

The PolySoft hernia patch used with the ONSTEP technique to treat inguinal hernias

Medtech innovation briefing

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Summary

<p>Effectiveness</p> <ul style="list-style-type: none">• The PolySoft hernia patch with the ONSTEP technique would be presented as an option in the standard clinical pathway for surgical inguinal hernia repair.• Two published case series involving 698 and 80 patients have reported initial experience of using the PolySoft hernia patch with the accompanying ONSTEP surgical technique for inguinal hernia repair.• The authors of the larger of these studies compared their findings on duration of surgery with those from a separate study of another open total extraperitoneal approach hernia repair technique, suggesting that the duration was reduced.• Both studies recommended more extensive comparisons of hernia repair techniques over a longer follow-up period to establish efficacy.	<p>Adverse events and safety</p> <ul style="list-style-type: none">• Five types of complications were reported in both the identified studies. These included haematoma and residual pain. Initial use shows complication rates (of 0.7% and 7.5%) to be potentially lower than those of other open total extraperitoneal and Lichtenstein techniques.
<p>Cost and resource use</p> <ul style="list-style-type: none">• The PolySoft hernia patch used with the ONSTEP technique has an NHS acquisition cost of £116.30 per box excluding VAT. Each repair needs 1 box. No evidence on cost and resource use was available.	<p>Technical factors</p> <ul style="list-style-type: none">• The PolySoft hernia patch with the ONSTEP technique would be used within general surgery for inguinal hernia repair by surgeons with suitable training and experience.

Introduction

An inguinal hernia is a protrusion of an internal part of the body through a weakness in the abdominal wall in the groin. Inguinal hernias can be split into two types: indirect and direct. An indirect inguinal hernia is formed from a hernia sac slipping through the internal inguinal ring. A direct hernia is formed by a bulge through the floor of the inguinal canal (Jenkins and O'Dwyer, 2008).

Inguinal hernias are the most common type of hernia, accounting for around 75% of abdominal wall hernias. They are more common in men than women, occurring in approximately 1 in 4 men and 3 in 100 women. Risk factors include age, obesity, heavy lifting, a long-term cough and long-term constipation (NHS Choices 2012).

Inguinal hernias can cause a soft swelling in the groin area, which will disappear if pressed. This may be associated with discomfort, which often increases with activity. They are not usually associated with pain. If part of the bowel protrudes and gets stuck, strangulation or obstruction can occur which requires emergency repair (Jenkins and O'Dwyer, 2008).

Inguinal hernias can be repaired surgically to reduce symptoms and prevent serious complications, using a technique that minimises the risk of recurrence. There is a wide variety of suitable repair techniques and products which are currently in use in the NHS. Bruising and haematoma are potential early complications of hernia surgery. Late complications include hernia recurrence, chronic pain and infertility (Jenkins and O'Dwyer, 2008).

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology for other indications and settings.

About the technology

CE marking

The PolySoft hernia patch is a class I medical device which received its CE mark in November 2005. The CE mark is held by Davol Inc., a subsidiary of CR Bard Inc., for the design, development and manufacture of partially absorbable and non-absorbable synthetic meshes for soft tissue repair.

Description

The PolySoft hernia patch is a self-expanding, non-absorbable, sterile mesh for the repair of inguinal hernias using a pre-peritoneal technique and an anterior approach. The mesh is supported by a monofilament polyethylene terephthalate memory recoil ring, which has a gap in it to allow the patch to be cut to create a slit for the spermatic cord if needed. The patch is supplied in boxes of 2, and is available in medium (14×7.5 cm) and large (16×9.5 cm).

This patch is not suitable for people under the age of 18 because using mesh in hernia repair may compromise future growth in this age group.

Intended use

The PolySoft hernia patch is considered here only in use with the ONSTEP hernia repair surgical technique for direct and indirect inguinal hernias. The PolySoft hernia patch is currently the only patch designed to be used with the ONSTEP surgical technique, although it is possible to use the patch with other hernia repair techniques.

The ONSTEP technique is an open variation of the totally extraperitoneal repair laparoscopic technique. It can be carried out under local or general anaesthetic. After the site is prepared, a 4 cm horizontal incision is made in the lower abdomen. In men, the spermatic cord is isolated and an incision made in the transversalis fascia. This allows a 20×20 cm gauze to be inserted behind the transversalis fascia into the pre-peritoneal space, to dissect the space needed for the hernia patch. A slit is cut into the PolySoft hernia patch through the gap in the memory recoil ring. The patch is positioned with the spermatic cord within the slit and the 2 tails of the patch are stitched together using 3 sutures. The gauze is then removed from the patient and the patch is inserted into the

pre-peritoneal space and smoothed with the fingers. The patch is fixed in place by fibrous tissue which forms after surgery, unlike other techniques where sutures or clips are used. The incision in the skin can be repaired using the surgeon's choice of suture and technique. In women, the patch is not split and is placed completely pre-peritoneally.

If the inguinal hernia is not in a position where the spermatic cord is within the area of the patch, the stage in which a slit is cut in the patch can be omitted.

The manufacturer's instructions for use warns that where the patch is cut, care must be taken to ensure that the ring remains intact, because damage to the memory ring can cause complications such as bowel or skin perforation and infection.

Setting and intended user

The PolySoft hernia patch with the ONSTEP technique would be used for inguinal hernia repair in general operating theatres. Surgeons who perform this technique should be suitably trained and regularly carry out the procedure.

Current NHS options

There are a wide range of inguinal hernia repair options available on the NHS and the PolySoft hernia patch with the ONSTEP technique would be used instead of other current hernia repair methods. Surgical repair can be carried out as either an open or laparoscopic procedure, with or without mesh. Mesh repair is recommended over sutured repair because the rate of hernia recurrence is lower (Jenkins and O'Dwyer, 2008). This is supported by an intervention review from the Cochrane Library comparing laparoscopic and open techniques for inguinal hernia repair (McCormack et al. 2003). McCormack et al. also concluded that there was no apparent difference in hernia recurrence between laparoscopic and open methods that use mesh. Although patients whose inguinal hernia was repaired using laparoscopic methods experienced less post-operative pain and numbness and a shorter recuperation period, the length of operation was increased and the serious complication rate was higher than for open techniques.

Laparoscopic surgery for inguinal hernia repair (NICE technology appraisal guidance 83) recommends laparoscopic surgery as a treatment option for inguinal hernia repair. The guidance also recommends that people should be informed of the risks and benefits of both open and laparoscopic hernia repair, to allow an informed choice to be made.

There is limited information available on the mortality rates associated with hernia repair in England. Bay-Nielsen et al. (2001) published results from a Danish hernia database, which concluded that for elective surgery, the 30-day mortality rate was 0.02% for patients under 60 years old and 0.48% for those over 60. For emergency surgery, this rate rose to 7% for all age groups.

NICE is aware of the following CE-marked devices with appropriate repair techniques that have a similar function to the combination of the PolySoft hernia patch used with the ONSTEP technique:

- Kugel hernia patch with Kugel hernia operation (Bard)
- PROLENE Polypropylene Hernia System (Ethicon)

Costs and use of the technology

Based on information from the manufacturer, the PolySoft hernia patch costs £116.30 per box excluding VAT. The patch is designed to be non-absorbable and permanent, so its anticipated lifespan is the lifetime of the patient having the hernia repair. One patch is used per inguinal hernia repair procedure and a patient might have 1 or 2 inguinal hernias. There is no publicly available information on how much the ONSTEP technique costs, but the weighted average cost of inguinal, umbilical or femoral hernia procedures (NHS reference costs 2012/13 codes FZ18E, G–K) is £1754 (Department of Health 2013), and could be considered the average cost per treatment. The NHS reference cost comprises capital, human resources, training and overheads and includes the cost of any patch material used. One specialist commentator observed that the unit cost of the PolySoft hernia patch is similar to that of others; although cheaper patches are available, some patches are much more expensive, particularly those used for laparoscopic umbilical or ventral hernia repairs. Therefore it is reasonable to use an overall weighted average cost. Another specialist commentator noted that the ONSTEP technique appears to be prohibitively expensive in patients for whom an open Lichtenstein-type repair was otherwise being considered. Without evidence on cost estimates of different techniques, conclusions on the resource implications of the ONSTEP technique using the PolySoft hernia patch cannot accurately be drawn.

Surgeons may take time to learn the ONSTEP technique, but literature reports that it is a predictable short learning curve (Lourenço and da Costa, 2013). No other practical difficulties have been identified in using or adopting the technology.

Likely place in therapy

The PolySoft hernia patch with the ONSTEP technique would be presented as an option in the standard clinical pathway for surgical inguinal hernia repair.

Specialist commentator comments

One specialist commentator thought that for established surgeons the operation duration is comparable for laparoscopic and open procedures, and that the risk of serious complications is low for both types of procedure.

It was also noted by 1 specialist commentator that if the hernia recurs after initial repair using the ONSTEP technique, it may be more difficult to correct than with other procedures. This is because the patch is placed only partly pre-peritoneal, with some of the patch placed in the conventional plane used with the open Lichtenstein repair technique.

Another specialist commentator noted that the unit cost of the PolySoft patch is similar to that of others, and that it was reasonable to infer an overall weighted average cost of inguinal, umbilical or femoral hernia procedures for the ONSTEP technique.

One specialist commentator added that there may be financial implications when using the ONSTEP technique for hernias in patients for whom standard open surgery was being considered, and that this was unlikely to be true for patients being considered for laparoscopic surgery. Another specialist commentator thought that adoption of the ONSTEP technique would be resource-neutral; hospital stay, operative time and complication rate would be the same as for any other open hernia technique.

One specialist commentator noted that the ONSTEP procedure is noticeably quicker than other conventional or laparoscopic hernia repair techniques, and that this is an advantage over other, cheaper meshes.

Equality considerations

NICE is committed to promoting equality and eliminating unlawful discrimination. We aim to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women, and
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief, in the way we produce our guidance. (NB these are protected characteristics under the Equality Act (2010)).

Inguinal hernias are more common in men than in women. Sex is a protected characteristic under the Equality Act (2010).

The PolySoft hernia patch with the ONSTEP technique is not suitable for people under 18 years, a group covered by the Equality Act (2010), because using mesh in hernia repair may compromise future growth in this age group.

Evidence review

Clinical and technical evidence

Two published studies of the PolySoft hernia patch used with the ONSTEP inguinal hernia repair technique were identified. Both studies are case series that reported initial experience in surgery. Lourenço and da Costa (2013) reported the initial clinical experience of 693 patients having surgery performed by 2 different surgeons in 2 Portuguese hospitals (see table 1).

Table 1 Summary of the Lourenço and da Costa (2013) study

Study component	Description
Objectives/hypotheses	To report on initial experience with a novel hernioplasty procedure: the PolySoft repair patch with the ONSTEP repair technique.
Study design	Reporting surgery results. The follow-up period was a visit between 1 and 2 months after surgery and another 1 year after surgery.
Setting	Hernia repair surgery at 2 Portuguese hospitals.

Inclusion/exclusion criteria	Adults (>18 years) having inguinal hernia repair surgery.	
Primary outcomes	Duration of surgery, absence of chronic pain, time taken to return to normal activities, and complication and recurrence rates.	
Statistical methods	Simple averages, standard deviations and percentage rates were used to quantify the outcomes and complications.	
Participants	693 adults having inguinal hernia repair.	
Results	ONSTEP hernia repair using the PolySoft patch	Analysis
Participants	n=693	577 and 116 patients were treated at each hospital.
Patient characteristics	Men/women, n=579/114 (82%/18%) Mean age (years) [±SD]=60.6 [±7.5] Age range (years)=18–86 Type of hernia: direct=254 (37%), indirect=429 (62%), femoral=10 (1%), previous hernioplasty=76 (11%)	No comments were made in the paper discussing the population. 18% of women is a higher proportion than expected for this patient group.
Outcomes	Duration of surgery: mean (minutes) [SD]=17 [±6], range (minutes)=12–32 Time to discharge (range in hours)=2–23 Time to return to daily activities: mean (days) [SD]=6.1 [±3.0], range (days)=3–10	A study of 106 patients having open TEP hernia repair found the mean duration of surgery was 32.6 ±10.5 minutes. (Yang et al. 2010)

Complications	Early complications (within 1 week): seroma=3 (0.4%), haematoma=2 (0.3%), wound infection=3 (0.4%)	Overall complication rate was 0.7%. Complications in open TEP by Yang et al. (2010) was 11.3%.
	Late complications (6 months): residual pain=4 (0.6%)	Residual pain was resolved by the removing the memory ring in 3 patients and pain disappeared spontaneously in the other.
	Recurrence (all within 2 months): overall, n=4 (0.6%), women, n=3/114 (2.6%), men, n=1/579 (0.2%)	Recurrence after open TEP hernia repair was 1.9% (Yang et al. 2010), laparoscopic TEP repair 0% to 9% (McCormack et al. 2005, Kuhry et al. 2007, Napier et al. 2008)
Conclusions	<p>The ONSTEP procedure using the PolySoft hernia patch was found to be simple and reliable and was associated with very low complication and recurrence rates.</p> <p>The extended lateral recoil ring in the mesh was responsible for the few complications (residual pain) observed. The report suggests that the use of a different prosthesis may help improve outcomes, but does not offer a specific alternative.</p> <p>Long-term follow-up is awaited as well as randomised trials to compare with other hernia repair techniques.</p>	
Abbreviations: n, number of patients; SD, standard deviation; TEP, total extraperitoneal repair.		

Andresen et al. (2014) reported on the initial clinical experience of introducing the ONSTEP technique for inguinal hernia repair in a general surgical department. The study involved 80 patients who were treated by 4 surgeons at a Danish hospital (see table 2).

Table 2 Summary of the Andresen et al. (2014) study

Study component	Description
Objectives/hypotheses	To investigate postoperative pain and complications after ONSTEP repair of inguinal hernia.

Study design	A report of the first 80 surgery results. Follow-up involved all patients being asked by letter in January 2013 to complete an Inguinal Pain Questionnaire, a Carolinas Comfort Scale and an Activity Assessment Scale. The median follow-up time was 4 months with a range of 1 to 13 months.	
Setting	Hernia repair surgery by 4 surgeons at a Danish hospital.	
Inclusion/exclusion criteria	Patients having inguinal hernia repair who chose the ONSTEP technique. All patients were free to choose the Lichtenstein repair technique instead.	
Primary outcomes	Duration of surgery and complications including post-operative pain and recurrence.	
Statistical methods	Simple averages and percentages were used to report the outcomes.	
Participants	80 patients having inguinal hernia repair.	
Results	Standard method	Analysis
Participants	n=80	
Patient characteristics	Men/women, n=77/3 (96.3%/3.7%) Median age (years)=64 Age range (years)=19-93 Type of hernia: direct=28 (35%), indirect=49 (61%), femoral=3 (4%)	
Outcomes	Duration of surgery: median (minutes)=24, range (minutes)=13-53	Defined as cut to suture time.
	68 (85%) patients responded to the questionnaires.	66 in men and 3 in women (1 of the men had a double hernia, so 69 hernias in 68 patients).

	<p>Activity Assessment Survey results:</p> <p>53 patients (80.3%) had a score of less than 8.3, which was defined as no substantial impairment of function. No patient had any activity they were unable to perform.</p>	<p>Of the 68 responses:</p> <p>65 (95.6%) patients completed this survey.</p>
	<p>Carolinas Comfort Scale results:</p> <p>3 (5.2%) had a mean overall score >1.</p> <p>4 (6.9%) had a mean mesh comfort score >1.</p> <p>3 (5.2%) had a mean pain score >1.</p> <p>3 (5.2%) had a mean movement score >1.</p> <p>No patients reported disabling symptoms in any categories.</p>	<p>58 (85%) patients completed this survey. A mean score >1 in any of the categories was considered symptomatic.</p>
	<p>Inguinal Pain Questionnaire results:</p> <p>54 (80.6%) patients reported no pain.</p> <p>10 (14.9%) patients reported pain that was easily ignored.</p> <p>3 (4.5%) patients reported pain that could not be ignored and interfered with daily activities.</p>	<p>67 (98.5%) patients completed this survey.</p> <p>Three patients reported taking pain medication in the week before answering this survey. 80.9% of the patients reporting no pain also reported no pain 1 month post-surgery.</p>

Complications	<p>Perioperative complications, n=0 (0%)</p> <p>Contacted the department within 30 days, n=6 (7.5%): 1 superficial infection, 3 haematomas, 1 seroma and 1 case of discomfort related to the memory ring.</p>	<p>All complications were managed conservatively and/or with watchful waiting.</p>
Conclusions	<p>The ONSTEP technique seemed a safe method for inguinal hernia repair in terms of perioperative and postoperative complications. The occurrence rate of postoperative pain was equal to or lower than that after the Lichtenstein procedure. Further studies are needed, ideally blinded randomised clinical trials, before broader implementation.</p>	
<p>Abbreviations: n, number of patients; SD, standard deviation.</p>		

Two ongoing or in-development trials on the PolySoft patch for use with the ONSTEP technique were identified in the preparation of this briefing.

- [Chronic pain after inguinal hernia repair, the ONSTEP technique versus the laparoscopic approach \(ONLAP\)](#). This trial is not yet recruiting.
- [ONSTEP versus Lichtenstein, the Onli Trial](#). This trial is in the recruitment phase.

Costs and resource consequences

In 2012/13, approximately 75,325 surgical interventions were performed in England for inguinal, umbilical or femoral hernia procedures (NHS reference cost 2012/13 code FZ18E, G–K; Department of Health 2013). Usage of the PolySoft hernia patch will depend on how widely the ONSTEP technique is adopted. At present, the number of surgeons trained in the technique is limited.

Use of the PolySoft hernia patch will not need any changes to the way in which current services are organised or delivered. No additional facilities or technologies are needed alongside the PolySoft hernia patch when used with the ONSTEP technique. However, no published evidence on the resource consequences of the PolySoft hernia patch used with

the ONSTEP technique was identified in the systematic review of evidence. The manufacturer states that the resource implications of the ONSTEP technique compared with standard open or laparoscopic hernia repair are likely to be realised because of the reduction in treating postoperative complications such as chronic pain and the recurrence of hernias.

Strengths and limitations of the evidence

Both clinical studies were case series documenting initial experience with the device for this technique. They both used single study groups consisting of patients having inguinal hernia repair. The 2 studies described were completed in Portugal and Denmark, and 3 specialist commentators considered that these cohorts of patients would generally reflect those found within the UK.

Neither study identifies how much specific training the surgeons had received with the PolySoft hernia patch and ONSTEP technique, at the time of performing the procedures described. Two of the specialist commentators estimated that the learning curve for this procedure would be 20–30 procedures for a surgeon experienced in the Lichtenstein technique, but the third specialist commentator felt that it would be closer to 5–10. Surgeons who were at an earlier stage in their training would be assigned patients with few or no complications, for example, avoiding those with recurrent hernia or obesity.

A comparison of complication rates was made with other devices and repair techniques by using findings from previous studies conducted at different centres, rather than with a comparator group having an alternative intervention within the same study. A meta-analysis was not conducted, so there were no statistical comparisons. This is a general weakness of this type of study, but it is common for new surgical techniques because the priority is to assess if the technique is viable.

A more thorough comparison of hernia repair techniques could be made with a meta-analysis or random allocation of patients into groups for side-by-side trial study. This would allow a more accurate determination of the relative complication rates. Both papers acknowledge this in their conclusions by stating a preference for randomised clinical trials.

Lourenço and da Costa (2013) used 2 fixed follow-up periods of 1–2 months after surgery and 1 year after surgery. This method aimed to collect both short-term and longer-term complications.

Andresen et al. (2014) used a fixed date of January 2013 for their follow-up. Therefore patients were assessed between 1 and 13 months after surgery.

Both follow-up methods have advantages and disadvantages. Follow-up on a fixed date gives a greater spread of time after surgery, but may miss longer-term complications that are yet to appear. There may be a case for follow-up being conducted at fixed times after surgery for each patient, if those times can be shown to have clinical relevance. For example, if the follow-up time is too short, pain reported could be caused by normal post-operative recovery rather than chronic pain. Longer experience of using the PolySoft patch is needed to ensure the follow-up times are suitable to detect any complications that may be expected. Both studies express a preference for a longer follow-up period in their conclusions.

Specialist commentator opinions varied in terms of a suitable length of follow-up. Short-term complications would be identified within the first month but for long-term complications a 2-5-year follow-up was suggested, potentially backed by data from surgical registries.

Relevance to NICE guidance programmes

The use of the PolySoft hernia patch with the ONSTEP technique is not currently included in any NICE guidance programme.

References

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Search strategy and evidence selection

Search strategy

The following databases were searched on 18 February 2014 with the stated search criteria.

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) 1946 to Present and Embase 1974 to 2014 April 30.

For clinical evidence

1. hernia
2. bard
3. polysoft
4. onestep
5. #2 or #3 or #4
6. #1 and #5

PUBMED

For clinical evidence

1. hernia.mp.
2. bard.mp.
3. polysoft.mp.
4. onestep.mp.
5. #2 or #3 or #4
6. #1 and #5

Cochrane Library

For clinical evidence

1. hernia.mp.
2. bard.mp.
3. polysoft.mp.
4. onestep.mp.
5. #2 or #3 or #4
6. #1 and #5

Evidence selection

Total number of abstracts: 776

Duplicates: 85

Titles and abstracts reviewed: 683

Full papers reviewed: 6

Exclusion criteria: case studies, editorials, letters, reviews, conference proceedings/ abstracts, animal studies, and non-English language studies, not using the PolySoft patch for inguinal hernia repair.

Search strategy (economic evidence)

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) 1946 to Present and Embase 1980 to 2014 Week 19

1. hernia*.mp.
2. Inguinal hernia repair.mp.
3. Open hernia repair.mp.
4. ONSTEP hernia repair.mp.
5. ONSTEP.mp.
6. hernioplasty procedure.mp.
7. 2 or 3 or 4 or 5 or 6
8. PolySoft hernia patch.mp.
9. PolySoft.mp.
10. Bard.mp.
11. 8 or 9 or 10
12. cost*.mp.
13. economic*.mp.

14. #12 or #13

15. #1 and #7 and #11 and #14

16. limit #15 to English language

17. limit #16 to human

PUBMED

((("hernia") AND (Inguinal hernia repair OR Open hernia repair OR ONSTEP hernia repair OR ONSTEP OR hernioplasty procedure)) AND (PolySoft hernia patch OR PolySoft OR Bard)) AND (cost* OR economic*)

Cochrane Database of Systematic Reviews: Issue 5 of 12, May 2014, and Cochrane Central Register of Controlled Trials: Issue 4 of 12, April 2014

#1 hernia*

#2 Inguinal hernia repair or Open hernia repair or ONSTEP hernia repair or ONSTEP or hernioplasty procedure

#3 PolySoft hernia patch or PolySoft or Bard

#4 cost* or economic*

#5 #1 and #2 and #3 and #4

DARE (Database of Abstracts of Reviews of Effects), NHS EED (National Health Service Economic Evaluation Database), and HTA (Health Technology Assessment) databases

(Hernia) AND ((Inguinal hernia repair) OR (Open hernia repair) OR (ONSTEP hernia repair OR hernioplasty procedure)) AND ((PolySoft hernia patch) OR (PolySoft) OR (Bard)) AND ((cost) OR (economic)) IN DARE, NHSEED, HTA FROM 1960 TO 2014

Evidence selection (economic evidence)

Total abstracts: 14

Duplicates: 2

Abstracts reviewed: 12

Full papers reviewed: 0

Exclusion criteria: case studies, editorials, letters, reviews, conference proceedings/ abstracts, animal studies, and non-English language studies, not using the PolySoft patch for inguinal hernia repair.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers, and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by KiTEC. The [Interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality assured and approved for publication.

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The following specialist commentators provided comments on a draft of this briefing:

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