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Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health Technology Assessment of Scheduled Procedures

Referral thresholds for haemorrhoid procedures

November 2014

Safer Better Care

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1 Haemorrhoid procedures

1.1 Scope of this health technology assessment

This health technology assessment (HTA) evaluates the appropriateness and potential impact of introducing clinical referral and treatment thresholds for people who may require haemorrhoidectomy in Ireland. The effectiveness of this intervention 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 treatment thresholds that can be used in the assessment, referral and diagnosis of adults who potentially require haemorrhoidectomy. 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

Haemorrhoids result from swelling of blood vessels (the 'anal cushions') in the lower anal canal. These blood vessels are supported by connective tissue which, when weakened, leads to descent or 'prolapse' of the haemorrhoids.⁽²⁾ There are two types of haemorrhoids, external and internal; these are classified based on their location relative to the dentate line which lies at the junction of the upper two thirds and lower one third of the anal canal; internal haemorrhoids are located above this line, while external haemorrhoids arise below it.

The majority of haemorrhoidal symptoms arise from enlarged internal haemorrhoids, with painless rectal bleeding in association with bowel movement as the most common presenting symptom. As these haemorrhoids prolapse through the anal canal, the tissue can become traumatised and friable, leading to bleeding. The bleeding is typically bright red in colour.⁽³⁾ In addition to bleeding, internal haemorrhoids tend to also cause a sensation of incomplete evacuation, tissue protrusion and mucous discharge. External haemorrhoids, meanwhile, are typically associated with anal discomfort with engorgement, pain with thrombosis, and itching.⁽⁴⁾

Fifty percent of the population will experience symptomatic haemorrhoid disease at some point in their lives, with the peak incidence of symptomatic disease between the ages of 45 and 65 years.⁽³⁾ Factors that increase intra-abdominal pressure (for example, prolonged straining, constipation, pregnancy, ascites) contribute to the development of haemorrhoids.

1.3 Surgical options, alternatives and potential complications

The differential diagnosis of haemorrhoids includes anal fissure, perirectal abscess, anal fistula, anal stenosis (narrowing of the anal opening), malignancy, inflammatory bowel disease (inflammatory bowel disease [IBD], Crohn's disease and ulcerative colitis), anal condyloma ('warts'), pruritus ani, rectal prolapse, hypertrophied anal papilla, and skin tags.⁽⁴⁾ It is therefore important that these other conditions are ruled out before a diagnosis of haemorrhoids is arrived upon.

Internal haemorrhoids are graded based on their appearance and degree of prolapse; this is known as Goligher's classification:

- First-degree haemorrhoids (grade I): Bleeding, but without prolapse.
- Second-degree haemorrhoids (grade II): The anal cushions prolapse through the anus on straining, but reduce spontaneously.
- Third-degree haemorrhoids (grade III): The anal cushions prolapse through the anus on straining or exertion and require manual replacement into the anal canal.
- Fourth-degree haemorrhoids (grade IV): The prolapse stays out at all times and is irreducible.

The type and extent of treatment depends on the extent of prolapse. Non-operative strategies may be employed in the first instance, and are particularly appropriate to the management of first-degree haemorrhoids. These include:

- avoiding constipation
- avoiding straining to evacuate the rectum
- increasing dietary fibre
- oral laxatives
- topical combination creams containing local anaesthetics with steroid.

There are a number of interventional approaches available for management of proven haemorrhoids, which remain symptomatic despite conservative treatment. These include rubber band ligation, injection sclerotherapy, open and stapled haemorrhoidectomy and haemorrhoidal artery ligation surgery (HALS). Although the relative comparison of these techniques is beyond the scope of this present work, a brief description of common interventions is provided below.

Rubber band ligation

Rubber bands are applied at the base of the haemorrhoidal tissue in order to decrease the blood supply to that area. Up to three haemorrhoids can be banded at a single time. This treatment is often recommended as the initial surgical treatment for grades I to III haemorrhoids. Rates of success, defined as symptom relief for months to years, range from 70.5 to 97%.⁽²⁾ The risk of complications is low, reported in 1–3% of patients, and includes post banding pain, bleeding, and vasovagal symptoms.⁽³⁾ The procedure may be undertaken in the outpatient setting.⁽⁵⁾

Injection sclerotherapy

Sclerosants including 5% phenol in almond oil are injected into the submucosa around the pedicle of the haemorrhoid. This is commonly employed in the management of first- and second-degree haemorrhoids. A study by Chew et al. examined outcomes following rubber band ligation with sclerotherapy; the authors reported a recurrence rate of 16% and an overall complication rate of 3.1% (minor bleeding being the main side-effect). At average follow-up of 6.5 years, 19% reported residual bleeding, 21% reported itch and 20% reported the presence of a lump; 58% were asymptomatic and just 7.7% went on to have a formal haemorrhoidectomy.⁽⁶⁾ Similar to rubber band ligation, injection sclerotherapy may also be undertaken in the outpatient setting.⁽⁷⁾

Open and stapled haemorrhoidectomy

Operative haemorrhoidectomy is indicated in the treatment of combined internal and external haemorrhoids or third- and fourth-degree haemorrhoids.⁽⁴⁾ In excisional haemorrhoidectomy, an elliptical incision is made over the haemorrhoidal complex, which is then mobilised from the underlying sphincter and excised. The wound is either left open, to close by secondary intention (Milligan Morgan technique – most common technique in UK), or closed primarily with sutures (Ferguson technique – most common in United States). Stapled haemorrhoidectomy ('haemorrhoidopexy'), meanwhile, involves the removal of a circumferential column of mucosa and submucosa immediately above the haemorrhoids, thus interrupting the blood supply. The ring of staples fixes the downwardly displaced vascular cushions back into their original locations to restore anatomy and function. Compared with excisional haemorrhoidectomy, stapled haemorrhoidopexy is superior in terms of postoperative pain, time until return to work, and complications of pruritus and faecal urgency. However, it is associated with a higher long term risk of recurrent haemorrhoids and the need for additional procedures.⁽²⁾

Haemorrhoidal artery ligation surgery (HALS)

Haemorrhoidal artery ligation surgery is a relatively new technology that involves insertion of a Doppler probe into the anorectum to identify the abnormal engorged vessel complex which may subsequently be ligated accurately and confirmed using the same probe. Subsequent diminution of blood flow, along with any post-inflammatory mucosal fixation that occurs as a result of the surgery, is thought to be responsible for the therapeutic effects noted.⁽³⁾

1.4 Current practice in Ireland

Patients with haemorrhoids 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 where such thresholds are being used, or how consistently they are being applied. Although not common practice in Ireland, sclerotherapy and band ligation may also be undertaken by GP surgeons in the primary care setting.

Haemorrhoid procedures are routine scheduled surgical procedures 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 these procedures. A haemorrhoid 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 7,704 patients who underwent haemorrhoid procedures in 2012. Of these, 7,342 (95.3%) patients were admitted for their procedure on an elective (planned surgery) basis.

This data captures procedures provided as hospital day case and inpatient procedures, as in the other HTA reports in this series. Of the 7,342 procedures carried out in the pure elective setting 6,965 (94.9%) were reported as being done on a day case basis. It should be noted that the clinical codes included in this data gathering process included those for rubber band ligation and sclerotherapy of haemorrhoids, neither of which would ordinarily be expected to require a day case (or inpatient) admission. In a report entitled: 'Guidance on the Appropriate Delivery Location for Different Types of Elective Ambulatory Surgery' by the National Clinical

Programme in Surgery in conjunction with the Special Delivery Unit (SDU) and National Treatment Purchase Fund (NTPF) (in press) it is suggested that, in the main, both rubber band ligation and sclerotherapy are procedures that are amenable to completion in the outpatient setting.⁽⁸⁾ Day case rates for elective haemorrhoidectomy and stapled haemorrhoidectomy were 55.4% and 55% in 2012, respectively. A target that 60% of haemorrhoidectomies would be performed as day cases has been set by the National Clinical Programme in Surgery in its document, 'Model of Care in Elective Surgery'.⁽⁹⁾ It is noted that while day case rates remain somewhat below this target, HIPE data demonstrates that rates have improved significantly versus 2005, when 30% and 11% of haemorrhoidectomies and stapled haemorrhoidectomies were undertaken as day cases, respectively.

A total of 377 procedures were carried out on an inpatient basis, with an average length of stay (ALOS) of 1.8 days. It is noted that the ALOS for patients undergoing elective haemorrhoid procedures in public hospitals decreased from 3.1 days in 2005 to 1.8 days in 2012 (Figure 1.1); the ALOS for patients who underwent elective haemorrhoidectomy or stapled haemorrhoidectomy was 1.8 and 1.3 days in 2012, respectively; these had decreased from an ALOS of 3.2 days for haemorrhoidectomy and an ALOS of 2.4 days for stapled haemorrhoidectomy in 2005. The average age of patients undergoing haemorrhoid procedures in 2012 was 47.7 years.

The 7,342 elective haemorrhoid procedures recorded within the HIPE system in 2012 were performed across 40 different hospital sites (range 1-405 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 haemorrhoidectomy per HSE hospital group* (2012)⁽⁹⁾

Hospital group	Number	ALOS (days)	% Day Cases (Hospital Range)	Average age
	(%) (Range)			(years)
Dublin North East	1,516 (20.6%) (129-390)	1.7	96.0 (83.6-100)	47.9
Dublin Midlands	1,383 (18.8%) (1-390)	2.0	97.4 (93.9-100)	47.0
Dublin East	1,632 (22.2%) (4-405)	1.8	95.6 (76.7-100)	46.9
South/South West	1,019 (13.9%) (8-375)	1.5	89.5 (76-100)	47.7
West/North West	1,024 (13.9%) (98-379)	1.5	93.4 (68.4-98.4)	49.3
Midwest	768 (10.5%) (90-262)	3.8 ^	95.7 (86.8-100)	48.3
Total	7,342 (100)	1.8	94.9	47.7

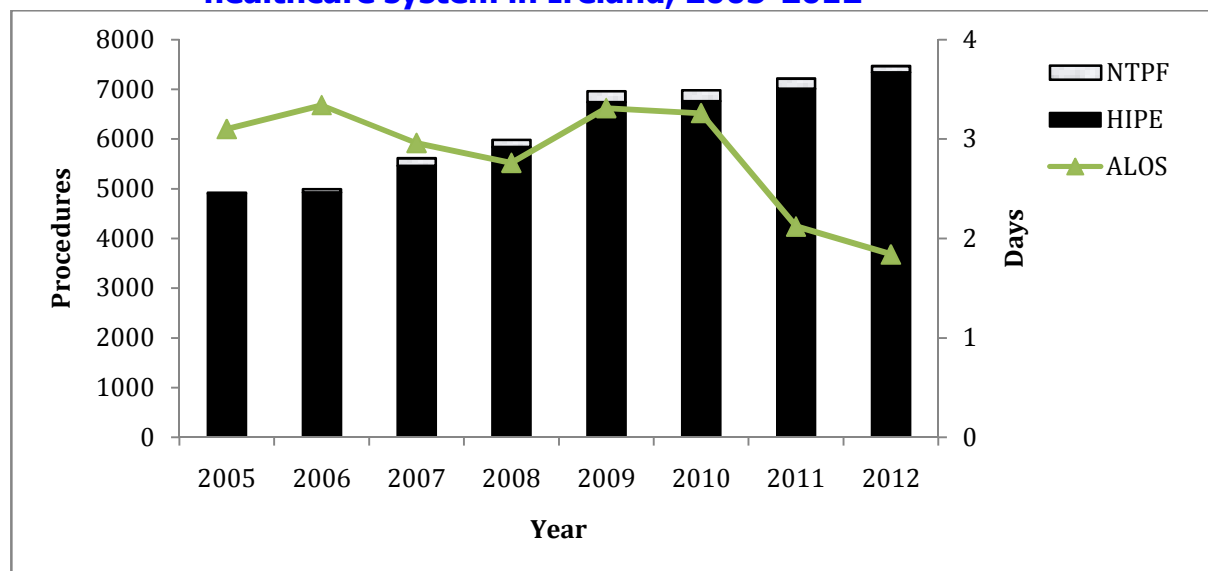
*Key: Range – the range in terms of number of procedures performed in individual institutions within the hospital group. ALOS – average length of stay for inpatients; See Appendix 1.1 for HIPE codes; *HIPE data includes all activity in publicly-funded hospitals, including procedures in patients that used private health insurance. ^This figure is significantly raised by a limited number of patients.*

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 pre-operative diagnosis. In 2012, the principal diagnosis – at the time of haemorrhoid procedure – was coded as ‘internal haemorrhoids without complication’ (32.7%); the next most frequently coded diagnoses were ‘internal haemorrhoids with other complications’ (26.1 %), and ‘unspecified haemorrhoids without complication’ (11.2%).

In addition to the activity levels in public hospitals, there were 1,151 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.

Figure 1.1 Number and average length of stay (days) for elective haemorrhoid procedures provided through the publicly-funded healthcare system in Ireland, 2005-2012⁽⁹⁾



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

The number of elective haemorrhoid procedures funded by the publicly-funded healthcare system increased by 51.7% from 4,921 in 2005 to 7,467 in 2012. This was primarily driven by increased use of rubber band ligation; HIPE data indicates a 3.6 fold increase over this time period (2005, 820 procedures; 2012, 2,923 procedures). In 2012, of the 4,016 procedures recorded in HIPE as injection sclerotherapy, 3,924 (97.7%) were recorded as being done as day cases with the remainder performed in the inpatient setting. Similarly, of 2,923 rubber band ligation procedures captured in HIPE that year, 2,865 (97.7%) were undertaken as day cases with the remainder in the inpatient setting. However, as noted earlier, for the majority of patients, rubber band ligation and injection sclerotherapy can ordinarily be undertaken in an outpatient setting and should not necessitate a day case or inpatient surgical admission. The one caveat to this, is where patients are undergoing treatment for haemorrhoidectomy, but require colonoscopy or sigmoidoscopy during the same treatment episode. It is possible that these figures underestimate the total number of rubber band ligation and injection sclerotherapy procedures provided by the publicly funded system, as those procedures provided in the outpatient setting are not captured in HIPE.

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.⁽¹⁰⁾ 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 outpatient waiting list at that time.⁽¹¹⁾

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.⁽¹²⁾ 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 will 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.^(12;13) 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 on the following page.

Table 2.1. Summary of literature search results

Publication Type	Number	References
Clinical Guidelines	8	(14-20)
Reviews	2	(21;22)
Cost-Effectiveness Studies	3	(23-26)

2.2 Clinical evidence

In 2013, a national commissioning guide for rectal bleeding in the UK was jointly published by the Association of Coloproctology of Great Britain and Ireland (ACPGBI) and the Royal College of Surgeons (RCS), with the National Institute for Health and Care Excellence (NICE) accrediting the process.^(17;23) Noting that rectal bleeding has a positive predictive value (PPV) for colorectal malignancy of 8% in patients aged over 50 years of age presenting to primary care, this report identified the following 'red flag' signs and symptoms:

- associated change in bowel habit, especially diarrhoea or increased frequency
- anaemia
- weight loss
- abdominal or rectal mass.

If onward referral is planned based on initial presentation, then digital rectal examination (DRE) is desirable, but may not be necessary. If the patient is staying in primary care, good practice requires DRE prior to definitively attributing rectal bleeding symptoms to benign causes. Furthermore, the guideline states that while proctoscopy may be used by some primary care clinicians as a screening tool in patients with rectal bleeding, it should not be used as a substitute for flexible sigmoidoscopy to rule out serious pathology.

This guideline adopted the recommendations of the 2005 NICE guideline regarding referral for suspected cancer,⁽¹⁹⁾ by stating that any patient with rectal bleeding that meets the following criteria should be referred urgently for review within two weeks:

- aged ≥ 40 years with rectal bleeding and change in bowel habit towards looser and/or more frequent stools for 6 weeks or more
- aged ≥ 60 years with rectal bleeding persisting for 6 weeks or more without change in bowel habit and without anal symptoms
- rectal bleeding and a palpable rectal mass.

The 2013 commissioning guide goes on to state that urgent referral should also be considered for patients with concerning symptoms that do not meet these two-week

wait criteria. In addition, in patients with rectal bleeding, the guideline notes that the following patient groups also require investigation (the guideline did not state whether these patients met the two-week referral criteria or whether a routine referral was appropriate):

- strong family history of colorectal malignancy
- anxiety about colorectal malignancy
- persistent rectal bleeding despite treatment for haemorrhoids
- rectal bleeding in patients with a past history of pelvic radiotherapy
- assessment of suspected inflammatory bowel disease.

Patients with symptomatic haemorrhoids should be given advice about topical treatment, oral fluid intake, high fibre diet and fibre supplementation. In low risk patients with rectal bleeding who are not overly anxious, it was deemed reasonable to manage their symptoms with treatment and adopt a 'watch and wait' policy. Although it was noted that minimally symptomatic haemorrhoids can be safely observed, routine referral was recommended for patients with persistent or highly symptomatic haemorrhoids.

It was suggested that referral for screening colonoscopy or genetics assessment may be appropriate when rectal bleeding has triggered access to medical care, but the primary concern is a strong family history of colorectal cancer; in contrast, direct access flexible sigmoidoscopy was deemed to provide the best reassurance for patients with rectal bleeding who are primarily concerned about malignancy – it was noted that there are significant savings if this can be offered locally.

The commissioning guide went on to categorise patients with persistent rectal bleeding into those aged less than, and greater than 45 years. For the former group, it was deemed that flexible sigmoidoscopy is the investigation of choice for patients who are concerned about pathology apart from haemorrhoids or who have received treatment for haemorrhoids and still have persistent bleeding. For older patients meanwhile, it was suggested that they be offered either colonoscopy or flexible sigmoidoscopy, with the combination of CT colonography and flexible sigmoidoscopy reserved for elderly, frail or unfit patients.

Finally, the guide discussed service configuration and suggested that direct access flexible sigmoidoscopy should be available to primary care. In addition, it noted the potential value of one stop clinics (which could provide treatment of haemorrhoids/fissures and perform flexible sigmoidoscopy to rule out proximal pathology) in either specialist community or secondary care.⁽¹⁷⁾

In 2007, NICE published its technology appraisal of stapled haemorrhoidopexy for the treatment of haemorrhoids.⁽²²⁾ This report noted that first- and second-degree internal haemorrhoids are generally treated by changing bowel habit, diet and lifestyle, and by using stool softeners or laxatives. It also suggested that for second-degree haemorrhoids, injection sclerotherapy, rubber band ligation or infrared coagulation may also be used.

The Italian Society of Colorectal Surgery published its guidelines for the management of haemorrhoids in 2006.⁽¹⁵⁾ This suggested that rectal bleeding, especially if associated with anaemia, must be considered an indication for total colonoscopy to exclude other colonic disease in patients over 50 years of age. In the case of patients with familial or other risk factors for colorectal neoplastic disease, colonoscopy was advised for those aged ≥ 40 years. For grade I haemorrhoids (bleeding, but not prolapsed), conservative management was recommended. The remainder of the document went on to discuss the various techniques available for management of grade II to IV haemorrhoids, but analysis of the relative effectiveness of these interventions is beyond the scope of this current work.

In 2004, the American Gastroenterological Association published its technical review concerning the diagnosis and management of haemorrhoids.⁽²¹⁾ This was based on a literature search from 1990 to 2002. This document noted the guidelines of the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT) which advocated a minimum of anoscopy and flexible sigmoidoscopy for bright red rectal bleeding. It was noted that complete colonic evaluation is indicated when the bleeding is atypical for haemorrhoids, when no source is evident on anorectal examination, or when the patient has significant risk factors for colonic neoplasia. The decision to pursue further evaluation was to be dependent upon the patient's age and general medical condition. This review also noted that haemorrhoids alone do not cause a positive result with a stool guaiac test, and thus faecal occult blood should not be attributed to haemorrhoids until the colon is adequately evaluated.

The most recent guidelines from the SSAT were last published in 2005 and reviewed in 2008; these state that all patients with rectal bleeding should have their colon examined to rule out proximal sources of bleeding, even in the presence of enlarged haemorrhoids.⁽¹⁴⁾ Patients should undergo flexible sigmoidoscopy as well as anoscopy to rule out other causes of bleeding. Intermittent protrusion or occasional bleeding does not require urgent consultation; however patients with acute bleeding, pain or incarcerated protrusions should be seen promptly. The ASGE published its most recent update regarding the role of endoscopy anorectal disorders in 2010; this states that diagnosis of internal haemorrhoids is made by inspection of the perineum,

DRE, and office anoscopy.⁽¹⁶⁾ Endoscopic evaluation for colorectal cancer should be performed depending on the clinical situation (for example, patient age, symptoms, previous evaluation, and family history). The guideline notes that internal haemorrhoids are best viewed by anoscopy or if flexible endoscopy is being performed, on retroflexion. It also states that medical management suffices for most patients with symptomatic internal haemorrhoids; the exact nature of treatment is dictated by the severity of symptoms and degree of prolapse, with the use of fibre demonstrating a beneficial effect for relieving overall symptoms and bleeding.

The American Society of Colon and Rectal Surgeons (ASCRS) published its guideline for the management of haemorrhoids in 2005.⁽¹⁸⁾ This noted that the physical examination should typically include visual inspection of the anus, DRE, and anoscopy. It was noted that complete colon evaluation is typically indicated for patients with rectal bleeding who meet any of the following criteria (these criteria were adapted from the multi-society task force on colorectal cancer):

- age ≥ 50 years if no complete examination within 10 years
- age ≥ 40 years with history positive for a single, first-degree relative with colorectal cancer or adenoma diagnosed at age > 60 and no complete examination within 10 years
- age ≥ 40 years if the history is positive for two or more first-degree relatives with colorectal cancer or adenomas diagnosed at age > 60 and no complete examination within 3 to 5 years
- positive faecal occult blood test
- iron deficiency anaemia.

This guideline was updated in 2010; the recommendations above were unchanged.⁽²⁰⁾ This updated report noted that dietary modification consisting of adequate fluid and fibre intake is the primary first-line non-operative therapy for patients with symptomatic haemorrhoid disease. Most patients with grade I to III haemorrhoid disease in whom medical treatment fails may be effectively treated with non surgical procedures, such as banding, sclerotherapy and infrared coagulation; surgical haemorrhoidectomy should be reserved for patients who are refractory to office procedures, who are unable to tolerate office procedures, who have large external haemorrhoids, or who have combined internal and external haemorrhoids with significant prolapse. The majority of patients with thrombosed external haemorrhoids benefit from surgical excision within 72 hours of the onset of symptoms.⁽²⁰⁾

In summary, the published literature uniformly highlights the need for caution when evaluating the patient with suspected haemorrhoids. 'Red flag' signs and symptoms

mandate the need for urgent referral to secondary care, as do a number of allied factors including anxiety of, and or a strong family history of colorectal malignancy. Although it seems clear that patients with mildly symptomatic haemorrhoids, in the absence of worrying features, can be managed in primary care in the first instance, they should be referred onwards if symptoms persist despite initial management.

2.3 Cost-effectiveness evidence

No published cost-effectiveness studies were retrieved that directly compared conservative measures with intervention in the management of patients with haemorrhoids. The following economic literature has been published on various aspects of treatment and is included to provide context (see Appendix 1.2). For ease of review, all costs presented have been inflated using the relevant local consumer price index for health to 2013 values and then converted to Irish Euro using the latest Purchasing Power Parities.

As part of their 2012 cost-effectiveness analysis of population based screening for colorectal cancer Sharp et al.⁽²⁶⁾ calculated the cost of colonoscopy and flexible sigmoidoscopy in this setting, in Ireland. The weighted average cost of colonoscopy was estimated at €710 (€568-€851) per procedure, while that of flexible sigmoidoscopy was estimated at €164 (€131-€197).⁽²⁶⁾

In 2008, Burch et al. published their HTA of stapled haemorrhoidectomy (haemorrhoidopexy) for the treatment of haemorrhoids.⁽²³⁾ The authors performed a systematic review in order to compare stapled with conventional haemorrhoidectomy. On average, the difference in costs between the procedures was €25 and the difference in QALY was -0.001, favouring conventional haemorrhoidectomy, over three years. The probabilistic sensitivity analysis showed that, at a incremental cost-effectiveness ratio (ICER) threshold of GBP£20,000–GBP£30,000 per QALY, the stapled procedure had a 45% probability of being cost-effective.

A 2011 study by Ribaric et al. also examined the cost-effectiveness of stapled haemorrhoidectomy; a probabilistic, cohort-based decision tree was employed to compare the use of stapled and conventional haemorrhoidectomy, for patients with third- and fourth-degree haemorrhoids.⁽²⁵⁾ The study was conducted in the UK in 2009, the time horizon was set at one year, and a payer (NHS) perspective was taken. Total hospital costs for each procedure were €1,310 and €1,344 for stapled and conventional haemorrhoidectomy, respectively; inclusion of the cost of recurrent prolapse however, resulted in a total cost at one year of €1,396 and €1,353 for the stapled and conventional procedures, respectively. When compared with

conventional haemorrhoidectomy, the stapled procedure provided an incremental gain in quality-adjusted life years (QALYs) of 0.0076 generating an ICER of €5,675.⁽²⁵⁾

In 2008, Kushwaha et al.⁽²⁴⁾ published the results of their randomised controlled trial comparing day case haemorrhoidectomy under general anaesthetic with that under local anaesthetic. The trial was carried out between 2005 and 2006 in a British day surgery unit. The cost of haemorrhoidectomy under local anaesthetic was estimated at €411; this compared with a cost of €583 per procedure under general anaesthetic.⁽²⁴⁾

In summary, no published evidence was retrieved that directly compared conservative measures with intervention in the management of patients with haemorrhoids. Other cost and cost-effectiveness literature, which was relevant to the Irish healthcare setting was included for context. Stapled haemorrhoidectomy has been found to be highly cost-effective compared with conventional haemorrhoid surgery.

2.4 Budget impact and resource implications

As noted in Section 1.4, the number of elective haemorrhoid procedures provided through the publicly-funded healthcare system has increased by over 51.7% since 2005. The current estimated annual national cost of elective haemorrhoid procedures is €3.5 million, with an average weighted cost per patient case of €1,028; the average weighted cost per inpatient case was €3,624, while that for day cases was €884 based on the latest Casemix costs (Table 2.3). These data may underestimate the total cost of care as HIPE data do not capture procedures undertaken in the outpatient setting.

Again, it is noted that 6,939 procedures captured in the HIPE data were either injection sclerotherapy (4,016) or rubber band ligation (2,923), the majority (97.7%) of which were recorded as being performed in the day case setting. It is clear from the National Clinical Programme in Surgery and the SDU (Scheduled Care) that the majority should instead be carried out in the outpatient setting. As noted in their guidance document on the appropriate delivery location for elective ambulatory surgery, there are substantial differences in resources required to operate a true surgical day case theatre and ward as opposed to a minor operations or outpatient facility. True day case theatres require more equipment, larger facilities, anaesthetic staff and greater nurse support than would be required for a minor operations or outpatient facility. The document goes on to suggest that the cost per week for outpatient-based procedures is one third that of a day case theatre.⁽⁸⁾ While a

number of patients undergoing treatment for haemorrhoidectomy will require colonoscopy or sigmoidoscopy during the same treatment episode, and hence must be managed in the day case setting, it seems reasonable to conclude that significant cost savings could be achieved if the factors that are hindering use of outpatient facilities for these procedures can be identified and addressed.

Table 2.3. HSE inpatient and day case acute hospital activity and costs for elective haemorrhoid procedures (where coded as the principal procedure) summarised by diagnosis-related group (based on 2011 costs and 2012 activity)⁽²⁷⁾

DRG code	Description	No.	% of total	Cost/ Inpatient (€)	Cost/ Day case (€)
G11Z	Anal & Stomal Procedures	2,141	55.7	3,461	1,310
G48C	Colonoscopy; Same day	869	22.6	654	550
G70B	Other Digestive System Diagnoses W/O Catastrophic or Severe CC	754	19.6	1,663	442
G46C	Complex Gastroscopy; Sameday	35	0.9	942	619
G47C	Other Gastroscopy; Sameday	9	0.2	578	403

*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.*

2.5 Advice on clinical referral/treatment threshold

Taking account of the available evidence that exists in relation to the management of haemorrhoidal disease, the following threshold criteria are advised for referral and treatment within the publicly-funded healthcare system in Ireland:

All patients meeting the criteria for referral as set out in the related health technology assessment (HTA), *Referral thresholds for patients with lower gastrointestinal symptoms suspicious for malignancy*, should be referred for secondary care review and or investigation within four weeks as per that threshold.

Patients who present to primary care with thrombosed haemorrhoids should be referred as an emergency for review in secondary care.

All patients presenting to primary care with symptoms and or signs of haemorrhoids should be offered an examination of their perineum and a digital rectal examination.

Patients with minimally symptomatic haemorrhoids, in the absence of the aforementioned lower GI signs or symptoms suspicious for malignancy, can be managed with conservative measures (including, for example, avoidance of straining to evacuate the rectum, increasing dietary fibre and preventing constipation, and the use of oral laxatives) in primary care in the first instance.

- If symptoms persist or become troublesome, patients should be referred for review in secondary care.
- Where doubt exists regarding the clinical diagnosis, patients should be referred for review in secondary care.

3 Discussion

Haemorrhoid procedures are routine, scheduled procedures performed across a wide range of hospital sites (n=40 in 2012) within the Irish public healthcare system. The number of elective haemorrhoid procedures increased by 51.7% between 2005 and 2012, largely driven by the 3.6 fold increase in utilisation of rubber band ligation. While increased utilisation of this latter procedure likely reflects the perceived failure of conservative measures in managing haemorrhoidal disease, it nevertheless highlights the fact that demand for interventional services is on the increase. It is in this context that there is a need for standardisation in referral practices, both to address increasing pressure on the public healthcare system, and to ensure consistency of clinical practice.

It is noted that while almost 95% of haemorrhoid procedures captured in HIPE were performed in the day case setting in 2012, the majority of these procedures were either rubber band ligation or injection sclerotherapy. These are procedures which can be done safely and effectively in outpatient procedure rooms and GP surgeries, and mechanisms should be in place to ensure that these and similar procedures are undertaken in the locations that are most appropriate to their complexity. This in turn should facilitate optimal use of resources and should further help to ensure that patients are treated in the right place and at the right time. As noted by the National Clinical Programme in Surgery and the Special Delivery Unit (SDU) / NTPF (*in press*), HIPE was originally set up to capture inpatient and day case activity only, and it has become practice for some hospitals to code significant proportions of minor operations and outpatient-type procedures in their HIPE returns while other equivalent type hospitals do not.⁽⁸⁾ It is clear that there is significant potential for cost savings to be made if the factors hindering performance of these types of procedures in lower complexity settings can be identified and addressed. In particular, it seems reasonable to suggest that mechanisms to ensure appropriate reimbursement to hospitals and general practitioners (GPs) should be in place such that they are incentivised to facilitate completion of low complexity interventions in low complexity settings.

Day case rates for haemorrhoidectomy (55.4%) and stapled haemorrhoidectomy (55%) remain below that recommended by the National Clinical Programme in Surgery (60%). That said, it is also noted that day case rates for both procedures, and the average length of stay for patients managed on an inpatient basis, have significantly improved compared with 2005. This suggests that the initiatives being implemented by the National Clinical Programme for Surgery – which aim to improve the elective surgical journey of individual patients – are having a positive impact.

It is recognised that the referral thresholds outlined above are unlikely to impact on the number of procedures performed. Rather, it is intended that these thresholds will ensure that only those patients who are likely to derive additional benefit from intervention versus conservative management will be referred for an opinion in secondary care. Of equal importance, it is intended that this stated threshold for haemorrhoid procedures will, when used in conjunction with the related HTA, *Referral thresholds for patients with lower gastrointestinal symptoms suspicious for malignancy*, provide clarity regarding the need or otherwise for urgent referral for patients with rectal bleeding and other lower gastrointestinal signs and symptoms. It is envisaged that this clarity will, in turn, help to speed up access for those who require surgical review, while also helping to manage patient expectation and ensuring that the appropriate resources are directed towards those who should receive conservative care.

It is noted that while development of this threshold should aid in defining who should be referred for 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.

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.

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Appendices

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

Intervention code	Description
3213200	Sclerotherapy for haemorrhoids
3213500	Rubber band ligation of haemorrhoids
3213501	Destruction of haemorrhoids
3213800	Haemorrhoidectomy
3213801	Laser haemorrhoidectomy
3213802	Stapled haemorrhoidectomy

Appendix 1.2 Evidence table summarising the data extracted from the economic evaluation literature

Study	Intervention	Analysis Details	Clinical and QALY Outcomes	Costs*	Results
Sharp et al. (2012) ⁽²⁶⁾	Population based colorectal cancer (CC) screening programme based on (i) biennial guaiac-based faecal occult blood testing (gFOBT) at ages 55–74, with reflex faecal immunochemical testing (FIT); (ii) biennial FIT at ages 55–74; and (iii) once-only flexible sigmoidoscopy (FSIG) at age 60 compared with no screening.	Country: Ireland Discount rate: 4% Perspective: Health care payer Time Horizon: 10 year Model Type: State transition model	-	The weighted average cost of colonoscopy was estimated at €710 (€568-€851) per procedure, while that of flexible sigmoidoscopy was estimated at €164 (€131-€197).	All scenarios would be considered highly cost-effective compared with no screening.
Burch et al. (2008) ⁽²³⁾	Stapled versus conventional haemorrhoidectomy – Systematic review of the economic literature	Country: UK Discount rate: NR Perspective:NR Time Horizon: NR Model Type:NR	On average, the difference in QALYs between procedures was – 0.001.	On average, the difference in costs between procedures was €25.	Conventional haemorrhoidectomy more favourable over 3 years. At a threshold ICER of GBP£20,000–GBP£30,000 per QALY, stapled procedure had a 45% probability of being cost-effective.
Ribaric et al. (2011) ⁽²⁵⁾	Stapled Hemorrhoidopexy (SH) versus conventional excisional hemorrhoidectomy (CH)	Country UK Discount rate - Perspective: Health care payer, societal Time Horizon: 1 year Model Type: Cost-utility analysis	Calculation of QALYs showed an incremental QALY gain of 0.0076 for stapled haemorrhoidopexy.	Decrease in operating time and hospital stay for SH - cost saving compared with CH (€36 per procedure at hospital level), incremental cost of €43 after 1 year from societal perspective.	SH is a cost-effective procedure, it seems that an innovative surgical procedure could be cost saving in routine clinical practice. The ICER for stapled haemorrhoidopexy was €5,675

Kushwaha et al. (2008) ⁽²⁴⁾	Day-care open haemorrhoidectomy: local (LH) versus general anaesthesia (GH)	Country: UK Discount rate: NR Perspective: Health care payer Time Horizon:-NR Model Type: Cost analysis - include cost of suture materials, anaesthesia, day-surgery bed (including staff costs), recovery room and postoperative medication.	-	Excluding cost of postoperative follow-up, LH 1.5 times cheaper than GH.	Difference due to saving in general anaesthesia and recovery room costs.
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CPI – Consumer Price Index; NR – Not relevant

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

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