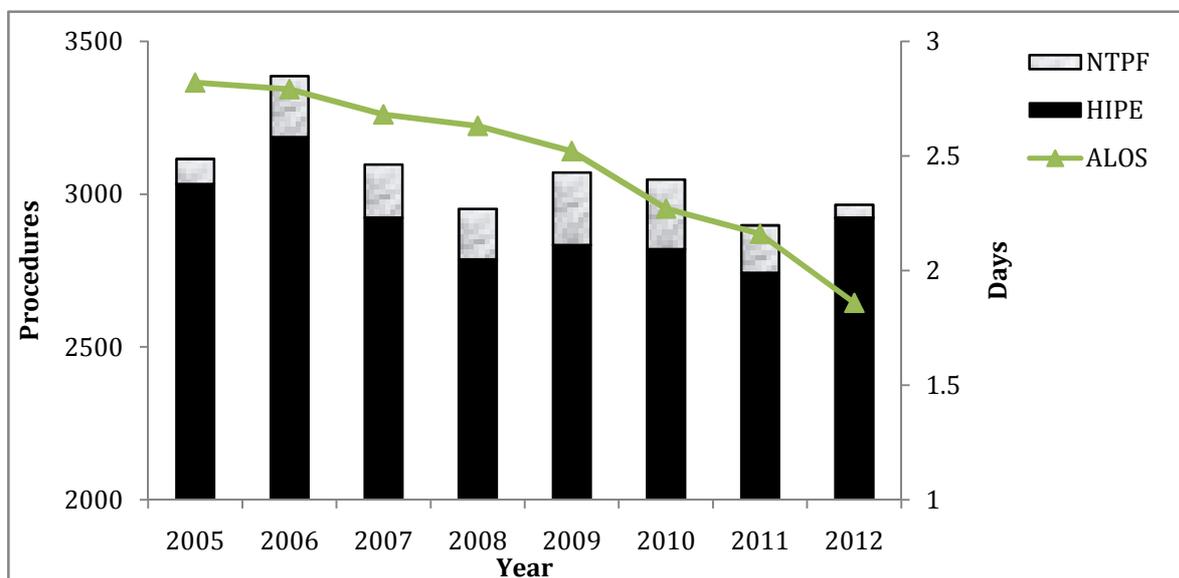
| Hospital group | Number | ALOS (days) | % Day Cases (Hospital Range) | Average age |
|----------------------|----------------------------|-------------|------------------------------|-------------|
| | (%) Range | | | (years) |
| Dublin North East | 473 (16.2) 34-121 | 1.6 | 56.4 (2.9-76.9) | 54.2 |
| Dublin Midlands | 460 (15.7) 49-141 | 2.3 | 60.9 (10.2-72.2) | 56.5 |
| Dublin East | 538 (18.4) 40-94 | 2.0 | 56.9 (16.1-83.3) | 54.8 |
| South and South West | 689 (23.6) 28-118 | 1.7 | 41.9 (3.8-78) | 56.3 |
| West and North West | 572 (19.6%) (29-147) | 2.0 | 43.7 (21.8-75.7) | 57.5 |
| Midwest | 191 (6.5%) (7-139) | 1.6 | 42.4 (14.3-100) | 57.3 |
| Total | 2,923 | 1.9 | 50.4 | 56.0 |

*Key: Range – The range in terms of number of procedures performed in individual institutions within the hospital group. ALOS – Average length of stay; See Appendix 1.1 for HIPE codes; * HIPE data includes all activity in publicly-funded hospitals, including procedures in patients that used private health insurance.*

All patients who undergo a surgical procedure in Irish public hospitals have an operative diagnosis coded as part of the HIPE coding process. This is recorded as the principal diagnosis at the time of procedure, and may not be synonymous with the preoperative diagnosis. In 2012, the principal diagnosis, at the time of hernia repair, was coded as 'unilateral or unspecified inguinal hernia, without obstruction or gangrene' (90.4%); the next most frequently coded diagnoses were 'bilateral inguinal hernia, without obstruction or gangrene' (3.8%), and 'unilateral or unspecified femoral hernia, without obstruction or gangrene' (2.8%).

In addition to the activity levels in public hospitals, there were 1,283 procedures procured by the public healthcare system via the National Treatment Purchase Fund (NTPF), from private hospitals, between 2005 and 2012. Data on the total number of procedures undertaken in the publicly-funded system, including the additional procedures funded by the NTPF in private hospitals, are shown in Figure 1.1. The total number of elective groin hernia repairs funded by the public healthcare system (2,965 in 2012) has decreased by 4.8% since 2005 (3,115), having peaked in 2006 (3,386).

Figure 1.1 Number and average length of stay (days) for elective groin hernia repairs in adults provided through the publicly-funded healthcare system in Ireland, 2005-2012⁽¹³⁾



Key: HIPE (Hospital In-Patient Enquiry Scheme) data; NTPF (National Treatment Purchase Fund) funded procedures in private hospitals. ALOS (average length of stay [inpatients]). HIPE data includes all activity in publicly funded hospitals, including procedures in patients that used private health insurance.

The length of time a patient must wait to be reviewed varies according to the referral pathway and the individual hospital and consultant to which a patient is referred. At

the end of July 2014, it was reported that there were 360,753 patients on the Outpatient Waiting List database collated by the NTPF, 34.7% of whom were waiting longer than six months, with 10.5% on the list for longer than 12 months.⁽¹⁴⁾

Speciality-specific figures were published at the end of July 2014 - referrals to general surgery (including ('gastrointestinal surgery')) constituted 10.3% (37,080) of the total waiting list at that time.⁽¹⁵⁾

Initiatives are underway by the HSE to standardise the management of outpatient services and to ensure that there are consistent management processes across all publicly-funded healthcare facilities that provide outpatient services. This includes the publication of a protocol for the management of these services by the NTPF in January 2013 which provides the core guidance of the Outpatient Services Performance Improvement Programme.⁽¹⁶⁾ The protocol specifies that patients should be treated based on clinical urgency, with urgent referrals seen and treated first. It is intended that the definition of clinical urgency and associated maximum wait times is to be developed at speciality or condition-level and agreed by the clinical programmes.

In January 2013, the NTPF published a national waiting list management policy that outlines the standardised approach to managing scheduled care treatment for inpatient, day case and planned procedures in all publicly-funded hospitals.^(16;17) It outlines a consistent structured approach that must be adopted in the management of the waiting list; monitoring of the implementation of the policy will be routinely undertaken by the NTPF in the form of annual quality assurance reviews.

2 Clinical referral/treatment threshold

2.1 Review of the literature

A comprehensive review of the literature was conducted during May 2014 to identify international clinical guidelines and health policy documents describing treatment thresholds that are in place in other healthcare systems. It also considered systematic reviews and economic evaluations examining the effect of the introduction of those thresholds. The approach and general search terms are described in Appendix 1 in the 'Background and Methods' document, and a summary of the results is included in Table 2.1. Examples of clinical algorithms and thresholds in use elsewhere are provided in Appendices 1.3 to 1.5.

Table 2.1. Summary of literature search results

| Publication Type | Number | References |
|------------------------------|--------|------------|
| Clinical guidelines | 5 | (5;18-21) |
| Reviews | 4 | (22-25) |
| Randomised controlled trials | 2 | (26;27) |
| Cost-effectiveness studies | 4 | (27-30) |

2.2 Clinical evidence

In 2013, a national commissioning guide for groin (inguinal, femoral, primary and recurrent) hernia in the UK was jointly published by the Association of Surgeons of Great Britain and Ireland (ASGBI), the Royal College of Surgeons (RCS) and the British Hernia Society, with the National Institute for Health and Care Excellence (NICE) accrediting the process.⁽¹⁸⁾ This stated that patients should be directed to appropriate supporting patient information. Diagnostic imaging should **not** be arranged at primary care level and referral was advised (see algorithm in Appendix 1.2) for:

- All patients with an overt or suspected inguinal hernia, except for patients with minimally symptomatic/asymptomatic/occult/recurrent inguinal hernias and who have significant comorbidity (American Society of Anaesthesiologists (ASA) grade 3 or 4) and do not want to have surgical repair (after appropriate information provided).
- 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) as a 'routine referral'.
- Men with symptomatic hernias that are irreducible and partially reducible inguinal hernias, and all hernias in women as 'urgent referrals'.
- Patients with suspected strangulated or obstructed inguinal hernia as 'emergency referrals'.
- All children <18 years with inguinal hernia to a paediatric surgical provider.

The commissioning guide then makes a number of recommendations regarding where the referral should be directed (see algorithm in Appendix 1.2):

- Patients with primary inguinal hernias who meet referral criteria can be referred generically to an appropriate secondary care provider.

- Patients with bilateral inguinal hernias should be referred to a surgeon who performs both open and laparoscopic repair.
- Patients with recurrent inguinal hernias who meet referral criteria should be referred to a surgeon who performs both open and laparoscopic repair and where possible to the named surgeon who performed the first repair (providing the patient does not request otherwise).
- Patients with multiple recurrent (more than one recurrence) inguinal hernias should be referred to a named surgeon who has subspecialty interest in hernia repair and performs both open and laparoscopic repair.

In 2014, the European Hernia Society (EHS) published its updated guidelines on the treatment of inguinal hernia.⁽²¹⁾ These were an update from the version published in 2009,⁽⁵⁾ and included all relevant level 1A and level 1B literature from May 2008 to June 2010. Specifically regarding indications for surgical intervention, both the 2009 document and its updated version recommended that in minimally symptomatic or asymptomatic inguinal hernia in men, a watchful waiting strategy should be considered. Although noting that it is very likely (>70% chance) that, in time, the symptoms will increase leading to surgical intervention, the 2014 guidance proceeds to state that watchful waiting should particularly be considered in older patients or in the presence of major comorbidity.⁽²¹⁾

In 2011, the Danish Hernia Database was used to develop national guidelines for the management of inguinal hernia.⁽¹⁹⁾ These guidelines were approved by the Danish Surgical Society. They state that diagnosis should be based on clinical examination, but suggested that where there is doubt, this examination might be supplemented by ultrasonography, computed tomography (CT) scan or magnetic resonance imaging (MRI), depending on local expertise. It was suggested that surgical treatment should be restricted to male patients with femoral hernia, and those with symptoms or complications of inguinal hernia, and that surgery should be offered to all females with an inguinal or femoral hernia, irrespective of symptoms or complications (Appendix 1.3).

In 2013, the Society for Surgery of the Alimentary Tract (SSAT) published the most recent version of its patient care guidelines for inguinal and femoral hernias.⁽²⁰⁾ These were developed based on critical review of the literature and expert opinion, with consensus agreement used to develop the finished report. This report notes that ultrasound or other radiologic studies are not required because the diagnosis can usually be made by physical examination, although it goes on to suggest that ultrasound or axial imaging may be useful in delineating a femoral hernia where the patient complains of pain in the thigh, but no bulge is found on physical examination; this is particularly the case for elderly and obese patients. Regarding referral, the

guidelines note that most groin hernias are readily reducible, have minimal or no tenderness, and can be electively referred to a surgeon within a period of weeks. However, if the hernia is tender and not reducible, the patient should be referred immediately due to the risk of strangulated bowel or other viscera. Aggressive attempts to reduce a groin hernia with sedation, ice packs, or sustained weight or pressure should not be pursued. Symptoms such as nausea and vomiting suggest bowel obstruction, which also mandate immediate referral to a surgeon.

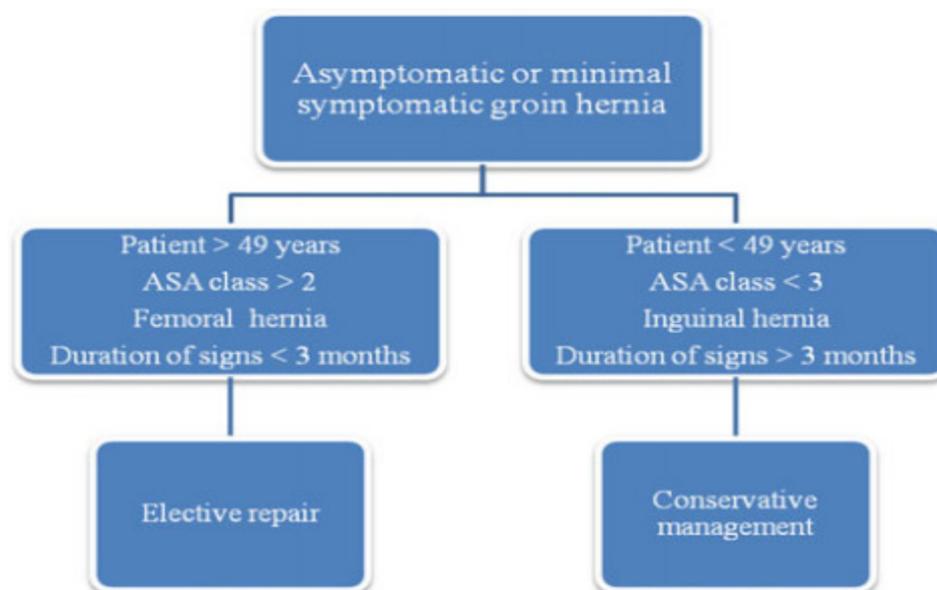
The Agency for Healthcare Research and Quality (ARHQ) in the United States published its comparative effectiveness review of surgical options for inguinal hernia in 2012.⁽²²⁾ Although the majority of this report dealt with surgical options (for example, open versus laparoscopic repair), it did attempt to address the issue of whether hernia repair differs from watchful waiting, in terms of patient-oriented effectiveness outcomes and or adverse events. However, just two studies were found which could inform this issue - one by Fitzgibbons et al. and one by O'Dwyer et al.^(26;27) - and both were considered to have moderate risk of bias for the outcomes reported. The authors felt that the evidence was sufficient – albeit of low strength - to permit a conclusion for one outcome: quality of life at six months and one year was better for those who had received a mesh repair versus those who were on watchful waiting. No recommendations could be made in relation to either long-term pain or the risk of acute hernia/strangulation.

A systematic review of the evidence regarding watchful waiting versus surgery for asymptomatic inguinal hernia was published by Mizrahi et al. in 2012.⁽²⁴⁾ The evidence from just two randomised controlled trials was found for inclusion in this review; these were the same two randomised controlled trials discussed in the aforementioned ARHQ review.^(26;27) All patients were male. Neither of the trials demonstrated a difference regarding pain and discomfort between the patients who had surgery and those who were followed-up. In patients with watchful waiting, the rates of strangulation were 0.27% after two years of follow-up and 0.55% after four years of follow-up; in patients who underwent elective surgery, meanwhile, the range of operative complications was 0% to 22.3% and the recurrence rate was 2.1%. A significant crossover ratio ranging between 23% and 72% from watchful waiting to surgery was found, mainly because of pain; the review concluded that both management options – watchful waiting and surgical intervention – are safe, but that most patients will develop symptoms over time and will require operation.⁽²⁴⁾

Van den Heuvel et al. addressed the same issue in their review, published in 2011.⁽²⁵⁾ Their recommendations were based on a literature search. They noted that the incidence of incarceration in the watchful waiting groups of the two aforementioned randomised controlled trials was 1.8 and 6.25 per 1,000 patients, respectively. Van

den Heuvel et al. reported that the risk of incarceration was higher in those aged greater than 60 years, those who have a femoral hernia and those with a short duration of signs. The authors also noted that when a groin hernia does incarcerate or strangulate and emergency repair is required, the morbidity and mortality rates are higher compared with elective repair in high risk patients. Risk factors for increased morbidity and mortality were identified as age above 49 years, delay between onset of symptoms and surgery greater than 12 hours, femoral hernia site, nonviable bowel and ASA-class 3 and 4. The authors suggested the following management algorithm:

Figure 2.1 Mangement algorithm for asymptomatic or minimally symptomatic groin hernia



From: Van den Heuvel et al., 2011.⁽²⁵⁾

In 2008 Barkun et al. published an evidence-based review regarding watchful waiting in inguinal hernia on behalf of the Canadian Association of General Surgeons (CAGS) and the American College of Surgeons (ACS).⁽²³⁾ This focused solely on the randomised controlled trial published by Fitzgibbons et al. in 2006 wherein authors compared watchful waiting with open tension-free surgical repair in men with asymptomatic or minimally symptomatic inguinal hernias.⁽²⁶⁾ The conclusion of this trial, which had randomised a total of 724 men and had a median follow-up time of 3.2 years, was that watchful waiting is a safe and acceptable option for this cohort of patients. Delaying surgery until symptoms increase is safe because acute hernia incarcerations occur rarely.⁽²⁶⁾ Barkun et al. noted that the operative complication rate reported by Fitzgibbons et al. was 21.7% in the surgical repair group and was

not significantly different from that of patients who crossed over during the course of the trial and had surgery after a period of watchful waiting (27.9% complication rate). The recurrence rate at two years was 1% among patients in the surgical repair group and 2.3% among patients who were assigned to the watchful waiting group, but crossed over to surgical repair. The trial authors observed a frequency of 1.8 events (hernia strangulation or incarceration) per 1,000 patient-years in those assigned to the watchful waiting group. Barkun et al. noted that the conclusions reached in the randomised controlled trial were heavily dependent on the definition of a 'minimally symptomatic' hernia; they noted that no definition was provided and that at baseline, about 8% of the study participants stated they had pain at rest and more than 15% had pain with exercise. It was also noted that study participants were recruited by radio advertising and thus the study population may have been different from that cohort of patients who seek out medical attention and are referred for surgical care. Despite these reservations, however, Barkun et al. were ultimately in agreement with the conclusions of the randomised controlled trial and suggested that it appears that given patient preference, observation is indeed a feasible and valid alternative to mandatory surgery in the short-term.⁽²³⁾

The use of referral thresholds by Primary Care Trusts (PCTs) in the English NHS has been common practice for several years. As part of the changes to the NHS brought about by the Health and Social Care Act 2012, PCTs and Strategic Health Authorities (SHAs) ceased to exist on 31 March 2013. Its responsibilities were taken over by Clinical Commissioning Groups (CCG) and the NHS Trust Development Authority. However, the thresholds that were previously developed by these trusts are likely to represent ongoing practice at a local level while new commissioning guides are being established. A summary of specific thresholds from a sample of three NHS PCTs and CCG areas is provided in Appendix 1.4. It is noted that all three examples identify the asymptomatic inguinal hernia as an inappropriate indication for referral for surgical opinion.

It is clear that much of the opinion regarding femoral hernia and symptomatic inguinal hernia is uniform in its recommendations for referral. However, for asymptomatic groin hernia, while RCT evidence supports the use of a 'watch and wait' policy (a stance supported by the PCTs and CCGs in the UK), issues with the methodology of these trials have been identified, so that the most recent national commissioning guide in the UK advocates for onward referral except in very specific instances.

2.3 Cost-effectiveness evidence

The four studies included in this section examine the potential cost-effectiveness of groin hernia repair in disparate groups of patients and settings. Two of the studies focused specifically on asymptomatic or minimally symptomatic patients^(27;29) - these are most relevant to the threshold being developed in this present work; the other studies are included for completeness.^(28;30) None of the studies were set in Ireland. For ease of review, all costs presented have been inflated using the local consumer price index for health to 2013 values and then converted to Irish Euros using the latest Purchasing Power Parities. An evidence table summarising the data extracted is included in Appendix 1.5.

Stroupe et al.⁽²⁹⁾ examined the cost-effectiveness of watchful waiting versus surgical intervention in the cohort of male patients with asymptomatic or minimally symptomatic herniae, studied in the RCT by Fitzgibbons et al.⁽²⁶⁾ that was discussed in section 2.2. The authors compared the total two-year healthcare costs of patients randomised to watchful waiting (n=358) or surgery (n=366), and determined the cost-effectiveness for patients as measured by cost per quality-adjusted life year (QALY). Costs were estimated from the healthcare payer's perspective and were adjusted to 2004 US dollars (\$USD) using the Consumer Price Index, these were transferred to Irish costs as described above. At two years follow-up, 78 patients (24%) who had been assigned to watchful waiting had requested and received a hernia repair (increase in hernia-related pain was the most common reason offered), and 50 patients (16%) who had been assigned to surgery refused or postponed repair and were treated with watchful waiting. Patients randomised to surgery incurred €2,133 higher costs (€9,174 vs. €7,041) and had a slightly higher mean QALY (0.031; 95% CI, 0.001-0.06) than patients randomised to watchful waiting. The ICER, which gives the cost per additional QALY, was €68,804/QALY (95% CI, €1,582-€375,986). The authors suggested that this cost per QALY gained with surgery would likely continue to decrease over time, as more individuals being managed with watchful waiting crossed over to have an operation. Noting that \$50,000 was generally regarded as a reasonable cut off for cost-effectiveness in the United States, the authors suggested that surgical intervention in those with asymptomatic groin herniae is on the margin of what is considered a worthwhile procedure.⁽²⁹⁾ However, the relevance of this 2004 American study to the current Irish public healthcare setting is debatable.

Similar to the study by Stroupe et al., the 2006 Scottish study by O'Dwyer et al.⁽²⁷⁾ took cohorts of patients from randomised controlled trials (RCTs) that had compared watchful waiting with surgical intervention.⁽²⁷⁾ This randomised 160 men aged ≥ 55 years with asymptomatic herniae in Glasgow. At 12 months, 19% of the patients in

the observational arm crossed over to surgery, mostly due to increase of pain. The authors reported that the incremental cost per patient to the NHS for the operation group was €578 at the median follow-up of 574 days. This took into account clinic and operative costs and the cost of complications for both groups. Despite improvements in general health, there was no significant QALY gain for the operation group (0.77) versus the observation group (0.77) at 12 months.⁽²⁷⁾

In 2013, Cronini-Cronberg et al. published their analysis of patient-reported outcome measures (PROMS) as a tool to measure the cost-effectiveness of elective inguinal hernia surgery in England.⁽²⁸⁾ This report comprises data from 17,776 patients between March 2009 and April 2010; a total of 68,640 eligible hernia repair operations were performed in England over this timeframe. Patients less than 18 years of age were excluded. Quality of life was assessed pre- and three months post surgery for patients undergoing open repair (n=13,971) and laparoscopic surgery (n=3,805). Assuming no health degradation for those who do not undergo surgery, it was estimated that the mean cost per QALY of surgery was €2,258 and as such surgery would be considered highly cost-effective. Laparoscopic surgery was estimated to be more effective (0.923 vs 0.817 QALYs) and less expensive (€1,706 vs €1,712) than open surgery, although it was noted that the cost of laparoscopic surgery may have been underestimated due to data limitations. Of note, the Casemix-adjusted mean cost of elective hernia surgery repair by NHS hospital varied seven-fold, ranging from €570 to €4,134 per procedure. As this study did not compare a surgical with a non-surgical cohort and included all patients who underwent elective hernia surgery, its relevance to this assessment is debatable.

In 2003 Stylopoulos et al. published the results of their Markov modelling analysis of a cohort of over 1.5 million patients.⁽³⁰⁾ Taking a societal perspective, the authors aimed to examine the cost-effectiveness of four different treatment strategies for inguinal hernia: (1) open mesh repair, (2) open non-mesh repair, (3) laparoscopic hernia repair, and (4) expectant management. The model calculated that laparoscopic hernia repair had a projected lifetime cost per patient of €5,485 and a mean quality-adjusted life expectancy of 9.04 QALYs. The cost of laparoscopic repair was 5% less than that of open mesh repair (€5,759) and 35% less than open non-mesh repair (€8,323); laparoscopic repair therefore dominated (that is, was less expensive and more effective than) both open mesh and open non-mesh repairs. Expectant management was both the least effective (6.35 QALYs) and the least costly strategy (€3,311); compared with expectant management, the incremental cost per QALY gained was €812 for the laparoscopic approach, €936 for open mesh, and €2,297 for open non-mesh repair.⁽³⁰⁾ Given the study design, year and setting, its relevance to current healthcare in Ireland may be limited.

To summarise, limited published literature relevant to this assessment was retrieved. The report by O' Dwyer et al.,⁽²⁷⁾ set in Glasgow, demonstrated that a significant cohort of patients who are initially managed with watchful waiting will eventually crossover to surgical intervention, although there may be no significant QALY gain for those who have surgery; these findings concur with the results of the study by Stroupe et al.,⁽²⁹⁾ which demonstrated only modest QALY gains for the surgical group. In conclusion, there is limited evidence regarding the cost-effectiveness or otherwise of surgical intervention in patients with asymptomatic groin herniae, and hence the threshold developed is primarily based on the clinical evidence presented in section 2.2 above.

2.4 Budget impact and resource implications

The number of elective groin hernia repairs in adults provided through the publicly-funded healthcare system has decreased by approximately 5% since 2005. The current estimated annual national cost of elective groin hernia repairs in adults is €8.5 million, with an average weighted cost per inpatient case of €4,229, and an average weighted cost per day case patient of €1,613, based on the latest Casemix costs (Table 2.3).

Table 2.3. HSE inpatient and day case acute hospital activity and costs for elective hernia repair procedures summarised by diagnosis-related group (based on 2011 costs and 2012 activity)⁽³¹⁾

| DRG code* | Description | Number (Principal Procedure) | % of groin hernia repairs | Cost/ inpatient (€) | Cost/ day case (€) |
|-----------|--------------------------------|------------------------------|---------------------------|---------------------|--------------------|
| G10B | Hernia Procedures W/O CC | 2,677 | 92.63 | 3,727 | 1,6 |
| G10A | Hernia Procedures W CC | 194 | 6.71 | 6,806 | 1,613 |
| G04C | Peritoneal Adhesiolysis W/O CC | 12 | 0.42 | 5,843 | 2,299 |

*Key: DRG- Diagnostic-related group; W-with; W/O-without; CC-complication or comorbidity. Data summary from HSE National Casemix Programme Ready Reckoner, 2013 based on the 2011 inpatient and day case costs reported by 38 hospitals participating in the programme that year. Activity is based on the latest 2012 HIPE data. *Note the remaining diagnosis-related groups accounted for five or fewer of the procedures each.*

Assuming the DRG code for uncomplicated open or laparoscopic groin hernia repair (G10B) and no change in overall activity levels, it is estimated that, were a target for day case rates of at least 90% for open inguinal hernia repair and 95% for laparoscopic inguinal hernia repair (as set out by the National Clinical Programme in Surgery) achieved, there would be a potential for opportunity cost savings versus the

present situation of up to approximately 1.9 million euro per annum (Table 2.4) facilitating more efficient use of available resources.

Table 2.4 Potential cost saving through achievement of National Clinical Programme target of at least 90% of elective open or 95% of elective laparoscopic groin hernias performed as day cases

| DRG code | Description | | | Cost/ inpatient (€) | Cost/ day case (€) | |
|----------------|------------------------------------|----------------|------------|--|-----------------------|------------|
| G10B | Hernia Procedures W/O CC | | | 3,727 | 1,613 | |
| | Open Inguinal Hernia Repair | | | Laparoscopic Inguinal Hernia Repair | | |
| Present | Day Cases (no. procedures) | 54% (1,041) | €1,679,133 | Day Cases (no. procedures) | 56.3% (263) | €424,219 |
| | Inpatient (no. procedures) | 46% (886) | €3,302,122 | Inpatient (no. procedures) | 43.7% (204) | €7,603,308 |
| | Total | 1927 | €4,981,255 | Total | 467 | €1,184,527 |
| Target | Day Cases (no. procedures) | 90% 1734 | €2,797,426 | Day Cases (no. procedures) | 95% 444 | €715,608 |
| | Inpatient (no. procedures) | 10% 193 | €718,193 | Inpatient (no. procedures) | 5% 23 | €87,026 |
| | Total | 1927 | €3,515,619 | Total | 467 | €802,633 |

Key: DRG- Diagnostic-related group; W-with; W/O-without; CC-complication or comorbidity. Data summary from HSE National Casemix Programme Ready Reckoner, 2013 based on the 2011 inpatient and day case costs reported by 38 hospitals participating in the programme that year. Activity is based on the latest 2012 HIPE data.

2.5 Advice on clinical referral/treatment threshold

Taking account of the available evidence that exists in relation to groin hernia and the associated risk of complications, the following threshold criteria are advised for referral and treatment within the publicly-funded healthcare system in Ireland:

Imaging is not required at primary care level.

All patients with a suspected strangulated hernia or with signs or symptoms of bowel obstruction or sepsis should be referred as an emergency.

All women with groin herniae should be referred for an urgent (within four weeks) surgical opinion in secondary care (femoral herniae are relatively common in women and these are more likely to result in complications unless addressed).

All men with symptomatic groin herniae should be referred for a surgical opinion in secondary care:

- if the hernia is not easily reducible, or where a femoral hernia is suspected, this should be an urgent (within four weeks) referral
- if the hernia is easily reducible, the referral should be routine.

Men with asymptomatic, easily reducible groin hernia may be managed with a 'watch and wait' policy once they are happy to do so following a discussion regarding the natural history of herniae, and an explanation of the pros and cons of surgical intervention. Where patients express a preference for surgical intervention following this discussion, they should be referred for a routine surgical opinion.

Where surgery is indicated, it should be made available at a time when the patient is most likely to derive maximum potential benefit, with due consideration given to their associated risk factors and risk of disease progression.

Patients who do not fit the above referral criteria should remain under the care of the general practitioner, with the need for reassessment dependent upon progression of signs and symptoms.

3 Discussion

Referral thresholds have been developed based on a comprehensive review of the literature and international referral guidelines. The aim of these thresholds is to ensure that the right patients receive referral and treatment at the right time, to avoid unnecessary interventions and, in particular, to ensure that those who would benefit most from prompt intervention are prioritised for review in secondary care. While referral thresholds may currently be used on an informal basis within the Irish system, this has not been done consistently. The thresholds developed here aim to provide primary care practitioners, surgeons and other clinicians involved in the care of these patients with a template upon which decision-making can be standardised.

It is noted that the number of elective groin hernia procedures has decreased by 4.8% when compared with activity in 2005. In this context, it is important to note that the introduction of the threshold outlined above is not expected to impact on the number of surgeries undertaken. Indeed, given the ageing population, and the association of hernia with increasing age, and increasing rates of obesity, it is likely that demand for surgical intervention in this setting will increase over the coming years.

The developed threshold suggests that all patients with groin hernia who request a surgical opinion should be afforded this opportunity. Whether the subsequent referral is prioritised as urgent or routine will depend on a number of factors, including gender and symptomatology, as highlighted within the threshold. In particular, for male patients who are asymptomatic or minimally asymptomatic, referral should not take place until there has been a discussion in relation to the pros and cons of surgical intervention and patients have indicated that they will be happy to proceed with surgery if considered suitable following assessment in secondary care. This will require additional time over and above a routine appointment in primary care, and thus a caveat to implementation of these guidelines is that this service is adequately resourced.

It is noted that while development of this threshold should aid in defining who should be referred for urgent review, the mechanisms around its practical implementation remain to be fully clarified. It is clear that the National Healthlink Project, which permits the secure transmission of clinical patient information between GPs and Hospitals, has facilitated improved communication of referrals between primary and secondary care. It is thus suggested that one mechanism through which this referral threshold might be implemented would be through its integration in the form of a standardised referral form into this Project.

The extent to which patients must wait for their hernia repair once they have been listed for this procedure is currently unclear. While efficiencies have been achieved in terms of length of stay, the total number of procedures carried out has fallen over time. It is unlikely, given the aforementioned demographic changes that demand for surgical intervention has fallen, and hence it is likely that waiting lists for groin hernia repair remain substantial and may even be increasing. This may influence primary care practitioners and other hospital specialists when considering the appropriateness of adopting a watchful waiting strategy with individual patients. Hence, a further caveat to implementation of these thresholds is that waiting lists for surgical intervention need to be optimised, such that patients who are listed for surgery receive this intervention at the time when they are most likely to derive maximum potential benefit, with due consideration given to their associated risk factors and risk of disease progression. One potential component of this optimisation process could be an investigation into the factors that are leading to wide regional variation and overall rates of day case surgery that are far below those standards set out by the National Clinical Programme in Surgery. As noted in section 2.4, minimisation of this variation and improvement in overall day case rates may hold potential for significant resource savings, without compromising patient care, thereby facilitating release of resources that could be used to enable timely access to necessary surgery for other patients.

In conclusion, the thresholds outlined above are consistent with well established clinical guidelines and published evidence. Hence, they are unlikely to represent a major change from current practice, but rather a standardisation of referral and treatment criteria across all areas of the publicly-funded healthcare system. As with all thresholds, it is imperative that there are opportunities for appeal mechanisms to ensure good governance.

4 References

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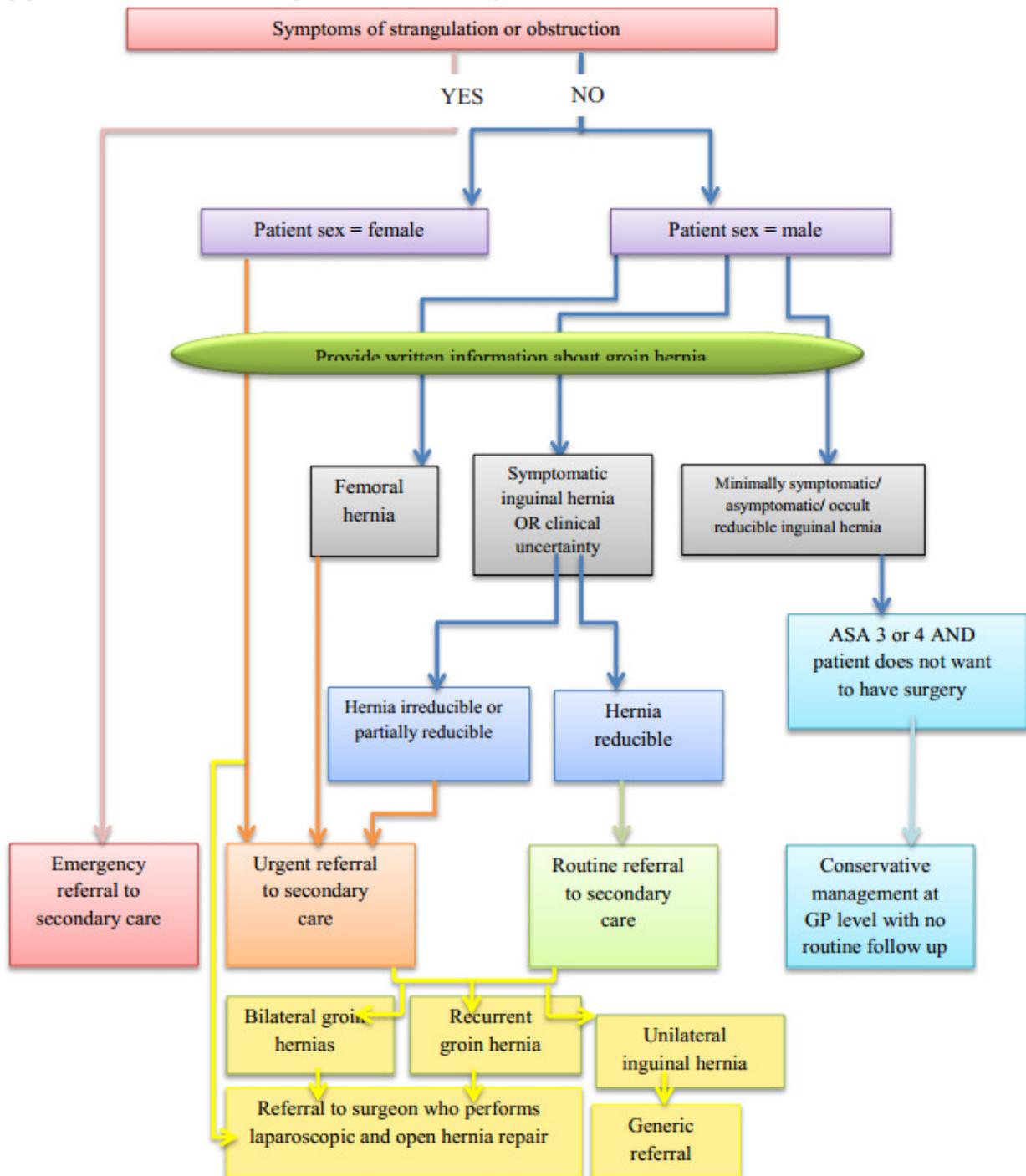
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Appendices

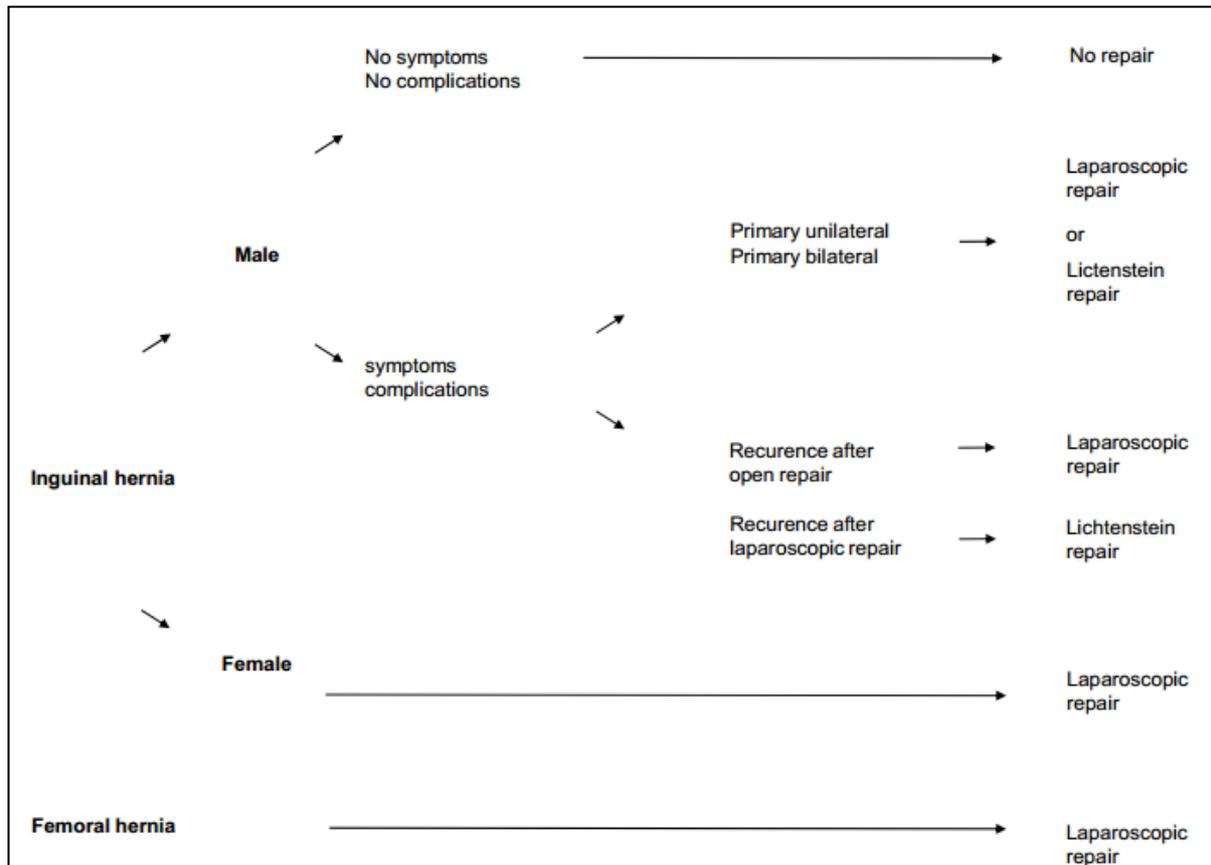
Appendix 1.1 – HIPE ICD-10AM/ACHI list of intervention codes for hernia repair procedures

| Intervention code | Description |
|-------------------|---|
| 3060902 | Laparoscopic repair inguinal hernia; unilateral |
| 3061402 | Repair of inguinal hernia; unilateral |
| 3060903 | Laparoscopic repair inguinal hernia; bilateral |
| 3061403 | Repair of inguinal hernia; bilateral |
| 3060900 | Lap repair of femoral hernia; unilateral |
| 3061400 | Repair of femoral hernia; unilateral |
| 3060901 | Lap repair of femoral hernia; bilateral |
| 3061401 | Repair of femoral hernia; bilateral |

Appendix 1.2 – Primary care flow diagram⁽¹⁸⁾



Appendix 1.3 – Flowchart of suggested treatment algorithm for elective inguinal and femoral hernia repair in adults⁽¹⁹⁾



Appendix 1.4 - Examples of CCG and PCT Thresholds, UK

NHS North West London Clinical Commissioning Group⁽³²⁾

NHS NWL CCG will fund surgery for hernia only in patients who meet the following criteria:

- History of incarceration, or real difficulty in reducing the hernia
- Inguino-scrotal hernia
- Progressive increase in size of hernia (month-on-month)
- Pain or discomfort significantly interfering with activities of daily living
- Presence of work-related issues e.g. missed work/unable to work/on light duties due to hernia
- Patients with suspected femoral hernias (including all women presenting with a groin hernia).

NHS NWL CCG will not fund surgery for the following:

- Small, asymptomatic hernias
- Minimally symptomatic hernias
- Large, wide necked hernia unless there is demonstrable evidence that it is causing significant symptoms.

NHS Cambridgeshire and Peterborough Clinical Commissioning Group (CCG)⁽³³⁾

Asymptomatic hernias which are easily reducible and do not have increased risk of incarceration or strangulation should be managed conservatively by observation and review.

Hernias with alarm symptoms should be urgently referred for surgery.

Alarm Symptoms in a patient with hernia:

- Signs and symptoms of strangulation including: irreducible mass which is firm, painful, and tender (and erythema over mass in later stages).
- Signs of bowel obstruction.
- Signs of sepsis: fever and raised white blood cell (WBC) count.

Assessment should rule out incarceration or strangulation as these are surgical emergencies requiring urgent referral.

Femoral Hernia:

Patients with femoral hernias should be referred for consultation. (Prompt referral.)

Inguinal Hernia:

The elective surgical treatment for asymptomatic or mildly symptomatic inguinal hernia will not be routinely commissioned in male adults and is considered a **Low Priority**. Watchful waiting following a fully informed discussion is recommended for those who are asymptomatic.

Patients can be referred if they have any of the following:

- History of incarceration or real difficulty in reducing the hernia.
- An inguino-scrotal hernia.
- Significant symptoms such as:
 - Increase in size, month to month.
 - Pain with strenuous activity, prostatism or discomfort significantly interfering with activities of daily living which may include inability to work.

Patients with groin pain and occult hernia (without clinical evidence of hernia) should be offered watchful waiting for their 'hernia'.

Divarication of Recti:

Diastases/Divarication of recti is a separation between the left and right side of the rectus abdominis muscle, and causes a protrusion in the midline, but is not a 'true' hernia and does not carry the risk of bowel becoming trapped within it and thus does not require repair.^{4, 5}

The CCG considers repair of divarication of recti as a cosmetic procedure and a low priority. Evidence suggests that divarication does not carry the same risks as that of actual herniation.

NHS Gloucestershire and Swindon⁽³⁴⁾

Inguinal hernia

Surgical intervention for inguinal hernia repair is supported for patients who meet the following criteria:

Objective increase in size month by month

OR

Pain or discomfort causing significant functional impairment. Significant

functional impairment is defined as:

- Symptoms prevent the patient fulfilling normal work or educational responsibilities
- Symptoms prevent the patient carrying out normal domestic activities

OR

History of incarceration or real difficulty reducing the hernia confirmed by ultrasound

Elective surgical treatment of asymptomatic inguinal hernias in adults is considered a treatment of limited clinical value and it is not normally funded by NHS Gloucestershire and Swindon.

Conservative management i.e. watchful waiting is an acceptable management option for mildly symptomatic or asymptomatic inguinal hernias.

Femoral Hernias

Femoral Hernias occur in the femoral canal posterior to the inguinal ligament. They are commoner in females and should be referred for repairs when diagnosed as the risk of strangulation is greater.

Hernia repair is not without complications, and therefore the risk/benefit for prophylactic surgery needs to be carefully considered.

Recurrence rate: 1.3-2.5%

Complications: early complication include haematoma, seroma, urinary retention, late complications include chronic pain in 2-10% of patients (depending on the technique).

Occasionally, differentiating types of hernias may be difficult. In such cases, referrals can be made for surgical opinion.

Appendix 1.5 - Evidence table summarising the data extracted from the cost-effectiveness literature

| Study | Intervention | Analysis Details | Clinical and QALY Outcomes | Costs* | Results |
|--------------------------------|--|--|--|--|--|
| Stroupe et al. (2006) | TFR versus WW in cohort of males with asymptomatic or minimally symptomatic herniae. | Country: USA Discount rate: 3% Perspective: Health care payer Time Horizon: 2 years follow up Model Type: CEA using previous RCT data. Applied Medicare reimbursement rates to patients' health-care use. Quality of life assessed using SF-36. (n=724 randomised, 641 available for economic analysis: TFR n=317, WW n=324). | Previously reported outcomes similar for TFR versus WW: pain that limited activities (2.2% TFR versus 5.1% WW; p=0.52); Physical Component Score of SF-36 (improvement over baseline, 0.13 points for TFR versus 0.29 for WW patients; p=0.79) TFR 0.031 higher QALY versus WW (95% CI, 0.0010.058). | TFR €2,133 higher mean costs than WW (€9,174 vs. €7,041) (95% CI, €476 - €3,546). | At 2 years, WW CE treatment option for men with minimal or no hernia symptoms. ICER: €68,804/QALY (95% CI, €1,582-€375,986). Probability that TFR CE at \$50,000 per QALY level - 40%. \$50,000 regarded as reasonable cut off for CE in US, author suggests TFR in asymptomatic groin herniae is on margin of what is considered a worthwhile procedure. |
| O' Dwyer et al. (2006) | TFMR versus WW in patients with asymptomatic hernia. | Country: UK Discount rate: Not included Perspective: Health care payer. Time Horizon: 12 months Model Type: CEA using RCT data. (n=160, TFMR n=80 randomised (n=75 had TFMR), WW n=80) | Despite improvements in general health, no significant QALY gain for TFMR (0.77) versus WW (0.77) at 12 months. | TFMR additional cost €578 per patient. | While TFMR is not CE within follow-up period of study, time trends in results suggest that, with longer follow-up, it would become increasingly CE. These include a growing number of patients in the observation group requiring operation, thereby reducing the cost difference and the cost of managing serious complications rising over time. |
| Cronini-Cronberg et al. (2013) | Surgery (open or laparoscopic) versus no surgery | Country: England Discount rate: 3.5% Perspective: Health care payer Time Horizon: 25 year Model Type: CUA populated with national PROMs, National Reference Cost and HES data. | Laparoscopic repairs report significantly larger gains in outcomes (0.923 QALYs) than open repairs (0.817 QALYs). Mean change in QALYs following elective hernia repair surgery is 0.826 (95% CI, 0.793-0.859) compared to no | Average cost of surgery is €1,866, estimated national average cost per QALY of €2,258 (range, €658-€16,833). Laparoscopic surgery | At €2,258 per QALY, the author suggests that hernia surgery appears to offer good value for money. |

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|---------------------------|---|--|---|--|--|
| | | | treatment. | less expensive than open surgery (€1,706 v's €1,712). | |
| Stylopoulos et al. (2003) | 4 treatment strategies for inguinal hernia: (1) OMR, (2) ONMR, (3) LHR, and (4) EM. | Country: USA Discount rate: 3% Perspective: Societal Time Horizon: Lifelong Model Type: Markov model | LHR: 9.04 QALYs, EM least effective (6.35 QALYs). | LHR: projected lifetime cost per patient of €5,485. LHR: 5% less than OMR (€5,759), 35% less than ONMR (€8,323). EM least costly strategy. | LHR most CE treatment strategy, both OMR and ONMR were more expensive and less effective (dominated). Incremental cost per QALY gained €812 for LHR, €936 for OMR, and €2,297 for ONMR compared to EM. |

WW – Watchful waiting; TFR - Tension Free Repair; TFMR - Tension Free Mesh Repair; OMR – Open Mesh Repair; ONMR – Open Non-Mesh Repair; LHR – Laparoscopic Hernia Repair; EM – Expectant Management; CEA – Cost-Effectiveness Analysis; CE – Cost Effective; CUA - Cost-utility model; RCT – Randomised Controlled Trial; HES - Hospital Episodes Statistics;

*All costs presented have been inflated using the local consumer price index for health to 2013 values and then converted to Irish Euro using the latest Purchasing Power Parities.

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