





### A dangerous waiting game?

A review of patient access to inguinal hernia surgery in England



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#### Overview

The surgical repair of inguinal hernias is one of the most common procedures undertaken in secondary NHS care, with nearly 80,000 procedures performed each year.<sup>1</sup> As highlighted in the 2010 Global Burden of Disease report, elective hernia surgery is a highly cost-effective treatment.<sup>2</sup>

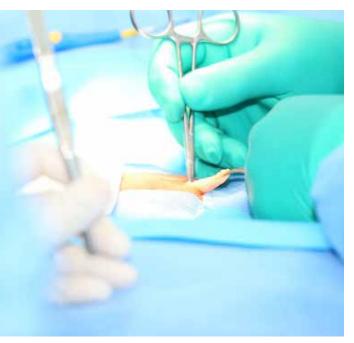
However, despite the effectiveness of inguinal hernia surgery, Clinical Commissioning Groups (CCGs) are increasingly restricting access to treatment for patients to save money and on the basis of unreliable Patient Reported Outcomes Measures (PROMs) data and misinterpreted trial data.

As part of this report, the Royal College of Surgeons (RCS) submitted Freedom of Information requests to all 195 CCGs in England. Policies from the 186 CCGs that responded to the survey (94%) showed worrying levels of variation in access to inguinal hernia surgery across England, with patients' pain and distress too often dictated by their postcode. Overall, 57% of CCGs in England have policies in place that restrict patient access to hernia repair. This has been shown to produce poorer outcomes for patients and can increase the risk of adverse events, including, in rare instances, death. This is an increase on the 29% of CCGs the RCS found to be restricting access in our 2014 report *Is Access to Surgery a Postcode Lottery?* 

The RCS and the British Hernia Society (BHS) are clear that patients' access to treatment must be based on clinical assessment and informed discussion between the clinician and patient. Failure to do so for inguinal hernia repair can increase costs for the health service and put patients at unnecessary risk.

This report from the RCS and the BHS sets out the scale of CCG restrictions, the impact these are having on patients, and what needs to be done at a local and national policy level to address this.

#### About inguinal hernias and surgical repair



Inguinal hernias, which constitute around 70% of all diagnosed hernias, occur in the groin and most frequently affect men – although women can also occasionally develop an inguinal hernia.<sup>3</sup> The hernia usually occurs when a weakness in the abdominal wall allows fatty tissue or a part of the bowel to protrude into the inguinal canal.

Symptoms of inguinal hernias include:

- A lump appearing in the area around the pubic bone (this usually grows in prominence when standing or when undertaking strenuous activity)
- » A pain or ache around the protruding lump
- A feeling of pressure in the groin
- Pain and swelling around the testicles,
  particularly in instances where the protrusion
  has reached the scrotum

NHS Digital. Hospital Episode Statistics (Procedures and Interventions). 2016/17.

<sup>&</sup>lt;sup>2</sup>Higashi H *et al.* Surgically avertable burden of digestive diseases at first-level hospitals in low and middle-income regions. *Surgery* 2015; **157(3):** 411–9; discussion 420–2.

<sup>&</sup>lt;sup>3</sup> British Hernia Centre. Inguinal Hernia. <u>https://www.hernia.org/types/inguinal/</u> (cited June 2018).

Inguinal hernia surgery, which can be performed as open surgery or laparoscopic (keyhole) surgery, involves returning the tissue or part of the bowel back to its original bodily location.

In rare instances, surgery is required to address severe complications such as strangulation or incarceration of the hernia. This occurs when the hernia becomes trapped in the abdominal wall, threatening blood supply to the tissue. In rare cases, if not treated in a timely manner then this can be a potentially fatal complication.

In 2016/2017 there were 78,733 inguinal hernia procedures carried out in hospitals in England, an increase of 0.8% from 2015/2016.<sup>4</sup> This includes primary (first time) repairs, along with repairs of recurrent inguinal hernias. Of these, around 3,741 were emergency admissions – a number broadly similar to that seen in the preceding year.

Elective hernia surgery is one of the most cost effective measures to reduce avertable morbidity and mortality, and is broadly comparable to the effectiveness of providing insecticide-treated bed nets for malaria. On this basis, the 2010 Global Burden of Disease report recommended that the provision of such procedures should be a fundamental component of any public health system.<sup>5</sup>

Guidance jointly published by the RCS and the BHS sets out how suspected inguinal hernias can most appropriately be managed in secondary care settings.

Under the RCS/BHS guidance, all patients with an overt or suspected inguinal hernia should be referred to a surgical provider (unless in circumstances where, after appropriate information has been provided, the patient does not want surgical repair).<sup>6</sup>

Following referral to a surgical provider, surgical repair should be offered to patients with a symptomatic inguinal hernia, and should be considered for patients under the age of 65 without symptoms (asymptomatic).<sup>7</sup>

Although conservative management of symptomatic inguinal hernias (through a 'watchful waiting' approach) is a potential option, the guidance is clear that the patient will likely require surgery in future.<sup>8</sup> This is also reflected in the *International Guidelines for Groin Hernia Management*.<sup>9</sup> Crucially, implementing this approach has been shown to lead to poorer outcomes for patients and is not cost effective for the health system as a whole.<sup>10</sup> A study assessing the impact of a watchful waiting policy in a single CCG reported on the proportion of emergency presentations before and after the policy change. Patients were:

- » 59% more likely to require an emergency repair
- » At an increased risk of adverse events (18.5% compared to 4.7%)
- » At an increased risk of mortality (5.4% compared to 0.1%)<sup>11</sup>

<sup>&</sup>lt;sup>4</sup>NHS Digital. Hospital Episode Statistics (Procedures and Interventions), 2016/17.

<sup>&</sup>lt;sup>5</sup>Higashi H et *al*. Surgically avertable burden of digestive diseases at first-level hospitals in low and middle-income regions. Surgery 2015; **157(3):** 411–9; discussion 420–2.

<sup>&</sup>lt;sup>6</sup>Royal College of Surgeons and British Hernia Society (2013). *Commissioning Guide: Groin Hernia*, p 4.

<sup>&</sup>lt;sup>7</sup>Royal College of Surgeons and British Hernia Society (2013). *Commissioning Guide: Groin Hernia*, p 6.

<sup>&</sup>lt;sup>8</sup>Royal College of Surgeons and British Hernia Society (2013). *Commissioning Guide: Groin Hernia*, p 6.

<sup>&</sup>lt;sup>9</sup>HerniaSurge Group (2018). International Guidelines for Groin Hernia Management.

<sup>&</sup>lt;sup>10</sup>Chung L, Norrie J, O'Dwyer PJ. Long-term follow-up of patients with a painless inguinal hernia from a randomized clinical trial. *Br J Surg*, 2011; **98**: 596–599.

<sup>&</sup>lt;sup>11</sup>Hwang MJ, Bhangu A, Webster CE. Unintended consequences of policy change to watchful waiting for asymptomatic inguinal hernias. Ann R Coll Surg Engl, **96**: 343–347 2014.

# Are patients in England able to access appropriate treatment?

The RCS and the BHS have had longstanding concerns that patients in England are being restricted from accessing appropriate treatment for inguinal hernias.

In 2014, the RCS published a report entitled *Is Access to Surgery a Postcode Lottery?* Published following the establishment of CCGs, the report found that 29% of CCGs surveyed had policies in place that restricted patient access to surgery. This included CCGs requiring evidence of sufficient pain and discomfort before treatment, a history of hernia incarceration, or evidence of the hernia increasing in size from month to month.<sup>12</sup>

The findings of the 2014 report revealed an unacceptable level of regional variation in access to surgical repairs for inguinal hernias. However, despite concerns being raised by the RCS and BHS, it appeared that CCGs were continuing to implement such policies as a way to reduce overall spend.

In light of anecdotal evidence that restrictions were increasing, the RCS undertook another review of CCGs' policies in April 2018. The review, which involved sending Freedom of Information requests to each CCG in England, found a significant increase in the percentage of CCGs encouraging conservative management of inguinal hernias or, in some cases, placing overly prohibitive and potentially dangerous criteria on accessing surgery.

#### Breakdown of 2018 survey results

Of the 184 CCGs that responded to the RCS's Freedom of Information request, 105 (57%) had policies in place that either restricted access to surgery or increased the risk of poorer outcomes (including adverse events and mortality).

A full breakdown can be found below:

- » 8 CCGs (5%) require patients to demonstrate a history of incarceration and/or their hernia increasing in size from month to month
- » 95 CCGs (52%) require evidence that the patient is suffering from pain or discomfort sufficient to impede their day-to-day activities or working life before surgery can be commissioned (a 'watchful waiting' approach is commonly required until this criterion is met)
- » 44 CCGs (24%) have policies that meet RCS/BHS guidelines
- » 35 CCGs (19%) have no commissioning policy relating to inguinal hernia surgery

<sup>&</sup>lt;sup>12</sup>Royal College of Surgeons (2014). Is Access to Surgery a Postcode Lottery?

#### What do these results show?

Of particular note, these results show significant regional variation in access to surgery, thereby meaning that outcomes are too often dictated by a patient's postcode and not by the nature of their condition.

It is particularly concerning that eight CCGs are requiring patients to demonstrate a history of incarceration and/or their hernia increasing in size from month to month before being able to access surgery. These CCGs are:

- » NHS Ashford CCG
- » NHS Canterbury and Coastal CCG
- » NHS West Kent CCG
- » NHS South Kent Coast CCG
- » NHS Thanet CCG
- » NHS Swale CCG
- » NHS Medway CCG
- » NHS Dartford, Gravesham and Swanley CCG

As highlighted in the 2014 report, hernias do not increase in size in a smooth fashion, with some months seeing significant growth and others seeing limited or no growth. This makes it extremely difficult to assess when a patient may require surgery. Additionally, a patient may not have a history of incarceration but could still suffer from debilitating pain that can have an impact on his or her quality of life.<sup>13</sup>

Crucially, these criteria increase the likelihood of hernia strangulation. Strangulation is a potentially lifethreatening complication that requires emergency surgical intervention. Such intervention is associated with a mortality rate that is seven times higher than when the operation is carried out electively<sup>14</sup>. This is also an extra burden on already stretched hospital resources.

It is also concerning to see that a majority (52%) of CCGs are requiring evidence of sufficient pain and discomfort before commissioning treatment, implementing a conservative 'watchful waiting' process in advance of this. This is a significant increase since the 2014 survey, in which 27% of CCGs had such a policy in place.

As highlighted above, conservative management of inguinal hernias has been shown to lead to poorer outcomes for patients. Studies looking at 'watchful waiting' versus surgery for asymptomatic/minimally symptomatic hernia patients have shown that virtually all patients developed symptoms and required surgery during the following 7.5 years, demonstrating the benefits in terms of costs and outcomes arising from timely surgical intervention.<sup>15</sup>

#### What can delaying treatment mean for patients?

Patients in areas with restrictive policies in place may experience severe and debilitating pain without being able to access appropriate surgical treatment. This can be a highly distressing experience for patients and their families which can reduce overall quality of life. As noted above, certain CCGs' policies may increase the risk of inguinal hernia strangulation. Patients with strangulated hernias usually notice a lump that does

<sup>&</sup>lt;sup>13</sup> Royal College of Surgeons, Is Access to Surgery a Postcode Lottery?, 2014

<sup>&</sup>lt;sup>14</sup> Nilsson H, et al, Mortality After Groin Hernia Surgery. Ann Surg, 2007

<sup>&</sup>lt;sup>15</sup> Chung L, Norrie J, O'Dwyer PJ. Long-term follow-up of patients with a painless inguinal hernia from a randomized clinical trial. Br J Surg, 2011.

not go away accompanied by nausea and feverish symptoms, or excruciating pain and a purplish colouring of the affected area. Strangulated inguinal hernias are a medical emergency, and failure to access appropriate surgical treatment can, in some cases, lead to death.

#### Why have CCGs been restricting access to surgery?

CCGs have looked to manage acute financial pressures through reducing spend on procedures of low clinical value, including inguinal hernia surgery. However, the RCS and BHS believe that the decision to identify inguinal hernia surgery as such a procedure has primarily been based on information captured as part of the PROMs data set.

Although PROMs data can be an effective way to assess patient experience and the effectiveness of commissioning decisions, NHS England and senior clinicians have recognised that PROMs is an inadequate method for assessing the effectiveness of inguinal hernia surgery.<sup>16</sup>

This is primarily due to the fact that there is no specific PROM questionnaire for inguinal hernias, with patients instead required to answer more general questions concerning mobility, pain and anxiety/depression. These questions do not adequately take into account the fact that persistent pain is common for up to three months after an inguinal hernia operation. Concerns have also been raised around the fact that questions relating to discomfort are not sufficiently clear or detailed for an effective comparison to be made.<sup>17</sup>

#### Recommendations

The RCS believes that patients' access to treatment must be based purely on clinical assessment and informed discussion between the clinician and patient. Denying access to treatment can have an impact on the outcomes of surgery and patient safety while also undermining the doctor-patient relationship in terms of deciding when and where patient surgery is appropriate.

With this in mind, we recommend the following:

- » Alignment with clinical guidance: NHS England and local healthwatch bodies should ensure CCGs' commissioning policies are in line with RCS/BHS guidance, and are able to deliver safe, equitable and cost-effective inguinal treatments for patients.
- » Addressing restrictive and potentially unsafe policies: given the potential patient safety issue of their commissioning policy, NHS England should take specific action for those CCGs with policies requiring a history of incarceration/an increase in size of a hernia from month to month.
- » Addressing shortcomings of PROMs data: NHS England must ensure that CCGs are aware that PROMs data in its current form is not a reliable indicator when assessing the value of inguinal hernia interventions.
- Improving patient outcomes data: NHS England and NHS Digital should develop a National Hernia Registry to ensure decisions regarding inguinal hernia surgery commissioning are based on high-quality patient outcomes data.

<sup>&</sup>lt;sup>16</sup> Hernia Outcomes Campaign (2017). Inguinal Hernia Surgery: Improving Patient Outcomes and Reducing Variation, p.8.

<sup>&</sup>lt;sup>17</sup> Hernia Outcomes Campaign (2017). Inguinal Hernia Surgery: Improving Patient Outcomes and Reducing Variation, pp 8–9.

