GID-HTE10080 Surgical mesh for treatment of primary ventral hernias

Final Protocol

Produced by: Peninsula Technology Assessment Group (PenTAG)

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Date completed: 09/02/2026

1. Decision problem

The purpose of this assessment is to 1) examine whether clinical and cost-effectiveness differences between alternative surgical meshes justify price variation and 2) investigate what other factors inform decision-making about the purchase of surgical mesh.

Table 1 summarises the decision problem to be addressed in this assessment. Further detail on each element can be found in the published scope for the assessment.

Table 1. Summary table of the decision problem

Item	Description	EAG comments
Population(s)	Use of surgical mesh for primary ventral hernia repair in adults.	
Intervention(s)	Surgical mesh for treatment of primary ventral hernia available for purchase in the NHS including • Synthetic mesh • Biological mesh • Hybrid mesh These surgical meshes should meet basic technology requirements and have one or more additional or innovative features.	
Comparators	Surgical mesh that meets basic technology requirements but does not have innovative features.	Depending on the products available it may be more pragmatic (and logical) to define the cheapest mesh as the baseline. However, other comparators will be considered relevant to the assessment if the value of innovative features are able to be assessed, and/or where the condition of the surgical field at the time of repair requires an alternative baseline.
Setting	Secondary care setting	
Outcomes eligible for inclusion	Intermediate outcomes: • Postoperative pain	

(organised by outcome type)	• Postoperative complications • Readmission within 30 to 90 days • Time to return to normal activities Clinical outcomes: • Surgical site occurrence (SSO) - Surgical site infection - Seroma - Hematoma - Wound dehiscence - Skin or soft tissue necrosis - Cellulitis - Chronic wound • Hernia recurrence • Mesh related complications: • Mesh infection - Chronic pain - Chronic foreign body sensation - Mesh migration - Mesh shrinkage or contraction - Mesh failure - Erosion into bowel or other organs - Fistula formation - Adhesion to bowel • Long term morbidity • Bowel and sexual function • Fertility outcomes • Reoperation or reintervention • Ileus • Small bowel obstruction Patient-reported outcomes: • Health-related quality of life • Pain and discomfort • Anxiety • Satisfaction • Body image • Cosmetic outcome • Impact on daily life Costs and resource use:	

	• Cost of surgical mesh • Cost of fixation materials • Staff training cost • Imaging cost • Operating room time including staff time and anaesthesia cost • Cost of surgical approach • Hospitalisation and perioperative resource use (length of hospital stay, readmission rates, emergency department visit, medication and postoperative imaging) • Cost of treating mesh related complication including treatment of SSI or SSO, infection, mesh removal, management of adhesion or erosion • Cost of treating recurrence • Monitoring costs and follow-up visits User preference and non-clinical outcome measures will be based on the prioritisation of outcomes as part of the user preference assessment.	
Economic analysis	A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.	Where possible and appropriate a fully incremental analysis will be conducted. However, due to the number of comparators (over 1,000 products), the analysis will be 'features based', with a willingness to pay established for a particular feature in terms of the value of health gains associated with that feature (or likewise cost offsets).

Abbreviations: SSI, surgical site infection; SSO, surgical site occurrence; VHWG, Ventral Hernia Working Group

1.1 Objectives

The objective of this existing use assessment (EUA) is to identify evidence for the effectiveness of the innovative features of surgical mesh for primary ventral hernia repair in the NHS, in order to identify the monetary value of such features. The outcome of the assessment will support NHS procurement and commission decisions. Specifically, the assessment will address the following research questions:

- What evidence is available to determine the clinical and cost effectiveness of innovative surgical mesh features for primary ventral hernia repair?
- Which innovative features of surgical mesh are associated with benefits for people undergoing primary ventral hernia repair and are these commensurate with the price charged by manufacturers?

The EAG proposes to take a broad view of what an “innovative feature” is, defining it as any incremental change from the baseline comparator mesh (as described in the scope). The final scope gives a list of examples of additional or innovative features. The EAG may further describe and explore other features that are identified during the evidence review. Such features are likely to include the type or structure of the material from which the mesh is made, as it is this which often drives incremental innovation in durability, biocompatibility, elasticity and weight.Given this inclusive definition of an innovative feature, and the wide variety of mesh types on the market, it is possible that more features and sub-features will be identified that can be incorporated into the assessment review and decision model. Consequently, the EAG will incorporate a step in the process to identify and prioritise the most important innovative features (i.e. those most potentially impactful on outcomes of importance for patients). The prioritisation process will be informed by 1) the available evidence base, 2) the companies’ own assessment of which features they consider are the most important, and 3) if timelines allow, the user preference assessment.

Ultimately, the findings of this assessment are intended to be used by clinicians, commissioners, and adults having primary ventral hernia repair, to inform decisions about the choice of surgical mesh product.

2. Evidence review methods

The EAG are aware that several systematic literature reviews (SLRs) in this topic area have been published in the past few years. A selection of six are shown in Table 2. Depending on the quality and coverage of these reviews, the EAG may use one or more of these or similar reviews as a basis for an updated review.

Table 2: Recent systematic reviews and meta-analyses

Citation	Objective	# included studies
Carvalho AC, et al. Meta-analysis of controlled studies comparing biologic and synthetic unabsorbable mesh in contaminated fields. Surg Endosc. 2025; 39(7):4094-4101.	To compare biological and synthetic mesh in contaminated environments with a focus on surgical site infection.	8 controlled studies
Al-Bustami IS, et al. Biosynthetic mesh in hernia repair: A systematic review and meta-analysis. International Journal of Abdominal Wall and Hernia Surgery. 2024; 7(2):p 55-66.	To review the literature on clinical outcomes among patients who undergo ventral hernia repair with biosynthetic mesh. The primary outcome assessed was hernia recurrence.	36 observational studies
Alzahrani A, et al A systematic review and meta-analysis of randomized controlled trials for the management of ventral hernia: biologic versus synthetic mesh. Updates Surg. 2024 76(8):2725-2731.	To compare synthetic and biological mesh in terms of complication and infection rates for managing elective incisional hernia.	6 RCTs
Shi H, et al Synthetic Versus Biological Mesh in Ventral Hernia Repair and Abdominal Wall Reconstruction: A Systematic Review and Recommendations from Evidence-Based Medicine. World J Surg. 2023; 47(10):2416-2424.	To compare the synthetic and biological meshes in ventral hernia repair and abdominal wall reconstruction. Outcomes included recurrence rate, surgical site infection, re-admission rate, and length of stay.	10 comparative studies
Siddiqui A, et al Mesh Type With Ventral Hernia Repair: A Systematic Review and Meta-analysis of Randomized Trials. J Surg Res. 2023; 291:603-610	To compare the clinical outcomes of utilizing biologic mesh versus synthetic mesh during ventral hernia repair. Outcomes included rates of major complications, hernia recurrence, and surgical site infection.	4 RCTs
Zhou H, et al. Comparison of outcomes of ventral hernia repair using different meshes: a systematic review and network meta-analysis. Hernia. 2022; 26(6):1561-1571.	To evaluate differences in outcome between different types of meshes in ventral hernia repair. Outcomes included recurrence rate, surgical site infection, and postoperative seroma.	23 studies (a combination of 3 RCTs and 20 cohort studies)

Abbreviations: RCT, randomised controlled trial

Previous systematic reviews have tended to compare classes of mesh – such as biological vs synthetic. While these reviews are likely to be useful, the EAG will also conduct its own evidence review to identify evidence evaluating such features. The EAG evidence review will involve two systematic literature searches for published evidence relevant to the decision problem:

- one literature search will be conducted to identify evidence for the clinical effectiveness and safety of innovative features of surgical mesh for treating primary ventral hernias.
- one literature search will be conducted to identify published economic evaluations of surgical mesh and health-related quality of life (HRQoL) and utility studies relevant to the decision problem.

The searches will be conducted separately as the inclusion criteria vary according to each evidence type.

Searches developed for the purposes of the evidence review will be devised by an experienced information specialist and quality assured by a second information specialist. The review will employ methods used to conduct SLRs (e.g. as outlined by the Centre for Reviews and Dissemination[1] including undertaking a systematic and transparent approach to the identification and analysis of published evidence. However, consistent with the NICE HealthTech programme manual[2] the evidence review will also incorporate pragmatic methods to ensure the evidence review best addresses the NICE decision problem within the timeframe of the assessment. This may include the use of artificial intelligence to identify relevant studies and a tiered evidence selection process.

If the EAG decide to use AI its implementation will be fully discussed with the NICE team. Its potential use is as a second reviewer in title and abstract and/or full text screening, and as an assistant during data extraction. The risks of using AI include the misclassification of studies, reduced transparency in decision-making, and incorrect decision-making due to poor prompting or AI algorithmic biases. To minimise these risks, all AI outputs will be reviewed by the project team. Human reviewers will retain full control over all screening and data extraction decisions. The EAG will maintain full documentation of AI settings, versions, and prompts used.

Following the NICE HealthTech programme manual,[2] the EAG will prioritise key studies if a large volume of evidence is identified. Prioritisation will be based on the innovative features covered and on the hierarchy of evidence for study designs. The EAG may also ask clinical experts for advice on key pieces of evidence if there is a large volume of high-quality evidence. The EAG may also consider potentially limiting the age of included evidence, based on input from clinical experts.

Further details of the review methods are provided in this section of the protocol.

Inclusion criteria

The inclusion and exclusion criteria for the clinical effectiveness and safety evidence are shown in Table 3. These criteria were informed by the NICE scope, discussion with the NICE team, and feedback from stakeholders to this assessment given in the scoping workshop. The criteria have also been informed by the need to capture the key evidence for the purposes of the assessment objectives. The EAG may prioritise key outcomes,[3] which will be determined with expert advice. The EAG will only include evidence in English.

Table 3. Inclusion and exclusion criteria

	Inclusion Criteria	**Exclusion Criteria**
Population	Use of surgical mesh for primary ventral hernia repair in adults.	Other hernia sites, incisional (secondary) hernias
Intervention	Surgical mesh for treatment of primary ventral hernia available for purchase in the NHS including • Synthetic mesh • Biological mesh • Hybrid mesh These surgical meshes should meet basic technology requirements and have one or more additional or innovative features.	
Comparators	Surgical mesh that meets basic technology requirements but does not have additional or innovative features.	
Setting	Secondary care setting	

Outcomes	Intermediate outcomes:
	• Postoperative pain
	• Postoperative complications
	• Readmission within 30 to 90 days
	• Time to return to normal activities
	
	Clinical outcomes:
	• Surgical site occurrence (SSO)
	  - Surgical site infection
	  - Seroma
	  - Hematoma
	  - Wound dehiscence
	  - Skin or soft tissue necrosis
	  - Cellulitis
	  - Chronic wound
	• Hernia recurrence
	• Mesh related complications:
	• Mesh infection
	  - Chronic pain
	  - Chronic foreign body sensation
	  - Mesh migration
	  - Mesh shrinkage or contraction
	  - Mesh failure
	  - Erosion into bowel or other organs
	  - Fistula formation
	  - Adhesion to bowel
	• Long term morbidity
	• Bowel and sexual function
	• Fertility outcomes
	• Reoperation or reintervention
	• Ileus
	• Small bowel obstruction
	
	Patient-reported outcomes:
	• Health-related quality of life
	• Pain and discomfort	

	• Anxiety • Satisfaction • Body image • Cosmetic outcome • Impact on daily life Costs and resource use: • Cost of surgical mesh • Cost of fixation materials • Staff training cost • Imaging cost • Operating room time including staff time and anaesthesia cost • Cost of surgical approach • Hospitalisation and perioperative resource use (length of hospital stay, readmission rates, emergency department visit, medication and postoperative imaging) • Cost of treating mesh related complication including treatment of SSI or SSO, infection, mesh removal, management of adhesion or erosion • Cost of treating recurrence • Monitoring costs and follow-up visits User preference and non-clinical outcome measures will be based on the prioritisation of outcomes as part of the user preference assessment.	
Study design	Any comparative trials (including RCTs, cohorts, before and after studies etc.). Systematic reviews and meta-analyses	Non-comparative trials (such as single-arm studies)
Language	English language only	

2.1 Search strategy

The literature searches for the evidence review are intended to interrogate a broad range of sources, to capture evidence relevant to the assessment that may or may not be indexed in traditional literature databases. This includes searching for grey literature sources.

The databases that we shall search are:

- Medline (via OVID)
- Embase (via OVID)
- Cochrane Library (trials and systematic reviews, via Wiley)
- CINAHL (via EBSCOhost)
- International HTA database (INAHTA)

In addition, we will search the following:

- Ongoing clinical trials will be searched in ICTRP and clinicaltrials.gov.
- Relevant UK guidance from NICE, SIGN, as well as relevant guidance from The European Hernia Society and the American Hernia Society
- MHRA field safety notices and the MAUDE database will be searched for adverse events of meshes for which data is described in the report

An example clinical search strategy (based on the search to be used in Medline) is listed in Appendix A. The clinical search combines terms for mesh and ventral hernia and with published filters for 1) RCTs,[4] 2) observational studies[5] and 3) systematic reviews and meta-analyses.[6] The observational studies filter has been modified to remove terms associated with case studies and case controls, and terms added to include interrupted time series and before and after studies.

These Medline searches will be fully translated into Embase. We will use shorter search strategies for other databases, however, given their smaller sizes and less comprehensive indexing. The clinical, economic and utility searches will be limited by date (up to a maximum of the last 20 years for primary research, shorter for

systematic reviews and meta-analyses), based on the EAG's assessment of the identified systematic reviews.

Information sent from companies and other stakeholders to NICE, as well as recent and relevant systematic reviews, will be scrutinised to identify additional relevant studies. We will review websites of the 21 suppliers of surgical mesh on the current Supply Chain Framework.[7] Additionally, submitted documents and information from manufacturers' request for information (RFI) and request for evidence (RFE) will be incorporated into our search results.

Search results, supplemental records and submitted information that meet the inclusion criteria will be added to an Endnote (v20) database for deduplication.

If the above search process provides insufficient evidence, supplemental searching, using Scopus (Elsevier) or Google Scholar may be used. In this case, up to ten of the included studies will be used as the basis for forward and backward citation chasing to identify evidence.

2.2 Study selection

Three levels of screening will be used to select relevant evidence for the assessment:

Level 1: titles and abstracts of identified publications will be screened using the population, intervention, comparator, and study design criteria shown in Table 3. Machine learning-powered priority screening algorithms and/or AI tools may be used to support screening (see section 2 on how the EAG would use AI and mitigate any risks with its use).

Level 2: full texts of publications included at level 1 will be screened according to the full eligibility criteria shown in Table 3. Reasons for exclusion will be noted. Included studies will be tagged using the following categories to aid prioritisation decisions: randomised controlled trial; single arm; UK trial.

Level 3: a final list of included studies will be prioritised for inclusion from those included at level 2. Where feasible, all studies identified at level 2 will be included, although if a large evidence base is identified, then a subset of the most relevant and

influential studies will be prioritised for inclusion. Studies tagged as randomised trials and UK studies at level 2 (randomised controlled trials, UK study) will be considered first for inclusion. To guide the prioritisation of other studies included at level 2, we will use the following criteria: economic evaluations conducted using a UK NHS and PSS perspective; studies with no obvious quality concerns (e.g. selection bias, high rates of missing data); studies addressing gaps in the prioritised evidence (e.g. evidence for intervention features for which no studies have yet been prioritised for inclusion); studies including utility data; economic evaluations presenting quality of life and cost and resource use data. Reasons why studies were not prioritised for inclusion will be noted and reported in the appendix of the report.

Through this Level 3 process we expect to identify a prioritised list of innovative features. Alongside this organic prioritisation process (i.e. based on the emerging evidence base), we shall also work with NICE to ask companies involved in the process to list those features that they consider are the most important to address in the assessment (i.e. those most potentially impactful on outcomes of importance for patients).

Consistent with NICE methods for conducting existing use assessments,[2] a single reviewer will screen each study at each level. Studies will be marked uncertain if further discussion about inclusion is required. Studies marked as uncertain will be discussed in team meetings and a determination made. As a quality assurance step, all studies included at level 2 but not prioritised for inclusion in the review will be screened by a second reviewer and discussed in team meetings as required.

The flow of studies through all three levels of screening will be recorded and displayed on a PRISMA diagram. The EAG shall not include in its report studies that do not meet the inclusion criteria.

2.3 Data extraction strategy

Data from prioritised studies will be extracted into a data extraction table (DET) in Microsoft Excel. The DET will be developed a priori and piloted on three studies of each study type (economic evaluations; primary utility studies; clinical effectiveness studies) to inform any final changes. A separate tab in the DET will be used for each study type.

The data extracted for each study will be aligned with the decision problem for the assessment, i.e., information about the study population, interventions, outcomes and study design that characterise its relevance for the decision problem. To guide decisions on data extraction where studies report the same outcome in multiple formats and at multiple timepoints, we will extract formats most likely to be comparable across studies.

In addition, we will prioritise the following:

- Prioritisation of HRQoL data in the form of utilities for the HRQoL review
- Prioritisation of economic evaluations most closely meeting the decision problem specification and carried out from a UK NHS and Personal Social Services (PSS) perspective.

2.4 Quality assessment strategy

Quality assessment will be in accordance with Section 3 of NICE's health technology evaluations manual.[8] Pivotal studies will be quality assured using a standardised tool specific to the research design. More broadly, a narrative summary including strengths and limitations and applicability of the studies included in the review will be provided in the report.

Economic evaluations will only be formally quality assessed if they compare surgical meshes meeting the effectiveness review criteria in a UK setting. We will not undertake a formal methodological quality appraisal of quality-of-life studies. Instead, we will provide a narrative synthesis of the overall strengths and limitations of the quality of life evidence base, with attention to study design, measurement approaches, and reporting quality.

Consistent with NICE's real-world evidence framework,[9] the Data Suitability Assessment Tool (DataSAT) will be completed to provide structured information on data suitability including provenance, quality and relevance.

The judgements made in the critical assessment of included evidence will be presented in the EAG report and considered in the evidence landscape and gap

map. Where feasible and relevant, critical assessment judgements will be considered in the synthesis/analysis.

2.5 Methods of synthesis and analysis

Depending on available evidence, narrative synthesis and network meta-analysis (NMA) will be used for evidence synthesis.

The EAG will use *component* network meta-analysis (CNMA) if feasible and appropriate. The meshes in the NICE scope are explicitly multi-component technologies and CNMA is a statistical extension of network meta-analysis that decomposes complex, multicomponent interventions into their individual components to estimate the contribution of each component (and, if specified, their interactions) to the overall treatment effect using evidence from comparative trials. The EAG will work with clinical experts and the companies to prioritise the innovative features to facilitate a robust CNMA.

3. Economic analysis methods

3.1 Model development

The EAG's proposed approach for the economic evaluation of features of surgical mesh for treatment of primary ventral hernias is based on the NICE methods for EARs, scoping searches conducted by the EAG, and input from stakeholders at the NICE scoping workshop for this assessment. The approach is subject to change dependent on the evidence identified in the evidence review.

The EAG will perform a pragmatic economic evaluation of the features of surgical mesh for treatment of primary ventral hernias in adults from the perspective of the UK NHS and PSS, consistent with the methods recommended in the NICE reference case.[8] Any deviation from the reference case will be identified and discussed as appropriate.

A *de novo* Microsoft Excel decision model is expected to be developed. The model will be constructed using available evidence, including any published models for hernia repair interventions, or models submitted by stakeholders, and following guidance on good practice in decision analytic modelling for HTA.

The structure of any model will be determined based on evidence identified via the evidence review, company RFEs, and from clinical expert advice. This includes input on:

- appropriate assumptions to make if there are data gaps in the information available to populate resource use or quality of life information per health state
- which outcomes should be included in the model (rather than considered separately within the separate user preference exercise).

All assumptions applied in the modelling framework will be stated and all data inputs and their source will be clearly identified. A decision model will not be developed if no suitable data are available.

If a *de novo* model is developed, it is expected to be a state transition model with a time horizon sufficient to capture the long-term outcomes of meshes for primary ventral hernia repairs, such as hernia recurrence, bowel, sexual and fertility functions, and other long-term morbidities that are deemed appropriate to include in the model. A state transition model has been selected because the long-term outcomes of primary ventral hernia repair would not be captured in a decision tree, nor do we consider it likely that the evidence base would be sufficient to warrant a more complex model structure. The cycle length of the model is to be determined based on the typical timepoints at which outcomes occur, which will be informed by the evidence review.

Consistent with the approach of analysing clinical effectiveness evidence (Section 2.5), comparisons in the economic evaluation are expected to be conducted at the feature level, rather than between different intervention classes. The comparator mesh will be one that meets basic technology requirements but does not have additional or innovative features (a standard or ‘basic’ mesh). The output of the economic analysis will be the economically justifiable price (eJP) or monetary value, and uncertainty around that, for each additional or innovative feature included in the model. The list of features included in the model will be based on the prioritised features list as described in the clinical section – based on claims made by manufacturers, impact of features on outcomes for patients, the NHS and/or surgeons, and data availability. The defined value will then be compared to the

additional cost currently being charged for meshes with those additional features, where possible, to identify which meshes provide value for money.

The expected model structure is subject to change during the assessment, principally in response to the evidence identified in the evidence review. Clinical experts will be consulted to provide input to key features and assumptions of the model structure. In addition, the model structure will be reviewed once the evidence review has been completed and company RFEs have been received.

Health benefits will be calculated through disutilities relative to an average utility for patients who have undergone surgery for primary ventral hernias, for the outcomes below. These outcomes were considered key events that may impact on the assessment. This list is subject to change, including input from the evidence review or from any expert elicitation process:

- Surgical site infection
- Seroma formation
- Hernia recurrence
- Mesh-related complications
- Foreign body inflammation
- Long-term morbidity
- Bowel and sexual function
- Fertility outcomes

If required, the EAG will use structured expert elicitation techniques to estimate quantitative values for model inputs where there are no published data. Given the requirements of this process, if used, it is likely that this will be focussed on a small number of model inputs and conducted with clinical experts, with support from the NICE team.

A matrix will be developed outlining the proposed mechanism of action through which each innovative mesh feature is expected to influence outcomes for each

mesh type. Outcomes will only be included in the model where there is an expected difference in either the rates or the scale of impact on cost and HRQoL across different mesh features.

It is expected that outcomes such as surgical site infection, mesh related complications, inflammation and bowel function will impact not only quality of life but will also impact on costs, as they are likely to result in requests for additional support from health care professionals. The matrix to be developed will be used to aid understanding of the relationship between modelled outcomes and the impact of each feature on HRQoL and costs. Some of the outcomes may be related, e.g. mesh related complications may lead to bowel and sexual function issues or seroma formation.

Costs will be considered from an NHS and Personal Social Services perspective. Costs will be informed by the economic evidence review and clinical experts, and may include:

- Cost of surgical mesh
- Cost of innovative feature
- Cost of fixation materials
- Staff training cost
- Imaging cost
- Operating room time including staff time and anaesthesia cost
- Cost of surgical approach
- Hospitalisation and perioperative resource use (length of hospital stay, readmission rates, emergency department visit, medication and postoperative imaging)
- Cost of treating mesh related complication including treatment of SSI or SSO, infection, mesh removal, management of adhesion or erosion
- Cost of treating recurrence

- Monitoring costs and follow-up visits

The EAG will select a cost estimate to represent the price of comparator interventions for use in the economic analysis. This cost will be selected to be representative of basic meshes that do not have any of the intervention features. Uncertainty in this estimate will be explored in sensitivity analyses where feasible.

The eJP for additional features will be calculated based upon a willingness-to-pay threshold of £25,000 per QALY, in line with the NICE methods guidance for EARs.

This eJP will then be compared to the additional cost currently being charged for meshes with those additional features, where possible, to identify which meshes provide value for money. The cost effectiveness of surgical mesh for treatment of primary ventral hernias with innovative features will therefore be estimated in terms of an incremental cost per innovative feature in comparison to the predetermined price range for a surgical mesh that meets basic technology requirements. Base case analyses will be probabilistic as this generates expected outcomes and costs and is in line with the NICE methods.[2,10] Additional scenario and one-way sensitivity analyses will be conducted where these add value or clarity. For example, scenario analysis may be explored to look at the impact of history of complications (e.g. repeat procedures) on cost-effectiveness.

Where appropriate, and if data allow, sensitivity analyses will be undertaken to explore uncertainty. These may include one-way and multi-way sensitivity analyses and use of probabilistic sensitivity analyses (PSA). The use of PSA involves sampling of parameter inputs from distributions that characterise uncertainty in the mean estimate of the parameter. PSA is used to characterise uncertainty in a range of parameter inputs simultaneously, to consider the combined implications of uncertainty in parameters. Parameter uncertainty around the eJP for each add-on feature will be presented as the 95% confidence interval from PSA.

Where probabilistic modelling is undertaken, results will be presented using the cost effectiveness plane and cost effectiveness acceptability curves and frontier (CEACs and CEAF). Options below the £25,000 per QALY threshold will be considered, and the optimal options with the highest probability of being cost-effective at the different thresholds will be depicted on the CEAF plot.

The EAG will consult clinical experts to assess the face validity of the final model and the results. This includes:

- the plausibility of the assumptions used
- that the model accurately reflects current treatment of primary ventral hernias with surgical mesh
- the plausibility and interpretation of model results.

4. User preference assessment

The EAG agrees with the final scope that healthcare professionals, mostly surgeons, make the choice about mesh product, while also noting that people who undergo hernia repair value shared decision making. NICE will be responsible for identifying a representative sample for the user preference assessment.

The objectives of the user preference assessment are to:

- identify the key criteria that are important to users of the technology when deciding which technology to choose
- understand the importance of these criteria to users
- understand how users apply these criteria when choosing a technology
- identify how well the clinical and cost effectiveness evidence presented in the assessment report captures criteria that are important to users.

4.1 Methods

The user preference process will incorporate two workshops, between which there will be two online surveys. The process will be split into the following four stages:

- Stage 1: identifying and defining criteria (workshop #1)
- Stage 2: ranking criteria in order of importance (online survey #1)
- Stage 3: weighting criteria (online survey #2)
- Stage 4: developing performance rules (workshop #2)

Stage 1: identifying and defining criteria

Users will be asked to identify key factors ('criteria') that are important when choosing a surgical mesh. A list of criteria and definitions will be identified and agreed on during an online workshop with users.

Stage 2: ranking criteria in order of importance

Users will be asked via an online survey to rank the criteria in order of importance to them. Ranked lists from all respondents will be collated, averaged and ordered from most important to least important, creating a final ranked list of criteria and definitions. This will be done using the SMART ranking technique,[11] ensuring equal say among the group.

Stage 3: weighting criteria

Users will be asked, via a second online survey, to weight the top 10 criteria to show how much more important 1 criterion is compared with the criterion ranked below (using the swing weighted technique[11]). Users will be asked to weight the top 10 criteria only, to ensure the weights assigned are meaningful.

To calculate the weighting, users will be asked to give each criterion a score from 0 to 100%. A score of 0% will mean that there "is no difference" in importance between a criterion and the criterion ranked below, while a score of 100% will mean that it is considered "twice as important". Weighted lists for all respondents will be collated, averaged and weights calculated.

Stage 4: developing performance rules

During the second online workshop, performance rules will be created by consensus for each criterion. To do this, users will be asked how they would measure performance of the technology against each criterion. For rules with multiple answers, users will be asked what would be considered acceptable or unacceptable levels of performance. In some cases, a level of acceptable performance may not be reached due to variation in opinion. The EAG will not develop performance rules for any criteria with a weight of less than 5%.

These steps will produce a ‘performance matrix’. This will include the most important criteria to users and how they would measure success in these criteria.

4.2 Integrating findings into the EAR

The findings of the user preference assessment will be used to refine the EAG’s conceptual model used in the economic analysis. Key outcomes identified during the user preference assessment that were not found in the literature review will – if possible – be added by the EAG to its analysis, and/or incorporated as additional scenario analyses where these are expected to have a meaningful impact on quality of life, cost or relative effectiveness. The narrative description and synthesis of the clinical evidence will also draw on the findings of the user preference assessment.

Any benefits of innovative mesh features that cannot be captured in the economic model will be described and outlined in the assessment report.

5. Handling information from the companies and other stakeholders

All data submitted by the companies in evidence and information requests by NICE, or data submitted by other stakeholders will be considered by the EAG if received by 6 March. Information arriving after this date will not be considered. If the data included in the information provided meets the inclusion criteria for the review, they will be extracted and quality assessed following the procedures outlined in this protocol. The EAG may seek clarification or additional information from companies and other stakeholders where necessary. All correspondence between the EAG and companies will happen through NICE.

Any ‘commercial in confidence’ data provided by a company and specified as such will be highlighted in blue and underlined in the assessment report. Any ‘academic in confidence’ data provided by a company, and specified as such, will be highlighted in yellow and underlined in the assessment report. If confidential information is included in the economic model, the EAG will provide a copy of the model with ‘dummy variable values’ for the confidential values (using non-confidential values).

6. Additional information sources

NICE will recruit experts for this assessment. Experts are recruited in accordance with NICE's appointments to advisory bodies policy and procedure. PenTAG may also discuss this project with further, independent, experts, recruited with the permission of NICE.

7. Competing interests of authors

The authors declare that they have no competing interests.

8. References

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Appendix A: Draft search strategy

Database(s): **Ovid MEDLINE(R) ALL** 1946 to February 06, 2026
Search Strategy:

#	Searches	Results
1	Surgical Mesh/	18371
2	((surgical or biologic* or synthetic or composite or hybrid or prosthe* or bioprosthe* or hernia or onlay or inlay or underlay or sublay or preperitoneal or intraperitoneal or IPOM or implant* or polypropylene or polyester or ePTFE or PTFE or lightweight or heavyweight or absorbable or nonabsorbable or resorbable or biodegradable) adj2 mesh*).tw.	10878
3	1 or 2	22359
4	hernia, abdominal/ or hernia, ventral/ or hernia, umbilical/ or incisional hernia/	15525
5	(hernia* adj3 (abdominal or ventral or umbilical or epigastric or spigelian or incisional or parastomal or lumbar)).ti,kw,ab. /freq=2	13077
6	(abdom* adj3 reconstruction).tw,hw,kf.	3163
7	("component separation" or "transversus abdominis release").tw,hw,kf.	1179
8	hernia repair*.tw,hw,kf.	16730
9	Herniorrhaphy/	13504
10	(abdominal or ventral or umbilical or epigastric or spigelian or incisional or parastomal or lumbar).ti,kw,ab. /freq=2	288215
11	(8 or 9) and 10	6894
12	4 or 5 or 6 or 7 or 11	26169
13	("Advanced Medical Solutions" or Aquilant or Assut or "B. Braun" or "Braun Medical" or Becton or Boston or Carrow or "Elemental Healthcare" or Eurosurgical or "HC21 Ltd" or "HC21 (UK)" or "Ideal Medical Solutions" or "Johnson & Johnson" or Lawmed or Medtronic or "pfm medical" or "Q Medical" or "Raise Healthcare" or "Sela Medical" or "TELA Bio" or "W.L. Gore" or "Gore & Associates").ti,ab,kw,in,ci.	670380
14	13 and 12	643
15	randomized controlled trial.pt.	654405
16	controlled clinical trial.pt.	95757
17	randomized.ab.	731505
18	placebo.ab.	266439
19	clinical trials as topic.sh.	206861
20	randomly.ab.	479910
21	trial.ti.	358787
22	or/15-21	1751657
23	Epidemiologic Methods/	31656
24	exp Epidemiologic Studies/	3609482
25	Observational Studies as Topic/	11919

26	Clinical Studies as Topic/	937
27	(Observational Study or Validation Studies or Clinical Study).pt.	196474
28	(observational adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	298363
29	cohort*.ti,ab,kf.	1145119
30	(prospective adj7 (study or studies or design or analysis or analyses)).ti,ab,kf.	639437
31	((follow up or followup) adj7 (study or studies or design or analysis or analyses)).ti,ab,kf.	200596
32	((longitudinal or longterm or (long adj term)) adj7 (study or studies or design or analysis or analyses or data)).ti,ab,kf.	434371
33	(retrospective adj7 (study or studies or design or analysis or analyses or data or review)).ti,ab,kf.	903815
34	((case adj control) or (case adj comparison) or (case adj controlled)).ti,ab,kf.	185431
35	(case-referent adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	649
36	(population adj3 (study or studies or analysis or analyses)).ti,ab,kf.	279670
37	((multidimensional or (multi adj dimensional)) adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	6767
38	(quasi adj (experiment or experiments or experimental)).ti,ab,kf.	28371
39	(interrupt* time* series or (segment$2 adj3 regression) or (before adj2 after)).ti,ab,kf.	390681
40	("single-arm" or "single arm" or "non random*" or "non-random").ti,ab,kf.	52453
41	or/23-40	5273710
42	(systematic review or meta-analysis).pt.	406684
43	meta-analysis/ or systematic review/ or systematic reviews as topic/ or meta-analysis as topic/ or "meta analysis (topic)"/ or "systematic review (topic)"/ or exp technology assessment, biomedical/ or network meta-analysis/	454491
44	((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).ti,ab,kf.	464224
45	((quantitative adj3 (review* or overview* or synthes*)) or (research adj3 (integrati* or overview*))).ti,ab,kf.	22249
46	((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).ti,ab,kf.	50648
47	(data synthes* or data extraction* or data abstraction*).ti,ab,kf.	56870
48	(handsearch* or hand search*).ti,ab,kf.	12342
49	(mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).ti,ab,kf.	43979
50	(met analy* or metanaly* or technology assessment* or HTA or HTAs or technology overview* or technology appraisal*).ti,ab,kf.	15066
51	(meta regression* or metaregression*).ti,ab,kf.	20577

52	(meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).mp,hw.	625815
53	(medline or cochrane or pubmed or medlars or embase or cinahl).ti,ab,hw.	471017
54	(cochrane or (health adj2 technology assessment) or evidence report).jw.	23144
55	(comparative adj3 (efficacy or effectiveness)).ti,ab,kf.	23876
56	(outcomes research or relative effectiveness).ti,ab,kf.	12893
57	((indirect or indirect treatment or mixed-treatment or bayesian) adj3 comparison*).ti,ab,kf.	5335
58	(meta-analysis or systematic review).mp.	584448
59	(multi* adj3 treatment adj3 comparison*).ti,ab,kf.	348
60	(mixed adj3 treatment adj3 (meta-analy* or metaanaly*)).ti,ab,kf.	190
61	umbrella review*.ti,ab,kf.	3438
62	(multi* adj2 paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	18
63	(multiparamet* adj2 evidence adj2 synthesis).ti,ab,kf.	20
64	(multi-paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	16
65	or/42-64	911309
66	(3 and 12) or 14	6649
67	66 and (22 or 41)	3324
68	limit 67 to yr="2006 -Current"	2921
69	66 and 65	503
70	limit 69 to yr="2016 -Current"	399
71	68 or 70	3092
72	exp animals/ not humans.sh.	5422940
73	(letter or editorial or comment or news or historical-article).pt.	2951338
74	71 not (72 or 73)	2897