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HealthTech Programme
Diagnostic Technologies Advisory Committee (DAC)
Technologies for the rapid diagnosis of endometriosis – 1st Meeting
10 June 2026

Technical analyst:	Michael Kertanegara
Technical adviser:	Evan Campbell
Committee lead:	Amit Parekh
EAG leads:	Anya Lissina & Rhodri Saunders
Link to Experts register for topic	Expert Advisers

The following documents are made available to the Committee:

1. Cover sheet
2. Final Scope [PUB]
3. External assessment report overview (ARO) [noCON]
4. Patient group organisation submissions
 - 4a. Fair Treatment for the Women of Wales [noACIC]
 - 4b. Hull and East Yorkshire Endometriosis Support [noACIC]
5. Professional expert questionnaires [noCON]
6. External Assessment Report (EAR) [redacted]
7. Company comments and EAG responses on the External Assessment Report (EAR) [redacted]
8. Register of interests [NoCON]

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

GID-HTE10082 Technologies for the rapid diagnosis of endometriosis

Final scope

1. Introduction

The technologies included in this NICE HealthTech evaluation are for the rapid diagnosis of endometriosis. The technologies are assessed for early use. Early-use assessment considers HealthTech products that could address a national NHS unmet need. It rapidly assesses products early in the lifecycle (but that have appropriate regulatory approval for use in the UK) or that have limited use in the NHS and need further evidence to support wider use.

Technologies considered for early use can be conditionally recommended for use while further evidence is generated during the evidence generation period. This enables early access to promising new technologies for patients. Conditional recommendations are for a fixed period of time and the technologies will be reassessed for routine use using the evidence generated.

This scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the [NICE HealthTech programme manual](#).

Using inclusive language in healthcare is important for safety, and to promote equity respect and effective communication with everyone. People with endometriosis may include women, trans men and non-binary people with endometriosis. NICE considers that healthcare professionals use their clinical judgement when implementing recommendations, taking into account the individual's circumstances, needs and preferences, and ensuring all people are treated with dignity and respect throughout their care.

2. The condition

Endometriosis is a chronic inflammatory disease defined as the presence of endometrial-like tissue (the womb lining) outside the uterus (womb). It is typically a disease of the reproductive years and although its exact cause is unknown, it is understood to be hormone mediated and typically associated with menstruation. Those with a first degree relative with endometriosis have a 7 to 10 fold increased risk of developing the condition ([Endometriosis CKS, 2025](#)).

Symptoms can vary depending on the extent and location of the endometrial tissue, but the most common symptom is chronic pelvic pain. Other symptoms include:

- period-related pain affecting daily activities and quality of life
- deep pain during or after sexual intercourse
- period-related or cyclical gastrointestinal symptoms, in particular, painful bowel movements
- period-related or cyclical urinary symptoms, in particular, pain passing urine or blood in the urine,
- subfertility or infertility in associated with 1 or more of the above
- fatigue ([NG73, 2024](#)).

Endometriosis can have a significant physical, sexual, psychological and social impact and affect ability to work. It is estimated that 10% of women in the UK of reproductive age have endometriosis ([Endometriosis UK, 2024](#)). With the prevalence of endometriosis in women with infertility estimated to be as high as 30 to 50% ([Endometriosis UK, 2024](#)). The symptoms of endometriosis can be frequent, chronic and severe.

3. Current practice

In the NHS, the referral, diagnosis and management of endometriosis follows:

- [NICE Endometriosis diagnosis and management guideline \(NG73, 2017 updated 2024\)](#)

Alongside:

- [NICE Endometriosis Clinical Knowledge Summary \(2025\)](#)
- [NICE Endometriosis Quality standard \(QS172, 2018\)](#)
- [European Society of Human Reproduction and Embryology \(ESHRE, 2022\)](#)
- [Getting it right first time Maternity and Gynaecology report \(GIRFT, 2024\)](#)
- [NICE Chronic pain in over 16s guideline \(NG193, 2021\)](#)
- [NICE Heavy menstrual bleeding assessment and management guideline \(NG88, 2018 updated 2021\)](#)

Endometriosis should be suspected in women (including those aged 17 and under) presenting with one or more symptoms or signs of endometriosis ([NG73, 2024](#)).

If endometriosis is suspected, a structured clinical assessment should be undertaken including a detailed history and examination, with consideration of risk factors, alternative gynaecological diagnoses and potential complications ([CKS, 2024](#)).

An abdominal and pelvic (internal vaginal) examination should be offered to identify abdominal masses and pelvic signs of endometriosis, such as reduced organ mobility and enlargement, tender nodularity in the posterior vaginal fornix, and visible vaginal endometriotic lesions. If an internal pelvic examination is not appropriate or declined, an abdominal examination should be carried out to exclude abdominal masses ([NG73, 2024](#)).

3.1 Diagnosis

Primary care should offer all women with suspected endometriosis a referral to imaging for transvaginal ultrasound scan, regardless of clinical examination findings. If a transvaginal ultrasound is declined or not suitable, a transabdominal ultrasound scan of the pelvis should be considered ([NG73, 2024](#)). In some cases, imaging investigations specialist pelvic ultrasound (transvaginal or transabdominal) or pelvic MRI (to assess the extent of deep

endometriosis) may inform diagnosis. However, experts acknowledge that the diagnostic performance of these investigations varies. This can be influenced by disease presentation and the training and experience of the healthcare professional carrying out the test and interpreting the results.

A referral to gynaecology services for further assessment and investigation should be considered if clinical suspicion remains or symptoms persist, even when abdominal or pelvic examinations and ultrasounds are normal, including:

- if the diagnosis is unclear
- for women with severe, persistent, or recurrent symptoms
- for women with pelvic signs of endometriosis
- if the initial management is not effective, not tolerated, or contraindicated ([CKS, 2025](#)).

A referral to a specialist accredited British Society for Gynaecological Endoscopy endometriosis centre should be made if there is suspected or confirmed:

- endometrioma (a type of ovarian cyst that forms when endometriosis affects the ovaries)
- endometriosis outside the pelvic cavity
- deep endometriosis involving the bladder, bowel or ureter ([NG73, 2024](#)).

If imaging findings are normal, surgical laparoscopy should be considered to diagnose endometriosis.

3.2 Management

Management options for endometriosis include pharmacological and surgical treatments. The diagnosis and referral for people with suspected or confirmed endometriosis may be done in conjunction with initial pharmacological treatment ([NG73, 2024](#)). The choice of treatment should be discussed in relation to symptoms, preferences and priorities with respect to pain

management or fertility or both. Endometriosis can affect women throughout, and sometimes beyond, their reproductive lives so discussion of management strategies should acknowledge the changes to priorities and preferences which may occur across this. Counselling services and support networks should also be discussed and signposted to ([NG73, 2024](#)).

Pharmacological treatments: To support the management of endometriosis related pain, healthcare professionals should first consider a short trial of paracetamol and or non-steroidal anti-inflammatory drug for the first-line management of pain. Hormonal treatment should be offered (for those not trying to conceive), including the combined oral contraceptive pill or a progestogen-only pill, implant, injectable, or levonorgestrel intrauterine system. If initial hormonal treatment is ineffective, not tolerated or contraindicated or earlier if symptoms are troublesome, they should be referred to a local gynaecology service ([CKS, 2025](#)).

Surgical treatment: Most often surgical treatment, in the form of laparoscopy is combined as a diagnostic and operative surgical procedure to remove endometriosis which is located. A previous Cochrane review reported laparoscopy can reduce pain and improve fertility but also has recurrence rates of approximately 40 to 50% at 5 years post-surgery ([Nisenblat et al, 2016](#)). In some cases, such as those with adenomyosis (when endometrial tissue grows in the muscle in wall of the womb) and heavy bleeding not responding to other treatments, a surgical hysterectomy could be indicated and discussed as a management option ([CKS, 2025](#)).

4. Unmet need

An All-Party Parliamentary Group (APPG) report on endometriosis, based on a survey of over 10,000 women, highlighted the significant unmet need within the current system (APPG, 2020). Average time to diagnosis in the UK is estimated to be 8 years and 10 months ([Endometriosis UK, 2024](#)). On average, people first seek help from a GP after 3 years and 9 months of symptoms, a delay understood to stem partly from societal perceptions that

pelvic pain and abnormal vaginal bleeding are normal ([Endometriosis UK, 2024](#)).

There are known limitations within the current diagnostic pathway. A Cochrane review reported that transvaginal ultrasound has moderate sensitivity but high specificity for some forms of endometriosis, including identifying endometriomas ([Nisenblat et al, 2016](#)). However, experts highlight considerable variation in sensitivity, influenced by differences in disease presentation such as volume of disease and operator training and experience. These factors may lead to not identifying disease and may contribute to inequities in access to specialist care. MRI can serve as an alternative diagnostic tool but typically does not identify superficial disease and is recommended mainly for diagnosing and assessing the extent of deep endometriosis ([NG73, 2024](#)). Diagnostic laparoscopy offers visual confirmation and therefore the definitive diagnosis of endometriosis, but it is an invasive and costly surgical procedure.

Multiple factors contribute to delays in achieving a diagnosis, including late initial presentation, delays in referral pathways, and limitations of current diagnostic tests. In the APPG survey, over half of respondents reported visiting their GP more than 10 times before receiving a diagnosis, and over half had attended an emergency department because of their symptoms ([APPG, 2020](#)). Many described these delays as contributing to increased suffering, prolonged ill health, and disease progression that can be more challenging to treat ([Endometriosis UK, 2024](#)). Additionally, 90% reported that they would have liked access to psychological support while managing symptoms and awaiting diagnosis, but said this was not offered ([APPG, 2010](#)).

Recent government responses to the Women and Equalities Committee ([Department of Health & Social Care, 2025](#)) acknowledge inadequacies in current management and recommend improving diagnostic times and increasing awareness of non-invasive diagnostic options. Minimally invasive

rapid diagnostic tests may offer the potential for earlier, less invasive diagnosis, with associated benefits for both individuals and the NHS.

5. The technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and publicly available information. NICE has not carried out an independent evaluation of these descriptions. All the included technologies are either currently or are expected to become available to the NHS by the publication of the guidance.

5.1 DotEndo (DotLab)

DotEndo is an in vitro diagnostic test intended to be used in women aged 18 to 49 years with unexplained pelvic pain, suspected endometriosis or both. Using a blood sample the test reviews microRNA biomarker levels with a machine-learning algorithm to identify whether endometriosis is likely to be present or not. The test is intended to be used alongside standard clinical practice to support the diagnosis, referral and management. It is not intended to be used as a standalone diagnostic test.

The technology is currently not available for use in the NHS and does not yet have regulatory approval in the UK.

5.2 Endotest (ZIWIG)

Endotest is an in vitro diagnostic test intended to be used in people aged 18 to 43 years with symptoms suggestive of endometriosis. The test uses a saliva sample to analyse salivary microRNA to provide a descriptive diagnosis. The saliva sample can be collected in either primary or specialist care settings and is sent to a laboratory for molecular analysis. The result is returned to the healthcare professional. Endotest is intended to be used alongside standard practice to support diagnosis, referral and management.

The technology is not yet in use in the NHS. It is regulated as a class C device under IVDR.

5.3 Endosure (Endosure Inc 3CPM)

Endosure is a diagnostic test that analyses the gastrointestinal myoelectric signal collected by the Electrogastrogram or Electroviscerogram. The system software analyses gastric, gastrointestinal and intra-abdominal myoelectrical activity signal data to identify patterns that are suggestive of endometriosis. It can be used for people of all ages. The technology may be used in primary care setting and specialty gynaecology consultant setting or a combination of both. The technology should only be used by healthcare professionals. Endosure is intended to be used alongside standard practice to support diagnosis, referral and management.

The technology is currently in use within the NHS in a research context. It is regulated as a class IIa medical device.

6. The place of technologies in the care pathway

The technologies are proposed to be used within primary care settings. They are intended for people with recurrent symptoms of suspected endometriosis, but with normal clinical examination and either negative imaging results for endometriosis or no imaging results because imaging is unacceptable. Testing should be overseen by a healthcare professional with expertise in endometriosis diagnosis and management to ensure appropriate use and interpretation of results.

6.1 Innovative aspects

The included technologies each use different techniques to detect endometriosis. Two include the use of biomarker-based methods from saliva or blood samples and a third uses myoelectrical data to produce an electroviscerogram.

All of the technologies provide innovation in offering a less invasive and faster approach to diagnosing endometriosis. Earlier decision-making in the diagnostic pathway supported by these tests may reduce delays to diagnosis and avoid some unnecessary investigations because of uncertainty in diagnosis. This could reduce the need for invasive diagnostic laparoscopy for

some people, with potential benefits for symptom burden, patient experience and NHS capacity.

7. Comparator

The key comparator for this assessment is current NHS practice, which includes clinical examination and imaging without the technologies. The assessment will compare the diagnostic accuracy, clinical outcomes, and cost-effectiveness of the new technologies in scope against this standard practice.

8. Patient and healthcare professional issues and preferences

Minimally invasive testing has the potential to enable earlier diagnosis of endometriosis, addressing a key unmet need. This would support recognition and validation of symptoms, reducing uncertainty and stress for people managing their condition.

Tests being minimally or less invasive supports care being accessible to as many people as possible, providing a more acceptable experience to women seeking a diagnosis than alternative internal transvaginal clinical examinations and transvaginal ultrasounds.

A positive result from minimally invasive testing may enable faster referral to secondary care, allowing earlier diagnosis and treatment. However, false positive test results could lead to unnecessary treatment.

9. Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

Endometriosis is a chronic condition of the female reproductive system. Diagnosis is often delayed and access to care is unequal, particularly for certain population groups.

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Issue date: February 2026

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- Sex and gender identity: people who do not identify as female, including trans men and non-binary people, may experience distress or exclusion when accessing care through specialist women's health services, potentially delaying diagnosis and treatment ([Endometriosis UK, 2024](#))
- Ethnicity: NICE Clinical Knowledge Summaries identify people with white ethnicity as presenting with a higher prevalence of endometriosis ([NICE, CKS, 2025](#)). However, evidence from the Royal College of Obstetricians and Gynaecologists suggests this may reflect research and diagnostic bias rather than true biological differences. People from ethnic minority backgrounds report additional barriers, including:
 - misdiagnosis (for example, black women being more frequently diagnosed with fibroids)
 - cultural barriers to discussing menstrual health
 - pain symptoms being more likely to be dismissed or minimised.

These factors contribute to poorer experiences and outcomes for some ethnic minority groups ([RCOG, 2024](#)).

- Age: adolescents and young people often face difficulties accessing diagnosis, as symptoms may not be taken seriously and there are limited age-appropriate referral pathways. This can result in significant delays in diagnosis at an early stage of disease ([NG73, 2024](#)).
- People with a learning disability or who are neurodivergent may have difficulties in communicating their symptoms and may find transvaginal ultrasound unacceptable, potentially delaying diagnosis and treatment
- Socioeconomic status: two of the technologies (Endosure and Endotest) for rapid diagnosis of endometriosis are currently available only in the private healthcare sector.

- Specialist centre locations: the limited number of specialist endometriosis services may mean that some people may need to travel long distances to access specialist management which may be particularly challenging for, disabled people, people living in rural areas, people experiencing homelessness, people with financial constraints, caring responsibilities, or inflexible work commitments may struggle to attend multiple appointments or specialist clinics, leading to delayed diagnosis. Local variation in service provision may also result in longer delays to diagnosis in some areas.

Personal reasons:

- some individuals may feel uncomfortable with invasive diagnostic testing including transvaginal examination or transvaginal ultrasound testing. This may be for a range of reasons and is likely to affect some groups more, including young people, survivors of abuse, people from certain faith groups or ethnic backgrounds, trans men and non-binary people.
- women who have decided not to have children are reported to feel their symptoms, concerns and management may be taken less seriously (Endometriosis UK, 2024).

No groups were identified as being disadvantaged by the introduction of these technologies.

10. Guidance type

The technologies for the rapid diagnosis of endometriosis are assessed for early use. This approach to guidance development is proposed because:

- the assessed technologies have limited or no current use in the NHS
- limited evidence is available for all technologies
- the technologies have the potential to address a high unmet need in the NHS
- the technologies have recent, ongoing or upcoming appropriate regulatory approval for use in the UK.

11. Decision problem

The key decision questions for this assessment are:

- Does offering these tests have the potential to be clinically and cost-effective use of NHS resources?
- Are there gaps in the evidence base and what are the key gaps?

Table 1: Decision problem

Type of assessment	Early use assessment
Population	<p>People who have or have had female reproductive organs (including women, trans men and non-binary people) with recurrent symptoms of suspected endometriosis with normal clinical examination and either negative imaging results for endometriosis or no imaging results because imaging is unacceptable.</p> <p>If the evidence allows, the following subgroups may be considered:</p> <ul style="list-style-type: none"> • Young people and adolescents • Perimenopausal and postmenopausal people • People who have fertility as a priority • People with higher body mass index • People who find transvaginal ultrasound unacceptable
Interventions	<ul style="list-style-type: none"> • Endosure • Dot Endo • Endo test
Comparator	Current practice including clinical examination and imaging without the technologies
Setting	<ul style="list-style-type: none"> • Primary care
Outcomes and costs (may include but are not limited to)	<p>Clinical outcomes:</p> <ul style="list-style-type: none"> • Diagnostic accuracy <ul style="list-style-type: none"> ○ Test sensitivity ○ Test specificity ○ Positive and negative predictive values • Time taken from initial presentation to referral to specialist services • Impact of false positives • Time taken to diagnosis • Time taken to starting treatment

	<ul style="list-style-type: none"> • Number of hospital attendances including admissions and emergency department attendances • Number of primary care consultations • Number of referrals for laparoscopy <p>Patient-reported outcomes:</p> <ul style="list-style-type: none"> • Overall pain • Symptom burden • Quality of life • Level of daily function • Patient experience • Ease of use and acceptability for patients and carers <p>Other</p> <ul style="list-style-type: none"> • Adverse events <p>Costs and resource use:</p> <ul style="list-style-type: none"> • Costs of equipment, • Costs of staff and associated training • Cost of testing, including time requesting, reviewing and communicating results • Cost of follow up appointments, including <ul style="list-style-type: none"> ○ Further investigations ○ Further treatment • Costs of appointments, investigations and treatments avoided
<p>Economic analysis</p>	<p>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.</p> <p>Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results.</p> <p>The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.</p>

12. Other issues for consideration

12.1 Validation of biomarkers

The European guidance published in 2022 ([ESHRE, 2022](#)) concluded that there was insufficient evidence at the time to support the diagnostic use of

biomarkers from endometrial tissue, blood, menstrual fluid or uterine fluid and therefore recommended that they should not be used in routine clinical practice. Although the evidence base in this area is evolving, experts remain cautious about the robustness of validation studies and the extent to which findings can be generalised to routine care.

12.2 Potential implementation issues

Implementation of biomarker tests would require laboratory analysis, with implications for integration within existing clinical pathways. Considerations include workforce requirements, including training for healthcare professionals involved in requesting, interpreting and acting on test results, as well as for laboratory staff and pathologists supporting delivery of the tests.

NICE team

Samantha Baskerville and Michael Kertanegara

Technical Analysts and topic leads

Evan Campbell

Technical Adviser

Lee Berry and Jo Heaney

Project Manager and Project Coordinator

February 2026

Early-use assessment

HTE10082 Technologies for the rapid diagnosis of endometriosis

Assessment report overview

This overview summarises key information from the assessment and sets out points for discussion in the committee meeting. It should be read together with the [final scope](#) and the external assessment report (EAR). List of abbreviations used in this overview is in [appendix A](#).

1. The technologies

This evaluation includes technologies for the rapid diagnosis for endometriosis, summarised in Table 1:

Table 1. Features of technologies

Technology (manufacturer) regulatory status	Technology description	Intended age group
EndoSure (3PCM/Endosure) UK MDR class 2a	Measuring gastrointestinal myoelectrical activity to detect abnormal electrical patterns in the gut caused by prostaglandins released by endometriosis tissue.	All ages
DotEndo (DotLab) CE class C IVDR expected in 2026	Quantifying endometriosis-specific microRNA biomarkers levels in blood samples	18 to 49 years
EndoTest (Ziwig) UK MDR class A IVDR	Detecting the presence of a 109-microRNA biomarker signature of endometriosis in saliva samples	18 to 43 years

Abbreviations: IVDR, In Vitro Diagnostic Regulation; MDR, Medical Device Regulation

EndoSure and EndoTest are currently used within the NHS in research settings.

2. The condition

Endometriosis is a chronic inflammatory disease defined as the presence of endometrial-like tissue (the womb lining) outside the uterus (womb). It is typically a disease of the reproductive years and although its exact cause is unknown, it is understood to be hormone mediated and typically associated with menstruation. It is estimated that 10% of women and those assigned female at birth of reproductive age in the UK have endometriosis ([Endometriosis UK, 2024](#)).

The most common symptom of endometriosis is chronic pelvic pain. Other symptoms include:

- period-related pain affecting daily activities and quality of life
- deep pain during or after sexual intercourse
- period-related or cyclical gastrointestinal symptoms, in particular, painful bowel movements
- period-related or cyclical urinary symptoms, in particular, pain passing urine or blood in the urine
- subfertility or infertility in associated with 1 or more of the above
- fatigue ([NICE guideline on endometriosis \[NG73, 2024\]](#)).

3. Current practice

Endometriosis is suspected in women (and those assigned female at birth) presenting with one or more symptoms or signs of endometriosis. An abdominal and pelvic (internal vaginal) examination should be offered to identify abdominal masses and pelvic signs of endometriosis.

When endometriosis is suspected, a referral to imaging for a transvaginal ultrasound scan should be offered by primary care, regardless of clinical examination findings. If a transvaginal ultrasound is declined or unsuitable, a transabdominal ultrasound should be considered. In some cases, specialist pelvic ultrasound or pelvic MRI (to assess the extent of deep endometriosis) may inform diagnosis.

If imaging findings are normal but endometriosis is still suspected, surgical laparoscopy should be considered to diagnose endometriosis.

Management options for endometriosis include pharmacological and surgical treatments. The diagnosis and referral for people with suspected or confirmed endometriosis may be done in conjunction with initial pharmacological treatment.

4. Unmet need

Diagnostic delays for endometriosis in the UK have worsened over time. The average time to diagnosis reached 9 years 4 months in 2025 ([Endometriosis UK, 2026](#)), up from 8 years and 10 months in 2023, and 8 years in 2020. On average, people first seek help from a healthcare practitioner after having 3.5 years of symptoms, a delay understood to stem partly from societal perceptions that pelvic pain and abnormal vaginal bleeding are normal ([Endometriosis UK, 2026](#)).

There are limitations within the current diagnostic pathway. Transvaginal ultrasound has variation in sensitivity depending on disease type and operator expertise, increasing the risk of missed diagnosis and delayed referral to specialist care ([Nisenblat et al., 2016](#)). MRI is useful for deep endometriosis, but it does not identify superficial disease ([NICE guideline on endometriosis \[NG73, 2024\]](#)). Diagnostic laparoscopy provides definitive diagnosis, but it is invasive and costly.

Delays in diagnosing endometriosis are associated with late initial presentation, delays in referral pathways, and limitations of current diagnostic tests. The government responses to the Women and Equalities Committee ([Department of Health & Social Care, 2025](#)) acknowledged inadequacies in current management and recommend improving diagnostic times and increasing awareness of non-invasive diagnostic options. Minimally invasive rapid diagnostic tests may offer the potential for earlier, less invasive diagnosis, with associated benefits for both individuals and the NHS.

During scoping workshop, healthcare professionals and patient representative organisations emphasised that:

- The largest unmet need is a delay to diagnosis and delay in access to specialist treatment in secondary care.
- They wanted the test in primary care due to speed up referral to secondary care.
- Transvaginal ultrasound should remain the first-line investigation in primary care to identify or exclude differential diagnoses.
- A negative ultrasound result does not rule out endometriosis, and the [NICE guideline](#) says the person should be referred to secondary care, but in practice there is a delay in referral if ultrasound imaging is negative or inconclusive.

The technologies being evaluated in this assessment will sit within the primary care setting. The technologies are intended to be used in people with suspected endometriosis who have normal clinical examination and negative or equivocal ultrasound results, or who have declined imaging.

5. Innovative aspects

The included technologies each use different techniques to detect endometriosis. Two include the use of biomarker-based methods from saliva or blood samples and a third uses myoelectrical data to produce an electroviscerogram.

All of the technologies provide innovation in offering a less invasive and faster approach to diagnosing endometriosis. Earlier decision-making in the diagnostic pathway supported by these tests may reduce delays to diagnosis and avoid some unnecessary investigations because of uncertainty in diagnosis. This could reduce the need for invasive diagnostic laparoscopy for some people, with potential benefits for symptom burden, patient experience and NHS capacity.

Further details, including descriptions of the interventions, comparator, care pathway and outcomes, are in the [final scope](#).

6. Clinical effectiveness evidence

The external assessment group (EAG) did literature searches to identify relevant clinical evidence, supplemented by evidence submitted by the companies. The study search and selection methods are in 4.1 of the EAR.

6.1 Overview of key studies

The EAG identified 28 studies across the three technologies. Results were available for 19 studies: 10 for EndoSure (2 published, 3 conference abstracts, 5 unpublished); 1 for DotEndo (published); and 8 for EndoTest (6 published and 2 conference abstracts).

The overview of key studies is summarised in Table 2.

- Sixteen studies reported diagnostic accuracy as primary outcome.
- Almost all studies (18/19) were conducted outside the UK, the only study conducted in the UK was unpublished.
- No studies were carried out in primary care settings.
- Most study participants were adults.
- Three studies reported costs of the technologies, one of them reported cost-effectiveness.
- One study reported clinician-reported outcome, and one study reported patient acceptability.

Table 2. Overview of key studies

Technology	Study name and design	Setting	Country	Study population	Outcomes
EndoSure	Noar 2022 Prospective open-label study (conference abstract)	Tertiary care centre	US	N=50 Women aged 17 to 45 years with chronic abdominal pain, negative CT/MRI and GI endoscopy, scheduled for laparoscopy	<ul style="list-style-type: none"> • Sensitivity • Specificity
EndoSure	Noar et al. 2024a Prospective open-label comparative study	Tertiary care and routine outpatient centre	US	N=154 Women aged ≥18 years; Cohort 1: n=62 non-endometriosis controls; Cohort 2: n=43 with histologically confirmed endometriosis; Cohort 3: n=49 with abdominal pain and negative imaging scheduled for laparoscopy.	<ul style="list-style-type: none"> • Sensitivity • Specificity • NPV • C-statistic
EndoSure	Noar et al. 2024b Prospective, open-label, multi-ethnic, multicentre validation study	Tertiary care and routine outpatient centre	US	N=50 Women aged 27 to 55 years, n=25 with endometriosis, n=25 without endometriosis (controls)	<ul style="list-style-type: none"> • Sensitivity • Specificity • PPV • NPV
EndoSure	Tanos et al. 2025 Prospective comparative study (conference abstract)	Specialised endometriosis tertiary care centre	Belgium	N=100 Adult females (aged 18 to 65 years) with suspected endometriosis	<ul style="list-style-type: none"> • Sensitivity • Specificity • Accuracy • Patient acceptance

Technology	Study name and design	Setting	Country	Study population	Outcomes
EndoSure	Andres et al. 2025 Prospective validation study (conference abstract)	Two tertiary hospitals	Brazil	N=43 Women aged 18 to 45 years	<ul style="list-style-type: none"> • Sensitivity • Specificity • Accuracy • PPV
EndoSure	Unpublished, structured, open-label, validation study by Tadpole Women's Centre	NHS secondary care centre	UK	N=10 Adolescent females (aged 9 to 18 years) with endometriosis and elevated activity index scoring during EVG	<ul style="list-style-type: none"> • Sensitivity • Specificity • PPV • NPV
EndoSure	Unpublished, structured, non-randomised, comparative, open enrolment study by Sheba Hospital Medical Centre	Tertiary care centre	Israel	N=55 People (aged 18 to 65 years) designated female at birth with: <ul style="list-style-type: none"> • Endometriosis undergoing planned laparoscopic surgery (n=35) • No known endometriosis undergoing planned laparoscopic surgery for benign gynaecological disease (n=20, control group) 	<ul style="list-style-type: none"> • Sensitivity • Specificity • Accuracy
EndoSure	Unpublished, structured, randomised, blinded, surgical validation study by M. Noar et al.	Tertiary treatment centre	Not reported (presumed US)	N=286 People designated female at birth (aged 9 to 81 years) n=233 with endometriosis n=53 without endometriosis	<ul style="list-style-type: none"> • Sensitivity • Specificity • Accuracy
EndoSure	Unpublished, structured, non-randomised, surgically validated study by Nezhat	Tertiary treatment centre	US	N=9 People assigned female at birth (18 to 65 years)	<ul style="list-style-type: none"> • Sensitivity • Accuracy

Technology	Study name and design	Setting	Country	Study population	Outcomes
	Minimally Invasive Surgery Institute			n=7 with endometriosis n=2 without endometriosis	
EndoSure	Unpublished, structured, non-randomised, surgically validated study by Mercy Hospital Gynaecological Surgery	Tertiary treatment centre	US	N=8 People assigned female at birth (aged 17 to 65 years) with pelvic pain suspected of endometriosis	<ul style="list-style-type: none"> • Sensitivity • Specificity • Accuracy
DotEndo	Moustafa et al. 2020 Prospective, case-control, independent validation diagnostic accuracy study	Tertiary treatment centre	US	N=100 People designated female at birth (aged 18 to 49 years) with symptoms suggestive of endometriosis. Following exploration by laparoscopy, patients were classified into two groups: n=41 with endometriosis n=59 without endometriosis (controls). The model was tested in an independent validation cohort (n=48)	<ul style="list-style-type: none"> • MicroRNA classifier • Sensitivity • Specificity
EndoTest	Bendifallah et al. 2022d Prospective single-centre development study (NCT04728152)	Tertiary care centre	France	N=200 Women (aged 18 to 43 years) with signs and symptoms suggestive of endometriosis. Following exploration by laparoscopy or imaging or both, patients were classified into two groups:	<ul style="list-style-type: none"> • Sensitivity • Specificity

Technology	Study name and design	Setting	Country	Study population	Outcomes
				n=153 with endometriosis n=47 without endometriosis (controls).	
EndoTest	Bendifallah et al. 2023 Prospective multicentre external validation study; interim analysis (NCT05244668)	Four tertiary care centres and one secondary care centre	France	N=200 Women (aged 18 to 43 years) with formal endometriosis diagnosis or suspected endometriosis. Following exploration by laparoscopy or imaging or both, patients were classified into two groups: n=159 with endometriosis n=41 without endometriosis (controls).	<ul style="list-style-type: none"> • Sensitivity • Specificity • NPV
EndoTest	Bendifallah et al. 2025 Prospective multicentre external validation study; full results (NCT05244668)	Tertiary or secondary care centres	France (16 centres) and Canada (1 centre)	N=971 Women (aged 18 to 43 years) with signs and symptoms suggestive of endometriosis. Following exploration by laparoscopy or imaging or both, patients were classified into two groups: n=749 with endometriosis n=222 without endometriosis (controls)	<ul style="list-style-type: none"> • Sensitivity • Specificity • PPV • NPV • Accuracy • Misclassification rate
EndoTest	Ferrier et al. 2023 Cost-effectiveness analysis	French healthcare system	France	Women with chronic pelvic pain	<ul style="list-style-type: none"> • Costs • ICERs <p>Secondary outcomes:</p> <ul style="list-style-type: none"> • Sensitivity

Technology	Study name and design	Setting	Country	Study population	Outcomes
					<ul style="list-style-type: none"> • Specificity
EndoTest	Nigdelis et al. 2025 Open web-based survey study	NA	Germany	N=141/190 members of German gynaecological endoscopy, endometriosis societies and endometriosis research foundation	<ul style="list-style-type: none"> • Clinician-reported outcomes • Costs
EndoTest	Rogalska and Brukała 2025 Desk-based comparative market assessment	Polish private healthcare market	Poland	NA	<ul style="list-style-type: none"> • Costs <p>Secondary outcomes:</p> <ul style="list-style-type: none"> • Sensitivity • Specificity
EndoTest	Moawad 2026a Unpublished conference abstract accepted for presentation at the Society of Gynecologic Surgeons meeting	Tertiary and secondary care centres	France	N=556 Women (aged 18 to 43 years) with symptoms suggestive of endometriosis: n=332 with superficial peritoneal endometriosis n=216 negative controls	<ul style="list-style-type: none"> • Sensitivity • Specificity • Accuracy
EndoTest	Moawad 2026b Unpublished conference abstract accepted for presentation at the American & Global College of Endometriosis Specialists meeting	Tertiary and secondary care centres	France	N=1,000 Women (aged 18 to 43 years) with signs or symptoms suggestive of endometriosis Three subgroups evaluated: 1. Infertile endometriosis patients versus all controls	<ul style="list-style-type: none"> • Sensitivity • Specificity • Accuracy

Technology	Study name and design	Setting	Country	Study population	Outcomes
				2. Infertile endometriosis patients versus nulliparous controls 3. Infertile endometriosis patients with SPE phenotype only or with SPE and deep endometriosis phenotype versus controls.	

Abbreviations: EVG, Electroviscerogram; ICER, incremental cost-effectiveness ratio; MRI, magnetic resonance imaging; NPV, negative predictive value; NA, not applicable; PPV, positive predictive value; SPE, superficial peritoneal endometriosis

Study quality

Out of the 19 studies in table 1, complete reporting of diagnostic accuracy outcomes was available for 6 studies (2 for EndoSure, 1 for DotEndo, and 3 for EndoTest). Risk of bias was assessed for these studies only and was judged to be high across all studies and across all technologies.

The most important applicability concern is that none of the included studies were conducted in a UK NHS primary care setting. The study populations were recruited from specialist surgical or gynaecology centres with a clinical indication for laparoscopy (secondary care). These populations do not reflect the expected patient mix in NHS primary care, where the prevalence of endometriosis and symptom severity may be lower. None of the included studies evaluated the technologies within the intended pathway, that is, for suspected endometriosis with equivocal or unavailable imaging. At lower prevalences of endometriosis, the reported positive and negative predictive values are likely to be less favourable. Thus, extrapolation of the published diagnostic accuracy estimates to the NHS diagnostic pathway requires caution.

6.2 Study results

Most included studies only reported diagnostic accuracy data. No studies reported the following clinical outcomes listed in the [scope](#): time taken from initial presentation to referral to specialist services, impact of false positives, time taken to diagnosis, time taken to starting treatment, number of hospital attendances (including admissions and emergency department attendances), and number of primary care consultations.

Due to lack of downstream outcomes of test results from the current evidence, the EAG noted that it is not possible to determine with certainty if use of any of the technologies would translate into meaningful patient benefit within the NHS diagnostic pathway for endometriosis.

Diagnostic accuracy

Table 3 summarises the findings of the 16 studies that reported diagnostic accuracy outcomes. Of these, 13 studies evaluated the accuracy of the technologies using diagnostic laparoscopy as the reference standard. Some studies used MRI or transvaginal ultrasound (TvUS) or both, as the reference standard. Three studies did not report the use of any reference standard. In addition to sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) some studies measured overall accuracy. This is the probability of correct classification for both positive and negative results and is calculated as the total number of correct results divided by the total number of all tested individuals.

Table 3. Diagnostic accuracy studies

Study	Technology	Reference standard	Diagnostic accuracy	Test sensitivity	Test specificity	PPV / NPV
Noar 2022	EndoSure	Diagnostic laparoscopy with biopsy	100%	100%	100%	NR
Noar et al. 2024a*	EndoSure	Diagnostic laparoscopy with biopsy	NR	95%/91% (age subsets ≤35/≥36 years)	96%/95% (age subsets ≤35/≥36 years)	PPV: 95%/91% NPV: 96%/95% (age subsets ≤35/≥36 years)
Noar et al. 2024b	EndoSure	Laparoscopic surgery/histology	NR	96%	96%	PPV: 96% NPV: 96%
Tanos et al. 2025	EndoSure	MRI, specialist TvUS, or laparoscopy	96%	100%	5%	NR
Andres et al. 2025	EndoSure	TvUS or laparoscopy	92% (versus laparoscopy) 47% (versus TvUS)	100% (versus laparoscopy) 82% (versus TvUS)	0% (versus laparoscopy) 26% (versus TvUS)	PPV: 92% (versus laparoscopy) PPV: 39% (versus TvUS)
Study by Tadpole Women’s Centre	EndoSure	None	NR	100%	67%	PPV: 88% NPV: 100%
Study by Sheba Hospital Medical Centre	EndoSure	None	98%	92%	96%	NR
Study by M. Noar et al.	EndoSure	None	92%	95%	85%	NR

Study	Technology	Reference standard	Diagnostic accuracy	Test sensitivity	Test specificity	PPV / NPV
Study by Nezhat Minimally Invasive Surgery Institute	EndoSure	Unclear, diagnostic laparoscopy, possibly also TvUS	100%	100%	100% (only two normal cases evaluated)	NR
Study by Mercy Hospital Gynaecological Surgery	EndoSure	Diagnostic laparoscopy	100%	100%	100% (only one normal case evaluated)	NR
Moustafa et al. 2020	DotEndo	Standard clinical assessment with diagnostic laparoscopy plus visual/histological confirmation	NR	83% (specificity-optimised) (90% balanced threshold)	96% (specificity-optimised) (90% balanced threshold)	NR
Bendifallah et al. 2022	EndoTest	Diagnostic laparoscopy with histology and/or MRI	NR	97%	100%	NR
Bendifallah et al. 2023	EndoTest	Diagnostic laparoscopy with histology and/or MRI	>92% (across all centres)	96% (95% CI: 94% to 97%)	95% (95% CI: 85% to 99%)	PPV: 95% (95% CI: 85% to 99%) NPV: 87% (95% CI: 78% to 90%)

Study	Technology	Reference standard	Diagnostic accuracy	Test sensitivity	Test specificity	PPV / NPV
Bendifallah et al. 2025	EndoTest	Diagnostic laparoscopy with histology and/or MRI/TvUS	97% (95% CI: 95% to 98%)	97% (95% CI: 96% to 98%)	94% (95% CI: 91% to 96%)	PPV: 98% (95% CI: 97% to 99%) NPV: 91% (95% CI 88% to 93%)
Moawad 2026a	EndoTest	Diagnostic laparoscopy with histology and/or MRI/TvUS	Overall: 96% (95% CI: 94% to 98%) In confirmed SPE subgroup: 95% (95% CI: 92% to 97%)	Overall: 97% (95% CI 95% to 98%) In confirmed SPE subgroup: 96% (95% CI: 90% to 99%)	Overall: 94% (95% CI 92% to 96%) In confirmed SPE subgroup: 95% (95% CI: 93% to 96%)	Overall PPV: 96.4% (95% CI 95% to 98%) NPV: 95% (95% CI 93% to 97%) In confirmed SPE group: PPV: 88% (95% CI 82% to 90%) NPV: 99% (95% CI 96% to 100%)
Moawad 2026b	EndoTest	Diagnostic laparoscopy with histology and/or MRI/TvUS	Overall: 95% (95% CI: 93% to 97%)	Overall: 96.7% (95% CI: 94% to 96%)	Overall: 94% (95% CI: 92% to 96%)	Overall: PPV: 93% (95% CI: 90% to 95%) NPV: 97%

Study	Technology	Reference standard	Diagnostic accuracy	Test sensitivity	Test specificity	PPV / NPV
						(95% CI: 95% to 99%)

*Test sensitivity and specificity for Noar 2024a across age subsets were derived from AI-based prediction modelling for cohort 2 (n=43) people who all had surgically or histologically confirmed endometriosis. Abbreviations: CI, confidence interval; MRI, magnetic resonance imaging; NPV, negative predictive value; NR, not reported; PPV, positive predictive value; SPE, superficial peritoneal endometriosis; TvUS, transvaginal ultrasound

Patient- and clinician-reported outcomes

One study (Tanos et al. 2025) reported patient-reported outcomes, which found that 60% of patients preferred EndoSure over TvUS. No other patient-reported outcomes specified in the [scope](#) were reported for any technology.

Clinician-reported outcomes were reported in Nigdelis et al. 2025, evaluating clinician attitudes to EndoTest. Overall support for adopting the technology was limited. Reported concerns included the cost of the test, uncertainty about its clinical utility, lack of robust external validation, and unclear impact on patient management. However, only 15% of participants surveyed had used the technology.

6.3 Ongoing studies

The EAG identified 8 ongoing studies: 2 studies on EndoSure, 3 on DotEndo and 4 on EndoTest. A summary of these studies is in section 8.1 of the EAR.

7. Health economic evidence

The EAG did a review to identify suitable health economic models for the technologies. From the literature search, 1 cost-effectiveness study (Ferrier et al. 2023) for EndoTest was included in the review to help inform the health-economic analysis.

The EAG also reviewed NICE clinical guidelines and economic models for endometriosis diagnosis. They found 1 [NICE clinical guideline](#) and 3 other relevant economic evaluations that reported an economic model. An overview of these models is presented in Table 8 in section 6.2 of the EAR.

7.1 Health economic model

The EAG developed a de novo early health economic model. The model structure comprised a Markov model (Figure 1) to represent patient pathways from initial presentation through to a potential diagnosis. Outcomes for individuals receiving either a single diagnostic test or multiple diagnostic tests were determined using separate decision trees (Figures 2 and 3), applied to the relevant proportions of the population.

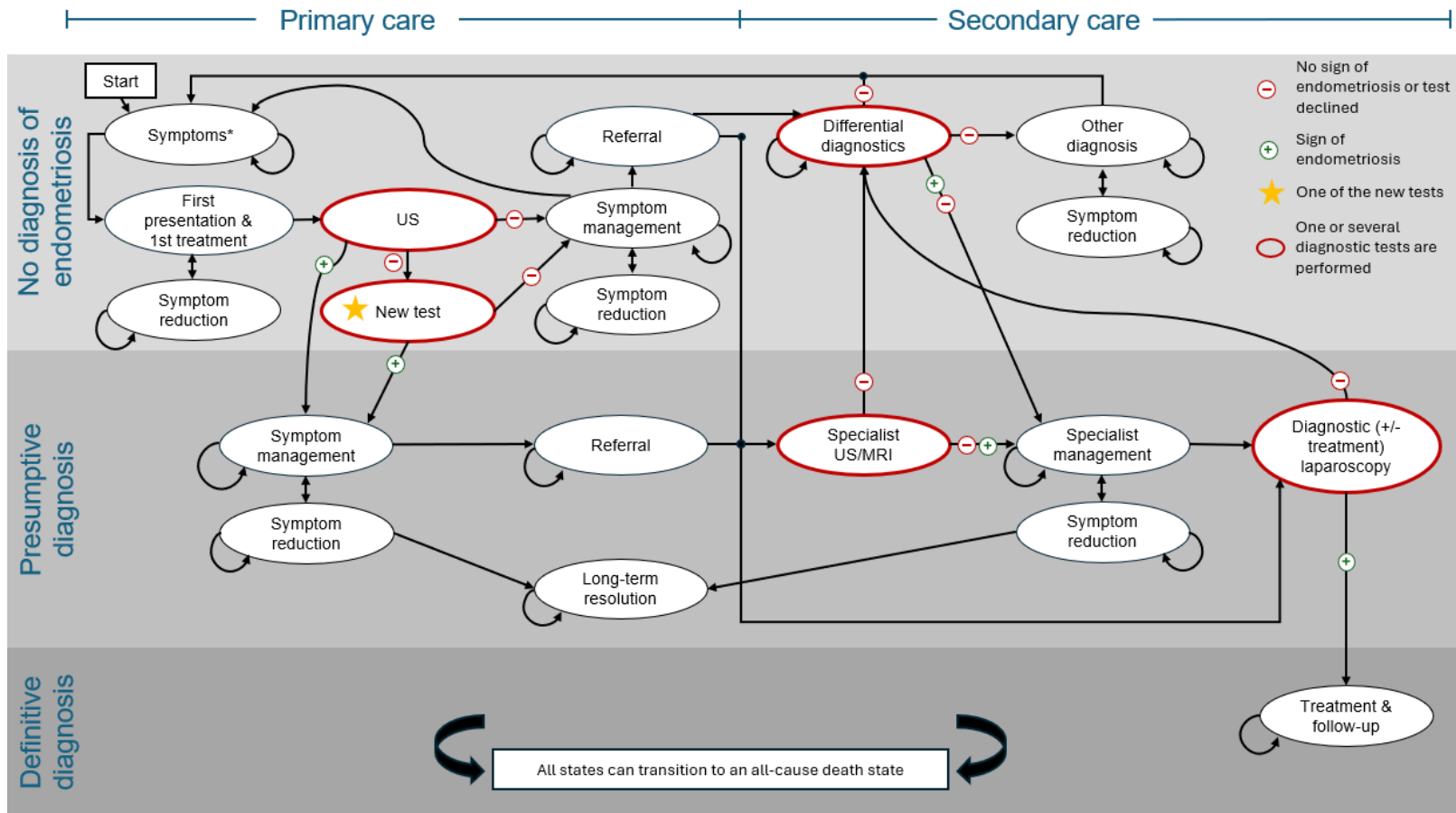


Figure 1 Model structure: Markov model of the endometriosis diagnostic care pathway. In each Markov model arm, either none or only one of the new diagnostic tests is offered; no combination of new tests was assessed. *Symptoms suggestive of endometriosis.

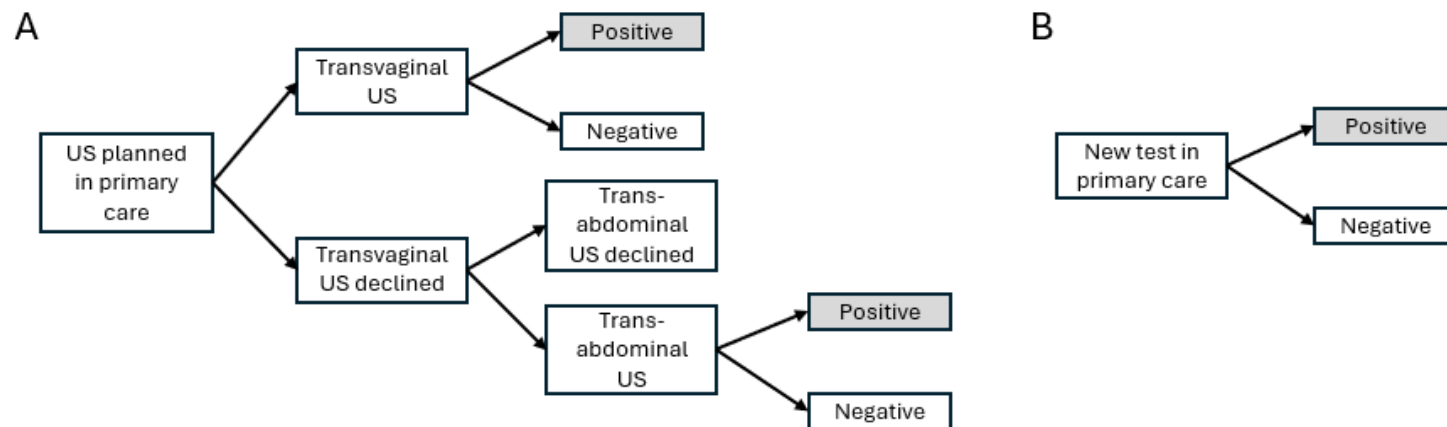


Figure 2. Embedded decision trees for the diagnostic Markov states in primary care. Ultrasound (US) and one new test per intervention arm (A). If endometriosis was detected, the outcome was positive; otherwise, it was negative (B).

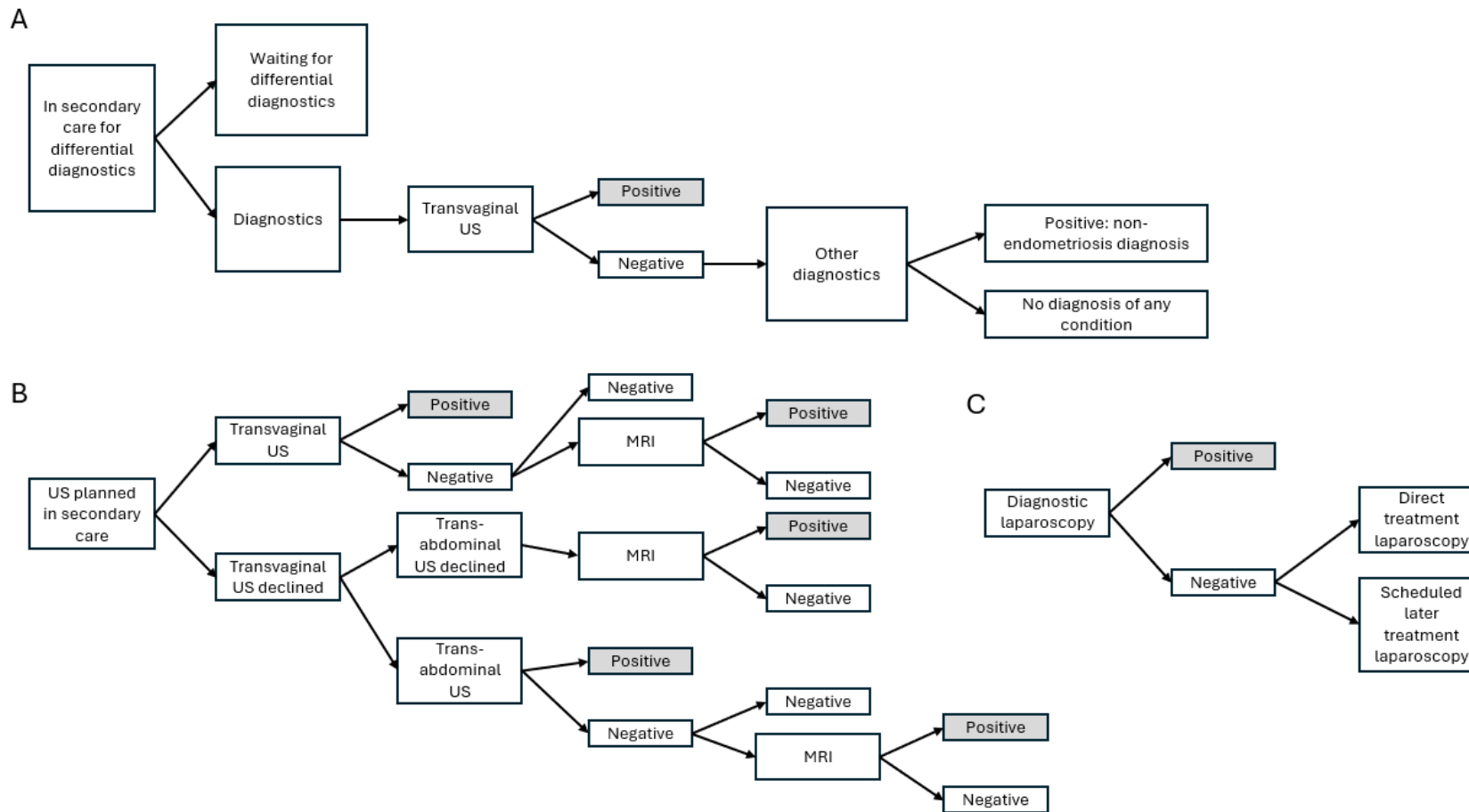


Figure 3. Embedded decision trees for the diagnostic Markov states in secondary care. Differential diagnostics (A), specialist ultrasound (US) and/or magnetic resonance imaging (MRI; B), and diagnostic laparoscopy with or without treatment laparoscopy (C). If endometriosis was detected, the outcome was positive; otherwise, it was negative.

The model base case used a lifetime time horizon of up to 60 years. Costs and outcomes were discounted at an annual rate of 3.5%, with costs valued in 2025 prices and considered from the NHS and Personal Social Services perspective. Each health state in the model was associated with probabilities and costs for resource use specific to that health state and its associated symptoms and diagnosis. An all-cause mortality was applied where death can occur at any time and from any state in the model. Death is the only absorbing state in the model.

The model was based on assumptions, informed by clinical experts and patient representatives. Key assumptions include:

- **Diagnosis status:** Having a presumptive diagnosis was assumed to improve treatment effectiveness and health-related quality of life, with further improvement following a definitive diagnosis. A single positive result from any diagnostic test was sufficient to establish a presumptive diagnosis, as all people entering the model were symptomatic of endometriosis.
- **Symptom status:** Unmanaged symptoms were associated with higher rates of unplanned primary care and emergency department visits. Symptom management through treatment was assumed to reduce healthcare utilisation and improve quality of life, with no endometriosis-related visits once symptoms were no longer clinically relevant.
- **Imaging diagnostics:** Every person entering secondary care was assumed to undergo at least one imaging test. Ultrasound was the default, with MRI used if ultrasound was declined. Ultrasound in primary care was included, and a small proportion of people were assumed to proceed directly to laparoscopy without imaging in secondary care.
- **New test uptake:** All people eligible for the new diagnostic tests were assumed to receive them, with no refusals in the new-test arms of the model.
- **Treatment pathways:** Treatment was assumed to be initiated at first presentation and continued until symptom resolution. First-line treatment was offered prior to initial ultrasound, with progression to second-line

treatment possible thereafter. Specialist treatments were available only within secondary care.

- **Referral to secondary care:** Not all people were referred to secondary care. Some would be managed entirely in primary care.
- **Symptom resolution in primary care:** A proportion of people would achieve symptom resolution in primary care.
- **Diagnostic accuracy of new tests:** The new tests have not been assessed in primary care. Sensitivity and specificity data were assumed to also apply in primary care.
- **Patient choice regarding laparoscopy:** A 50% uptake of laparoscopy was assumed in both current care and new test pathways, reflecting the person's choice.
- **Diagnostic findings:** A negative diagnostic result was assumed to indicate that endometriosis was not identified. In practice, some people may have multimorbidity and an alternative pathology may be detected.
- **Costs of treating other conditions:** This cost was set to zero due to uncertainty regarding alternative diagnoses and management.
- **Quality of life for other conditions:** Baseline quality of life values derived from populations with endometriosis were applied to people with non-endometriosis causes of similar symptoms.
- **Symptom reduction following misdiagnosis:** People incorrectly diagnosed with endometriosis were assumed to have a lower likelihood of symptom improvement with treatment.

Further details of the economic modelling are in section 6.3 of the EAR.

Population

The population in the model was a hypothetical cohort of people presenting in primary care with symptoms suggestive of endometriosis. This cohort included individuals with endometriosis and those without.

Comparator

The comparator in the model was current NHS practice including clinical examination and imaging without the new technologies.

7.2 Model inputs

Most model inputs were informed by literature review and company-submitted information. Where there was no or limited evidence, inputs were based on EAG assumptions or clinical expert advice, or both.

Cohort clinical parameters

The cohort clinical parameters of the conceptual model are described in Table 9 in section 6.3.5 of the EAR.

- The starting age in the model was 22.
- 42.5% of people with symptoms have endometriosis, 25% of whom also had other comorbidities.
- The average waiting time for first presentation was 8.9 months.
- Ultrasound is scheduled in 90% of people after first presentation.
- Waiting times for both differential diagnostics and waiting time after referral to secondary care with presumptive diagnosis (from GP) were 3.4 months.
- The waiting time for laparoscopy was 13.57 months.
- The proportion of people declining transvaginal ultrasound was 21.7% in primary care and 9.8% in secondary care.
- The proportion of people achieving symptom reduction was 36.56% in primary care and 45.70% under specialist management.
- The proportion of people achieving complete symptom resolution was 5.68% in primary care and 7.10% in secondary care.

Diagnostic accuracy parameters

Table 4 shows the diagnostic accuracy of new technologies and current diagnostic tools (ultrasound, MRI, laparoscopy). Sensitivity and specificity values for transabdominal ultrasound were assumptions due to lack of data.

Table 4. Diagnostic accuracy parameters of technologies

Variable	Sensitivity (95% CI)	Specificity (95% CI)
EndoSure	96.0%	95.0%

DotEndo	90.0%	90.0%
EndoTest	97.3% (96.4% to 98.0%)	94.1% (91.0% to 96.4%)
TvUS, primary care	25.0% (12.7% to 41.2%)	93.0% (78.0% to 99.0%)
Transabdominal ultrasound	20.0% (10.2% to 32.9%)	93.0% (78.0% to 99.0%)
Specialist TvUS	83.3% (62.3% to 95.3%)	97.4% (90.8% to 99.7%)
MRI	90.3%	91.0%
Laparoscopy	97.0%	77.0%

Abbreviations: CI, confidence interval; TvUS: transvaginal ultrasound

Costs parameters

Technology costs

Table 5 shows the technology costs. In addition to test cost per person or user, EndoSure is the only technology that would incur implementation cost. The implementation cost for EndoSure was calculated by assuming both capital cost and training cost would be spread across 120 people receiving the test

Table 5. Technology costs

Technology	Cost of implementation per person or user	Cost of test per person or user
EndoSure	Capital £70.83 Training £4.17	£350
DotEndo	None	£400
EndoTest	None	£1,381

Costs and resource use related to endometriosis diagnosis and management

Other costs in the model included:

- Costs of healthcare professionals
- Costs of GP, specialist, and emergency department visit
- Endometriosis treatment
- TvUS in primary care and secondary care

Further details of costs related to endometriosis diagnosis and management are in Table 13 in section 6.3.6 of the EAR. Details of resource use parameters are described in Table 11 in Section 6.3.6 of the EAR.

Health state utilities

Table 6 presents the health state utilities used in the model. All values were derived from a French study (n=253 in 2 tertiary cares) (Aubry et al. 2017) that reported EQ-5D-3L data. A UK study by Khan et al. 2018 was not used because it did not report all required utilities and disutilities. The EAG noted that use of a French EQ-5D-3L value may limit applicability to the UK population.

Dependent on each symptom or diagnosis state, a disutility is applied to the baseline utility. The utility values were then combined in a multiplicative approach. Everyone entering the model had a disutility of no diagnosis and disutility of unmanaged applied. As they moved through the model, utility will increase if they get a presumptive or definitive diagnoses in combination with benefits from symptom management. Details of utility calculations are in section 6.3.7 of the EAR.

Table 6. Health state utilities

Variable	Value	Brief notes
Baseline utility	0.5900	From Aubry et al. 2017.
No diagnosis disutility	0.0625	Assumed disutility for people with symptoms but no diagnosis, calculated by the EAG as the mean difference between baseline utility and utility for people reporting more severe symptoms (pain>7, dysmenorrhoea>7, pelvic pain>5, painful defecation moderate-severe)
Presumptive diagnosis disutility	0.0000	Assumed to be the same as baseline because all people had a presumptive diagnosis in the study
Definitive diagnosis disutility	-0.0625	Assumed utility increment for people with definitive diagnosis
Unmanaged symptoms disutility	0.0625	Assumed disutility for people with more severe symptoms

Managed symptoms disutility	-0.0750	Assumed utility increment for people with milder symptoms
No symptoms disutility	-0.2400	Assumed utility increment for people with no symptoms

7.3 Model results

Deterministic base case

In the deterministic base case analysis, current care was associated with an estimated lifetime cost of £20,163 over a 60-year time horizon and generated 14.43 quality-adjusted life-years (QALYs). Both EndoSure and DotEndo were associated with higher QALY gains and lower total costs compared with current care, and therefore dominated current care in the base case results. EndoTest also resulted in additional QALYs gains but incurred higher costs relative to current care, yielding an incremental cost-effectiveness ratio (ICER) of £6,068 per QALY gained. At a £20,000 per QALY threshold, both EndoSure and DotEndo showed net monetary benefits of £2,238 and £2,228, respectively and net health benefits of 0.11 for both, indicating they are cost effective compared with current care. EndoTest also showed positive net monetary and health benefits (£1,337 and 0.07), indicating it is cost effective, but to a lesser extent.

The full deterministic and probabilistic results are in section 6.5.1 to 6.5.2 of the EAR.

Scenario and sensitivity analyses

The EAG conducted one-way sensitivity analyses to identify the key drivers of model outcomes. For EndoSure, the primary cost driver was the proportion of people presenting in primary care who have endometriosis. For DotEndo, the most impactful cost driver was the cost of a secondary care visit, while in the EndoTest model the average age of the population was the most influential cost driver. Across all three technologies, test specificity was the main driver of QALYs. Lower specificity resulted in higher QALYs. This is because lower specificity leads to more false positive results. In the model, people with any

positive test result were assumed to have a presumptive diagnosis, which is associated with higher utility than having no diagnosis.

One-way sensitivity analyses results are described in section 6.5.2.1 to 6.5.2.3 of the EAR.

The EAG also conducted scenario analyses to test the results under alternative assumptions about the diagnostic pathway and key areas of parameter uncertainty, informed by key drivers in the one-way sensitivity analyses. Overall, the findings were largely consistent with the base-case results. DotEndo remained dominant in most (27/29) scenarios, with changes in cost-effectiveness result driven by an increase of sensitivity of transvaginal ultrasound (TvUS) in primary care and a decrease in the proportion of people presenting with endometriosis. EndoTest was only dominant in the scenario where all symptomatic individuals were assumed to have endometriosis, but in all other scenarios it is associated with higher costs and higher QALYs, with all ICERs below £14,000 per QALY gained. EndoSure remained dominant in most scenarios (21/26). In the remaining five scenarios, the technology shifted to generating higher costs and higher QALYs, with all ICERs below £4,000 per QALY gained. Cost increases were driven by increases in the sensitivity of TvUS in primary and secondary care, reductions in the sensitivity of EndoSure, a lower proportion of people with endometriosis entering the model, and fewer people achieving symptom reduction in primary care.

Full scenario analyses results are in section 6.5.4 of the EAR.

Additional model outcomes

All technologies reduced the average time to a presumptive diagnosis and to a definitive diagnosis (Table 7). Time to presumptive diagnosis varied between the technologies because of:

- Differences in sensitivity, meaning technologies with lower sensitivity will result in more false negatives, leading to a longer time for these people receiving their presumptive diagnosis from another test later in the pathway

- Some technologies have age restrictions, meaning some people were not eligible for all technologies, so they had to wait till later in the pathway to receive their presumptive diagnosis

Table 7. Time to presumptive and definitive diagnoses for current care and new technologies

Care	Time to presumptive diagnosis (years)	Time to definitive diagnosis (years)
Current care	3.52	9.68
DotEndo	2.08	8.72
Endosure	1.71	8.46
EndoTest	1.97	8.64

In deterministic results, DotEndo and EndoTest were associated with modest reductions in healthcare professional time for diagnostic testing compared with current care, while EndoSure increased healthcare professional time.

Full additional model outcomes are in section 6.5.3 of the EAR.

8. Equality considerations

The [final scope](#) and the [scoping equality impact assessment](#) describe equality considerations for this assessment. The key studies in this assessment did not report any subgroup data on: perimenopausal and postmenopausal people, people with higher body mass index, and people who find a TvUS unacceptable. Subgroup analysis was not explored due to the limited evidence. The EAG did not identify additional equality issues.

9. Evidence gaps

In the current evidence base, no evidence was identified for the following outcomes:

- Diagnostic accuracy in primary care settings

- Reduction in diagnostic laparoscopy rate and impact on the diagnostic pathway
- Time from symptom onset to confirmed diagnosis
- Quality of life
- Healthcare resource use

The full evidence gap analysis is presented in section 8.2 and key areas for evidence generation in section 8.3 of the EAR.

10. Key points, limitations and considerations

10.1 Clinical effectiveness

Key points

- EndoSure reported diagnostic accuracy (sensitivity 91 to 96%, specificity 95 to 96%) based on 2 peer-reviewed studies.
- DotEndo reported a sensitivity of 83% (90% balanced threshold sensitivity) and a specificity of 96% (90% balanced threshold specificity) from a single peer-reviewed study.
- EndoTest reported sensitivity (96 to 97%) and specificity (94% to 100%) across 3 published, peer-reviewed diagnostic accuracy studies. One external validation study demonstrated high diagnostic accuracy across endometriosis subtypes and patient subgroups.
- No adverse events were reported in the included studies.

Limitations

- All studies were associated with a high risk of bias due to some degree of conflict of interest.
- EndoSure and DotEndo studies had a single-centre design and lacked external, independent validation.
- EndoSure peer-reviewed studies reported the best predictive model for sensitivity and specificity based on AI-derived prediction modelling, incorporating area under the curve, symptom score, and age. However, the unit for symptom score was not described. Sensitivity and specificity

were also based on a cohort of 43 people who all had confirmed endometriosis (100% prevalence).

- All peer-reviewed studies reporting diagnostic accuracy outcomes were done outside UK.
- Most studies have very high endometriosis prevalence and may not be generalisable to NHS primary care setting population.
- None of the studies used the technology in primary care.
- None of the studies evaluated downstream outcomes such as time to diagnosis, reduction in laparoscopy rates, or quality of life.
- None of the studies enrolled participants with suspected endometriosis and equivocal or unavailable imaging.

Considerations for committee:

- To what extent is the evidence from studies outside the UK generalisable to the NHS?
- To what extent is the diagnostic accuracy evidence from secondary care populations generalisable to primary care?
- Do the technologies have the potential to address the unmet need?
- How well does the outlined pathway reflect current practice?
- Is the assumption that a positive result from a test will lead to faster referral to secondary care and result in earlier definitive diagnosis reasonable?
- Are there any implementation and adoption issues to consider?

10.2 Health economic evidence

Key points:

- The early health economic model found that DotEndo and EndoSure had dominant ICERs, while EndoTest was cost-effective.
- Across one-way sensitivity analyses, change in input parameters did change absolute results but not their interpretation.
- Interpretations were consistent across most scenario analyses for all technologies.

Limitations:

- The model did not capture the full complexity of real-world endometriosis care pathways, particularly for people with multimorbidity.
- The prevalence of endometriosis in people presenting with symptoms was derived from a UK study with 26 UK-based hospital populations and may not reflect those in primary care settings. The impact of different prevalence estimates on cost-effectiveness was explored in scenario analyses.
- The model assumed the access to service after a referral to secondary care would not create further capacity-related delays.
- The diagnostic accuracy inputs in the model for EndoSure (sensitivity 96% and specificity 95%) were taken from the company submission and the Noar (2024a) study which provided separate accuracies for people ≤ 35 years and people ≥ 36 years. However, the study reports 95% sensitivity and 96% specificity for people aged ≤ 35 years subgroup. The EAG also did not run a scenario using the diagnostic accuracy for people aged ≥ 36 years (91% sensitivity and 95% specificity).
- Evidence on the diagnostic accuracy of the new technologies was derived from secondary or tertiary care settings, as such evidence was lacking in the primary care setting.
- Health state utilities were derived from a French population using the French EQ-5D-3L value set, which may not fully reflect preferences of the UK population.
- Due to lack of data on disutility of no diagnosis, the EAG calculated this as the mean difference between baseline utility (0.59) and utility of people presenting with more severe symptoms (0.5275) in Aubry et al (2017), which evaluated people who already had presumptive diagnosis and who mostly received surgery. The difference in utility is representative of the difference in symptom burden and not in receiving a diagnosis. This value (0.0625) has been assumed to apply to the model population, which is in primary care, for health states receiving a

definitive diagnosis (as a utility increment), and unmanaged symptoms (as a disutility). Clinical expert opinion highlighted the importance of having a diagnosis, even if it is presumptive.

Considerations for committee:

- Are the early economic model structure, assumptions and clinical and cost parameters suitable to answer the decision question (see the [scope](#)) for this assessment?
- Is the evidence of potential benefit sufficient to support the use of the technologies in an evidence generation context?
- Is the assumption and calculation of a benefit from an earlier presumptive and definitive diagnosis reasonable?
- Are there any economic risks associated with introducing the technologies alongside evidence generation?

Appendix A Abbreviations

CI	Confidence interval
EAG	External assessment group
EAR	External assessment report
ICER	Incremental cost-effectiveness ratio
NA	Not applicable
NPV	Negative predictive value
NR	Not reported
PPV	Positive predictive value
QALY	Quality-adjusted life year
TvUS	Transvaginal ultrasound

HealthTech Programme

HTE10082 Technologies to support the rapid diagnosis of endometriosis (provisional title)

Patient organisation submission

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on patient experience of using the technology in the context of current clinical practice that is not typically available from the published literature.

To help you give your views, please use this questionnaire. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
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- Your response should not be longer than 10 pages.

Information about your organisation

Organisation name	FTWW: Fair Treatment for the Women of Wales
Contact person's name	
Role or job title	Director
Email	
Telephone	
<p>Brief description of the organisation, such as:</p> <ul style="list-style-type: none"> - Who funds it? - How many members does it have? - What region your organisation represents <p>For the most part, FTWW relies on grant-funding from a range of philanthropic grant-makers, including National Lottery, Esmee Fairbairn Foundation, Waterloo Foundation, Rosa UK, but also receives funding from the Welsh Government's 'Equality & Inclusion' grant.</p> <p>The organisation has around 2500 members living / receiving healthcare in Wales, UK.</p>	

Declarations

Do you have any conflicts of interest? Please let us know if you have a question on the [NICE policy on declaring and managing interests](#).

How did you gather information about the experiences of patients and carers to include in your submission?

Regular dialogue via our digital community forum and various consultations over the last several years on endometriosis, and menstrual / gynaecological health, involving surveys and focus groups.

Are you willing for this submission to be shared on our website?

Yes X (but **please remove individual author's name** and attribute to FTWW: Fair Treatment for the Women of Wales – thank you).

We may invite you to a scoping meeting and/or committee meeting where this technology is to be discussed. Would a member of your organisation be willing to join such a meeting (this may be in person or virtually)?

Yes X

Does the organisation have any direct or indirect links with, or funding from, the tobacco industry?

No X

Impact of the symptoms and condition on patients and on family and carers

1. What is it like to live with the condition?

FTWW members living with endometriosis describe it as physically and mentally exhausting, with symptoms not just focused on pelvic pain but systemic, chronic pain, organ dysfunction, and fatigue. Those living with endometriosis describe a wide range of symptoms affecting every part of the body and a significant impact on mental health and wellbeing because symptoms are so intrusive; members describe detrimental impact on the ability to maintain relationships, education / employment, social participation, fertility, and quality of life. Not only do the physiological aspects of the disease have serious negative consequences for wellbeing, the experience is compounded by societal taboos surrounding conditions which have a menstrual / gynaecological component, gender stereotypes which often see symptoms normalised or dismissed, and delayed diagnoses which make it harder to secure support from others.

Experiences and availability of current health technologies

2. How do the existing diagnostic tests play a role in managing the condition, and what are their advantages and disadvantages? What new technologies do you know of that you could tell NICE about?

Largely, diagnosis of endometriosis firstly relies upon clinical suspicion: there is currently no routinely available, accessible, non-invasive test to make a diagnosis and initiate treatment, including surgery. Patients in Wales can wait on average around 10 years and have 26 medical appointments ahead of confirmed diagnosis. Whilst a diagnostic test available within primary care settings would be advantageous, it is likely that it would still require both patient and clinician to have recognised symptoms and suspect endometriosis as the cause before ordering the test; a degree of patient and clinician education and communication will likely still be necessary therefore.

In Wales, we have worked with colleagues in Cardiff University as part of Women's Health Research Wales, and NHS Wales, to coproduce the Welsh Government-endorsed Endometriosis Cymru Symptom Reporting Tool (Estr) <https://endometriosis.cymru/estr/> to encompass both symptom-tracking (in line with NICE symptoms which can indicate endometriosis) and improve communication between patient and clinician to expedite referral into gynaecology where appropriate.

The tool has the potential to also help facilitate the ordering of diagnostic tests, as well as enabling patients & clinicians to monitor impact and efficacy of treatment options.

As it stands, hormone-based therapy and analgesia for the management of endometriosis symptoms can still be commenced without a formal diagnosis. However, patients report this being problematic for a couple of key reasons: firstly, these approaches 'mask' rather than resolve symptoms; disease can still progress whilst symptoms are managed, with the result that patients may still require surgical intervention and / or fertility treatment later on; secondly, having a diagnosis provides both personal validation and opens up avenues for additional support, including help-seeking and reasonable adjustments.

Diagnosis can be made via ultrasound scan but, for the most part, this will only identify the presence of endometriomas; for patients whose endometriosis is not so readily visualised, ultrasound scans can often prove inconclusive. Whilst highly specialised ultrasound technicians can identify location of endometriosis outside of the ovary, access to this kind of expertise is not commonplace, particularly within the NHS. We would suggest that this warrants an important training need, as using scans in this way can also assist surgeons to visualise and identify location of lesions as part of surgical planning and excision of disease.

The most commonly utilised diagnostic tool at present is the diagnostic laparoscopy; however, in the absence of either a diagnostic proforma to standardise procedures or universal training in minimally invasive surgery and advanced laparoscopic skills, it is not uncommon for endometriosis to go undiagnosed following such a procedure. This can have devastating consequences for patients and is not a good use of stretched NHS resources. Nevertheless, where surgery to diagnose endometriosis is undertaken, it should always also involve surgical treatment (removal of endometriosis) so it is not necessarily equivalent to a non-invasive diagnostic test.

In terms of new technologies to diagnose endometriosis, there is much activity underway in Wales as in the rest of the UK / globally to develop methodologies and tools. Our view remains that diagnosis is one, albeit key, part of the puzzle that is endometriosis: we also need to see improved (non-hormonal) treatments, even a cure.

About the health technology being assessed

3. NICE are looking to review minimally invasive technologies to support rapid diagnosis of endometriosis, such as saliva or blood sampling to effectively diagnose endometriosis. What are the potential benefits of the health technology/technologies being assessed?

For many patients, a diagnosis is vital to opening up both treatment pathways and additional support. At present, the average diagnostic delay in the UK is around 8-10 years which, for a condition whose symptoms often start at onset of puberty, means those affected will spend the entirety of their secondary school career struggling with a non-visible, often misunderstood, stigmatised health condition.

Even without treatment, a diagnosis can give people validation and empower them to seek help and assistance, including familial, educational, and workplace support. For those who don't want to engage with formal healthcare subsequently, a diagnosis can help them to research and develop their own ways to self-manage the condition. A non-invasive diagnostic test therefore presents opportunities for patients to secure both support and improve psychological wellbeing. For some, where a diagnosis facilitates the ability to access reasonable adjustments, it could enable improved attendance and productivity in their educational or working lives, reducing costs to the economy.

For those who do need or want additional medical or surgical treatment, an effective non-invasive diagnostic test could expedite referral and access to different treatment modalities by enabling more effective triage. A non-invasive diagnostic test could also improve NHS ability to collate data on prevalence and impact, enabling more targeted investment in training and service-provision. Further, if tests / tools developed also enable identification of disease recurrence and its location, they could enable patients and clinicians to track treatment efficacy, thereby improving opportunities for more focused research and provision of treatment options.

4. What are the potential disadvantages of these types of health technologies being considered for assessment?

The technologies under consideration still rely on clinical suspicion of disease for them to be initiated, so there remains a need for improved awareness, education, and communication amongst and between healthcare professionals and patients, alongside a firm commitment to embedding shared decision-making in treatment planning.

Non-invasive diagnostic tests will only form part of disease management for patients: effective treatment will still be required and, for the growing number who don't wish to use hormone-based therapies, this usually means surgical intervention. It may be that numbers wanting surgery go up with an anticipated growth in formal diagnosis, thereby increasing waiting lists further. Indeed, we know that waiting lists for non-cancer gynaecology patients are amongst the longest in the UK, so the NHS should be looking to expand investment and provision in this area as a matter of urgency. Early evidence suggests that waiters for gynaecology are

more likely to be of working age compared to those on other waiting lists, so there are undoubtedly knock-on impacts on the wider economy, something which has been reported by the NHS Confederation in its 'Investing in the 51%' report <https://www.nhsconfed.org/publications/womens-health-economics>.

We are concerned also about the possibility of false readings and, indeed, where patients are advised of a negative test when symptoms remain. We know from FTWW's community that many already encounter this, even where surgical interventions are involved, and that subsequent diagnosis is not infrequently made when they are able to access tertiary, more specialised surgery. In the intervening period, however, a significant number report being dismissed as having nothing 'wrong' with them, and encountering disbelief and disparagement from their social circle. The negative impact on psychological wellbeing can be significant, so test results must both be accompanied by careful, sensitive counselling, and not preclude patients from accessing a second medical opinion and / or investigations.

Equality issues

5. Are there any groups of people who might benefit more or less from the technology than others?

We are concerned that technologies must be universally accessible and usable for all who need them. As it stands, some have age-related cut-off points which need explanation. For example, we know that women over the age of 40 already face barriers to diagnosis because it's assumed that onset of peri-/menopause will ameliorate endometriosis symptoms when, for many, it does not. There is a lack of research into the prevalence and impact of endometriosis within this demographic and endometriosis post-menopause remains an omission from current NICE guidance.

Affordability of the technologies will be important for those who experience socio-economic disadvantage. Geographical inequity of access to services is also a concern. Where the technologies enable earlier diagnosis, this must be accompanied by development of pathways that enable patients, no matter where they live in the UK, to access optimal treatment including surgery in tertiary centres / amongst suitably specialised personnel.

6. Are there any groups of people that might need further consideration in using the technologies (for example, because they have higher levels of ill health, poorer outcomes, problems accessing or using treatments or procedures)?

Use of technologies and the outcomes from deploying them must be carefully communicated to patients: for those with learning disabilities, different / additional communication needs, or for whom English is not their first language, this is a vitally important consideration, especially where counselling on results and next steps is needed. Access to both interpreters and psychological support is already variable, resulting in inequity of care so, where a test or technology becomes part of a pathway to symptom resolution / treatment or chronic disease management, this must be resolved.

7. Are there any potential [equality](#) or [health inequality](#) issues that should be taken into account when considering this condition and the technology?

Please see above

Additional information

8. Please include any additional information you believe would be helpful in assessing the value of the technologies.

NA

Key messages

In up to 5 bullet points, please summarise the key messages of your submission.

- 1) Quicker diagnosis can be validating and empowering for patients and those seeking support from their wider networks

- 2) Non-invasive technologies are not a panacea; improved awareness, education, training, and communication on endometriosis and its treatment will still be needed
- 3) In the absence of optimal pharmacological treatments, access to specialised surgery will still be necessary and there already exists variation and inequity in this space which needs resolving
- 4) Patients with endometriosis post-menopause and / or outside of the pelvis remain under-served within existing guidelines and pathways; new technologies must not compound these inequities.

Thank you for your time. Please return your completed submission to medtech@nice.org.uk

If you haven't already, please register as a stakeholder by completing the [stakeholder registration form](#) and returning it to medtech@nice.org.uk

Did you know NICE meetings are held in public? You can [register on the NICE website](#) to attend a meeting up to 20 working days before it takes place. Registration will usually close 10 days before the meeting takes place.

HealthTech Programme

HTE10082 Technologies to support the rapid diagnosis of endometriosis (provisional title)

Patient organisation submission

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on patient experience of using the technology in the context of current clinical practice that is not typically available from the published literature.

To help you give your views, please use this questionnaire. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
- Your response should not be longer than 10 pages.

Information about your organisation

Organisation name	Hull and East Yorkshire Endometriosis Support CIO
Contact person's name	
Role or job title	Marketing, Communications & Events Planning Manager
Email	
Telephone	

Brief description of the organisation, such as:

- Who funds it?
- How many members does it have?
- What region your organisation represents

The organisation is funded by fundraising efforts from our service users as well as grants made by funders and private organisations. It currently has over 2,000 members, most of whom are in the Hull and East Yorkshire area. However, the organisation does support people with Endometriosis from elsewhere in the UK as well as several members from other countries. The organisation is primarily run via an online support group through social media, with other platforms used such as Instagram and TikTok, as well as in person meetings at a support clinic ran locally.

Declarations

Do you have any conflicts of interest? Please let us know if you have a question on the [NICE policy on declaring and managing interests](#).

Our scientific advisor is Dr Barbara Guinn, who has developed EndoTect, currently awaiting NICE trials

How did you gather information about the experiences of patients and carers to include in your submission?

We ask for service users to give their experiences of Endometriosis and confirm that they are happy for us to use this in any reports that we are involved in

Are you willing for this submission to be shared on our website?

Yes X No

We may invite you to a scoping meeting and/or committee meeting where this technology is to be discussed. Would a member of your organisation be willing to join such a meeting (this may be in person or virtually)?

Yes X No

Does the organisation have any direct or indirect links with, or funding from, the tobacco industry?

Yes No X

Impact of the symptoms and condition on patients and on family and carers

1. What is it like to live with the condition?

Living with endometriosis can be profoundly debilitating and life-limiting. It affects every aspect of daily life, not just during flare-ups but often continuously, leaving many people struggling to function at a level they once could.

Physically, the pain and fatigue associated with endometriosis can be severe and overwhelming. Symptoms can interfere with basic mobility, sleep, and the ability to carry out everyday tasks, with pain often persisting despite treatment. Flare-ups can be unpredictable, making it difficult to plan or maintain any sense of normal routine.

The impact on mental health is significant. Living with constant pain, uncertainty, and the ongoing need to manage symptoms can lead to anxiety, depression, emotional exhaustion, and feelings of isolation. The cumulative effect of not being believed or adequately supported can further worsen psychological wellbeing.

Endometriosis also has a substantial impact on work and education. Pain, fatigue, and frequent medical appointments can make it extremely difficult to sustain consistent attendance or performance. Many people are forced to reduce their hours, change roles, or stop working altogether, leading to financial strain and long-term consequences for career progression.

Day-to-day activities and relationships are often heavily affected. Tasks such as household chores, exercise, socialising, and maintaining relationships can become exhausting or impossible. Plans are frequently cancelled at short notice, and individuals may feel they must constantly push through pain or conceal their symptoms in order to cope.

Overall, living with endometriosis means managing a condition that is physically, mentally, and socially debilitating, with a profound and ongoing impact on quality of life.

Experiences and availability of current health technologies

2. How do the existing diagnostic tests play a role in managing the condition, and what are their advantages and disadvantages? What new technologies do you know of that you could tell NICE about?

Whilst we have had none of our service users come forward to state that they have had experiences with an existing diagnostic test, the advantages to using diagnostic tests would prove substantially beneficial to sufferers who already face an average diagnostic time of over 8 years. Disadvantages would be not reliably showing where the endometriosis cells are growing and the impact of that on the sufferer who can experience other issues linked to endometriosis, such as infertility

About the health technology being assessed

3. NICE are looking to review minimally invasive technologies to support rapid diagnosis of endometriosis, such as saliva or blood sampling to effectively diagnose endometriosis. What are the potential benefits of the health technology/technologies being assessed?

A key benefit is earlier and faster diagnosis, addressing the well-documented delays that many individuals experience before receiving a diagnosis. Earlier identification can enable timely access to appropriate treatment and support, potentially reducing symptom progression and long-term impact.

These technologies may also reduce reliance on invasive diagnostic procedures, such as laparoscopy, thereby minimising surgical risks, recovery time, and associated physical and psychological burden for patients.

Non-invasive sampling methods are generally more acceptable to patients and can be delivered in primary or outpatient care settings, improving accessibility and patient experience.

From a system perspective, minimally invasive diagnostics have the potential to improve efficiency by reducing repeated investigations and demand on surgical services, with associated cost savings.

Overall, these technologies offer the opportunity to deliver earlier, safer, and more patient-centred diagnosis of endometriosis, with benefits for both individuals and the healthcare system.

4. What are the potential disadvantages of these types of health technologies being considered for assessment?

Disadvantages that we would be concerned about would be a postcode lottery on a test that would be in high demand and, potentially, not readily available for all patients.

There would be some concerns as to the pathway for the patients; would these new technologies be the only diagnostic tool and reduce diagnostic time, or simply add to that diagnostic time by adding another required test to the procedure

Will patients presenting with symptoms of endometriosis to be offered a test at primary care level? Or would they require further imaging tests first?

Will there be delays in diagnosis when it comes to BSGE centre criteria? How would a consultant at a BSGE centre know if the patient is a good candidate? If reliance is still on MRI imaging and Ultrasounds, is the diagnostic time going to be sufficiently reduced?

Equality issues

5. Are there any groups of people who might benefit more or less from the technology than others?

People who may benefit more from the technology would include people who do not have the means to pay for private medical treatments and who would, therefore, be subject to the current NHS waiting lists

People who may benefit from these tests may include patients who have not heard of endometriosis before and/or may not suspect that they have it

6. Are there any groups of people that might need further consideration in using the technologies (for example, because they have higher levels of ill health, poorer outcomes, problems accessing or using treatments or procedures)?

We would like to highlight the patients with endometriosis who also have co-morbidities such as adenomyosis, PCOS, fibromyalgia. There are also autoimmune diseases such as lupus and MS, gastrointestinal issues such as IBS and IBD, infertility, and certain cancers such as ovarian. Some patients may present with other symptoms first with endometriosis as a secondary issue.

7. Are there any potential [equality](#) or [health inequality](#) issues that should be taken into account when considering this condition and the technology?

The BAME and LGBTQ+ communities are statistically more likely to suffer from health inequality and should be considered when testing this technology

Additional information

8. Please include any additional information you believe would be helpful in assessing the value of the technologies.

We would strongly recommend that listening to the patient and community voices regarding primary care experiences. These should be taken into consideration when determining the advantages to new tests

Key messages

In up to 5 bullet points, please summarise the key messages of your submission.

- Clarification on the pathway of a patient and the test
- An early diagnostic test would prove substantially beneficial for patients with endometriosis, if used correctly with the view of reducing diagnostic times
- Pathway of patients who require BSGE centre medical care to be clarified
- Pathway for patients who present with secondary symptoms of endometriosis
- Clear eligibility if required

Thank you for your time. Please return your completed submission to medtech@nice.org.uk

If you haven't already, please register as a stakeholder by completing the [stakeholder registration form](#) and returning it to medtech@nice.org.uk

Did you know NICE meetings are held in public? You can [register on the NICE website](#) to attend a meeting up to 20 working days before it takes place. Registration will usually close 10 days before the meeting takes place.

Health Tech Programme
Diagnostic Technologies Advisory Committee (DAC)
Technologies for the rapid diagnosis of endometriosis
10 June 2026

This document contains the Patient Expert Questionnaires submitted by all individuals who have been appointed to the role of professional expert for this evaluation.

View results

Respondent

5 Anonymous

179:07

Time to complete

This questionnaire is only to be completed and submitted by Health and care practitioners

This questionnaire should be completed by those whose role is, or is directly related to, one of the specialisms below. For each assessment, we engage with professionals with expertise relevant to the topic under evaluation. By completing this questionnaire, you acknowledge and consent to being considered for the role of professional expert on this assessment.

Please indicate which option best describes your area of expertise. If there is no option which you feel relates to your role, please select 'Other' and let us know your role and why you think we should include your knowledge and expertise on the assessment.

For expressions of interest and/or to share your lived experience please email pjp@nice.org.uk

Note:

Please ensure all necessary edits or amendments are completed on your questionnaire before the portal close date. A final submission pull will be conducted after closure, and the portal will then be locked. Any changes made after the closing date will not be included in the final submission.

<https://techcommunity.microsoft.com/blog/microsoftformsblog/you-can-now-save-and-edit-your-survey-responses/3865033>

1. Please indicate which option best describes your area of expertise by selecting an option below. If your role is not listed but you feel it ought to be included, please select 'Other' and let us know your role and why you think we should include your knowledge and expertise on the assessment if not already listed.

- Consultant Gynaecologist with special interest in endometriosis
- Doctor of Obstetrics and Gynaecology
- Reproductive endocrinologists
- Endometriosis surgeon including advanced laparoscopic surgeon and consultant in endometriosis and minimal access surgery, thoracic surgeon specialised in minimally invasive surgery (VATS)
- GP with extended role in Women's Health / special interest in endometriosis
- Clinical nurse specialist in endometriosis, including advanced endometriosis practitioner
- Clinical psychologist, specialising in gynaecology / pelvic pain
- Radiologists specialised in endometriosis including Gynaecological radiologist and female pelvic imaging radiologist.
- Consultant in Anaesthesia and Pain Management with special interest in endometriosis / women's health / pelvic pain management.
- Physiotherapist, specialising in women's health, including pelvic floor physiotherapist.
- Other

2. Topic Title

HTE10082 Technologies to support the rapid diagnosis of endometriosis

3. Name: *

Deepthi Lavu

4. Job title *

Academic GP

5. Organisation

University of Exeter, RCGP

6. Professional organisation or society membership/affiliation

Royal College of General Practitioners ; Royal College of Obstetricians and

Gynaecologists

7. Nominated/ratified by (if applicable)

RCGP (Royal College of General Practitioners)

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC - 7052436

Consent to publish response

How NICE will use this information: The information that you provide on this form may be used to develop guidance on this topic.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Where relevant your name, job title, organisation and your responses, along with your declared interests may be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

Please note: if consent is not given, you will not be eligible for the role of professional expert on this assessment.

For more information about how we process your data please see our privacy notice.

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below: *

- Yes, I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above.
- No, I do not give my consent for the information in this questionnaire to be used and it may not be published on the NICE website as outlined above.
- Other

11. If you do not consent to us publishing your response, please explain why below:

No answer provided.

Contact confirmation

Please indicate if you would like to opt in to NICE contacting you regarding other technologies/treatments in the future for your advice, or if you would only like to be contacted regarding this specific technology:

12. Please select what NICE may contact you about: *

- NICE can use my details to contact me for advice on this and future assessments.
- NICE can use my details to contact me for advice on this topic only, but not for others.

13. Please select what the External Assessment Group (EAG) for the assessment may contact you about:(The EAG is an independent academic group who assess clinical and economic evidence and produce a report which is presented to the committee) *

- The EAG on this assessment can contact me for further information and advice on this assessment.
- The EAG on this assessment cannot contact me for further information and advice.

14. Date *

20/12/2025



Experience

Please answer the following questions as fully as possible to provide further information about the procedure/technologies and/or your experience

15. Please describe your level of experience with the procedure/technologies, for example:

- Are you familiar with the procedure or technologies which currently support diagnosis of endometriosis?
- Do you have any experience of : Endotest, DotEndo and Endosure?
- Please indicate your experience with these technologies, including how widely these are used within the NHS or private sector? If known, please describe the settings they are used in (primary / secondary) or who they are used by (clinicians in other specialities)
- Please highlight any other technologies you are aware of which propose to support rapid diagnosis of endometriosis for consideration in this assessment

- I am an academic GP. In clinical practice I assess and diagnose / refer people with suspected or confirmed endometriosis as appropriate. I am familiar with the risks and benefits of using procedures like ultrasound, MRI and laparoscopy for this condition.

- In addition to my current clinical practice, I trained in Obstetrics and Gynaecology in the past (am a member of the RCOG having passed membership exams). I have the experience of having assessed women with symptoms, recommended testing and carried out laparoscopies for these women in secondary care.

-Both the above give a brief overview of my experience in the clinical front in primary and secondary care. My dual experience has given me a good understanding of both sides of offering care to women with symptoms of endometriosis.

- In addition to the above, I have undertaken research in women's health - esp. endometriosis.

1. We have a paper currently under review in the Lancet on endometriosis prevalence and diagnosis.

2. My previous research was on the *diagnostic accuracy of USS and MRI* on deep pelvic endometriosis:

a. Early Learning Curve in the Assessment of Deep Pelvic Endometriosis for Ultrasound and Magnetic Resonance Imaging DOI: 10.1155/2020/8757281

b. Application of International Deep Endometriosis Analysis (IDEA) group consensus in preoperative ultrasound and magnetic resonance imaging of deep pelvic endometriosis

DOI: 10.1002/uog.21960

c. Diagnostic Accuracy of Ultrasound and MRI in the Mapping of Deep Pelvic Endometriosis Using the International Deep Endometriosis Analysis (IDEA) Consensus DOI: 10.1155/2020/3583989

3. More recent work is around menstruation and mental health. As is known, endometriosis can have negative impact on mental health:

a. Intersection of menstrual and menopausal health with mental health: implications for general practice DOI: 10.3399/bjgp24X739149

b. ReproWell Exploring feasibility and acceptability of digital methods for collecting intensive data relevant to female reproductive and mental health. (Grant)

- Despite my experience mentioned above and the research work on diagnostic accuracy of endometriosis using some techniques, I do not have any experience of using the technology mentioned : Endotest, DotEndo and Endosure

- I am also not aware of any other technologies that propose to support rapid diagnosis of endometriosis.

16. Please indicate your research experience relating to this procedure or technology (please choose one or more if relevant): (Please highlight your choice(s))

- I have done bibliographic research on this procedure or technology
- I have done research on this procedure or technology in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure or technology involving patients or healthy volunteers.
- I have published this research.
- I have had no involvement in research on this procedure or technology.
- I have not done research on the rapid diagnosis technologies but have done research on USS and MRI techniques for the diagnosis of endometriosis

Current management

17. Please describe the current standard of care that is used in the NHS to diagnose endometriosis. Please note any clinical guidelines used routinely in the NHS which are relevant to the care pathway

Primary care assessment in step wise manner:
-History taking, examination and next steps based on these.
-Transvaginal ultrasound preferable (if not able to then transabdominal)
-If positive findings on the above - refer to gynaecology to treatments / help with management.
-If negative findings but clinical suspicion - refer to gyn.
-Ca 125 - might give an indication of underlying endometriosis but it is not a recommended test.
-MRI can be ordered in primary care but as results once back will need to be actioned from primary care + no expertise in interpretation - unlikely that GPs will consider ordering MRIs in primary care (although some might).

In secondary care
- MRI for mapping and planning treatment for endometriosis
- Diagnostic laparoscopy is considered gold standard
-Next stage laparoscopic surgery for treatment can be planned if significant findings in initial diagnostic laparoscopy.

Guidance routinely used:
<https://www.nice.org.uk/guidance/ng73/chapter/recommendations>
<https://cks.nice.org.uk/topics/endometriosis/>
<https://www.eshre.eu/Guidelines-and-Legal/Guidelines/Endometriosis-guideline.aspx>

18. Where would the technologies be most appropriate in the care pathway? Consider where they would be most value to the system. Please include what setting this would involve (primary care, general hospitals, specialist centres, women's health hubs).

It is important for this point to be noted when considering the care pathways: The average diagnostic interval between first recorded symptom and diagnosis of endometriosis is 4-4 years (finding from our paper under review in the Lancet - Massen et al. Temporal trends in endometriosis incidence and prevalence and symptom burden in England 2010-2020: A population-based cohort study).

1. Most appropriate setting for the technology would be in the primary care setting - Young women attended with complaints of suspected endometriosis. Ultrasound scans might not show anything and leave women unsure of next steps. Rapid diagnosis (accuracy is important) helps reassure women or refer as appropriate. This would decrease multiple attendances with complaints linked to uncertain diagnosis. This also reduces pressure for ultrasound scans and frees up spaces for using this in other conditions as diagnosis is not operator dependent (rapid tests which are less subjective will be good to have) This would also allow prioritising referrals to secondary care. Current referrals for diagnosis to secondary care are close to 2 years in waiting.
2. In women's health hubs - if people attend for problems related to suspected endometriosis, it will be useful as referrals won't need to include ultrasound scans, referral back to GPs and add to long diagnostic wait times at hospitals.
3. These will be useful in neighbourhood centres when they start coming into action. Quicker diagnosis and more tailored treatments.
4. It is possible that in secondary care - those patients with diagnostic uncertainty and/or needing confirmatory and/or requiring treatment will be sent. In this setting rapid diagnosis might be useful in acute abdominal pain attendances where pain is poorly controlled and other acute cases are ruled out, possibly in A&E settings or on gynaecology wards when looking at alternative causes for pelvic pain. Use in primary care and tailoring referrals from there might ease diagnostic burden on secondary care (giving the opportunity to catch up with waiting lists) and move quicker to treatment linked procedures.

In short - likely used most in primary care. This will have a positive impact on secondary care demands. Bringing value to the whole system.

19. Do these technologies have the potential to replace current standard care, or would it be used as an addition to existing standard care?

In primary care, alongside history taking, clinical examination, in place of / alongside ultrasound imaging? In secondary care, used prior to repeat imaging or laparoscopy?

In primary care, it will be used alongside history taking, clinical examination.

It is likely to replace ultrasound imaging as first line with ultrasound reserved for ones with diagnostic uncertainty especially if endometriosis is the main clinical condition suspected.

In secondary care, it might be used in the wards (like point of care tests) in adjunct with ultrasounds for acute attendances.

This could be used instead of ultrasounds in outpatient clinic settings where MRI could be planned as next step or even surgery.

Depending on accuracy and test, it could be used after treating endometriosis (laparoscopy) to consider re surgery or a wait and watch approach to symptom resurgence.

20. Approximately how many people each year would be eligible for an intervention with these technologies. Please (give either as an estimated number, or a proportion of the target population) *Please state this in the context of the point in the pathway you feel it is best positioned.*

Context of primary care (findings from our paper in review in the Lancet Massen et al. Temporal trends in endometriosis incidence and prevalence and symptom burden in England 2010-2020: A population-based cohort study.):

The incidence and prevalence of endometriosis has increased considerably between 2010 and 2020.

The incidence of endometriosis is 1.86 per 1,000 person-years in 2019.

The estimated prevalence of endometriosis was 2.50%

Potential patient benefits and impact on the health system

21. What do you consider to be the potential benefits to patients from using these technologies?

Are there any groups of patients who would particularly benefit from these technologies?

Are there any groups in which these technologies would be less effective or would be less likely to benefit?

Are there any potential equality issues that should be considered when assessing technologies for this condition?

Benefits to patients:

1. Time to diagnosis : Less time to diagnosis - less psychological distress associated with uncertainty
2. If used in primary care - would not need to wait for secondary care appointments (given long waiting lists) for a diagnosis
3. Timely treatments: Treatments can be discussed in line with diagnosis or referrals expedited as appropriate
4. Improved quality of life linked to less uncertainty and distress, potentially correct and quicker treatments tailored to findings.
5. Improved trust in the healthcare system - as often when people are not diagnosed or awaiting a diagnosis they feel unheard or not believed.

Groups that will benefit:

1. Endometriosis affects women in their working years of life and so working women might see the most benefit from quicker, less invasive testing that can be carried out in primary care.
2. Women from ethnic minorities who might have cultural beliefs and fears linked to hospital procedures will benefit
3. Women from deprived backgrounds who are more likely to be diagnosed with chronic pains and functional problems - benefit from a test of this nature
4. Women who are not sexually active and/or those with concerns around transvaginal ultrasound scans
5. Trans men - as diagnosis will not involve intimate procedures.

Groups less likely to benefit:

1. Depending on the accuracy of the test - ones where there is diagnostic uncertainty or those with mild endometriosis which might not be picked up on testing
2. Women who might be less likely to be referred despite genuine symptoms based on the test result - if negative
3. Those who might have medical conditions which interfere with the reliability of the test result (am not sure of that these conditions might be as I am not fully aware of the functioning of these tests and cross reactivity etc).
4. Women with adenomyosis (if this gets picked up by the test too) and this can mean laparoscopy for those who might not benefit from it (will need thought on such conditions which can mimic endometriosis and whether they give a positive or negative result for those tests.

Equality issues:

1. Might be more acceptable by Trans men
2. Funding discrepancies in different regions and referral processes that get based on the presence or absence of these tests.
3. Affordability of the tests in all practices
4. If they are based only in Womens health hubs it might not be accessible by all or helpful in primary care
5. Working women, women with caring responsibilities, people from ethnic minorities are less likely to accept surgical interventions / laparoscopy for diagnosis and if such tests are not available might choose to live in uncertainty and possibly experience poorer quality of life as a result of pain etc. This might be different if a rapid test diagnosis suggested possible endometriosis , in which case they might choose to proceed with surgical treatments

22. What do you consider to be the potential benefits to the system from using these technologies? Could it lead, for example, to a reduced number of appointments, reduced investigations, improved care pathway, more efficient NHS staff time use?

Primary care

1. Reduce consultations (mean 9-15 consultations before diagnosis in the 5 yrs leading to diagnosis. From our paper under review : Massen et al. Temporal trends in endometriosis incidence and prevalence and symptom burden in England 2010-2020: A population-based cohort study)
2. Reduced investigations - might not need ultrasound scan if positive
3. Reduced time to referral for treatments
4. Less diagnostic uncertainty for the clinician and can tailor treatments accordingly
5. Staff time can be used in other areas of care
6. More trust in healthcare systems - esp around womens health - as currently womens health negative perceptions associated with testing available and delays in diagnosis and treatments
7. Reduced admin burden linked to lower consultations
8. Quicker diagnosis leading to reduced treatments that might not work
9. Targeted therapies and low waste of tests and pharmacy products
10. Lower waiting times for patients / better flow of care
11. Is it cheaper than an ultrasound scan?
12. Lower carbon foot print possible - including scan wastage, travel to and from, reduced consultations, quicker diagnosis and targeted treatments
13. Improved understanding of diagnosis might reduce A&E attendances

Secondary care

1. Less diagnostic uncertainty at the time of receiving the referral
2. Treatment options might be started prior to offering laparoscopy if appropriate.
3. Care pathway might mean direct referral for MRI by primary care teams for positive results - and referral from there to secondary care teams. This can mean better work flow and secondary care seeing patients who need to be seen
4. Lower waiting lists linked to diagnosis - some areas it is currently 2 years
5. More targeted care for those admitted with pain on the acute wards and/or diagnosis at the point of discharge - reducing need for laparoscopy for diagnosis
6. Less admin and staff time for working on waiting lists and procedures for just diagnosis. Can plan direct treatment linked procedures if diagnostic lapa can be reduced in some cases.

23. What (if any) clinical facilities (or changes to existing facilities) are needed to implement this technology safely? What are the potential implementation challenges of these types of technologies in the pathway?

Might need to stock the items.

Training for use of tests is needed.

No other changes to clinical facilities is anticipated (unsure of storage - fridge space etc).

Unsure of reporting / disposal processes linked to the tests and whether this will need any adaptation of clinical facilities.

24. Is any specific training needed in order to use these technologies with respect to efficacy or safety? Who would this training be required for?

Standard training needed with any new test in care - how to correctly carry out the test, how to interpret the result and safety precautions when carrying out the test for the patient and the professional.

It is likely a test that can be administered by HCAs, nurses or doctors if trained.

Safety and efficacy of the procedure/technologies

25. What are the potential harms of the technologies? Please list any adverse events and potential risks you might consider with these technologies use (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Please list any uncertainties or concerns about the efficacy and safety of these technologies?

1. Reliability of the test
2. Accuracy of the test
3. Missing true endometriosis and further delays in diagnosis
4. False positives of the test and unnecessary interventions
5. Injury to patient or practitioner - linked to needles and equipment
6. Expired tests and/or storage linked problems
7. Any materials or chemicals in the test that might cause adverse reactions for the person handling them

26. Please list efficacy and safety outcomes that are key to be captured for these technologies. Please suggest the most appropriate method of measurement for these outcomes and timescales (where appropriate) and highlight any challenges to capturing these.

1. Reliability in diagnosis
2. Diagnostic accuracy - missed diagnosis, diagnostic delays.
3. Unintended consequences of testing errors
4. Ease of use

27. Are you aware of any additional issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS? This could include costs, resource, staffing for example.

1. Cost
2. Low reliability or poor accuracy leading to more uncertainty in the care pathway
3. Time taken for result and accurate recording of results
4. Transporting samples (if different to correct techniques)
5. Issues that might arise from unequivocal tests, repeat testing and difference in results - consultations linked to this.

28. Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of which may be appropriate for consideration in this assessment.

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email:

samantha.baskerville@nice.org.uk

1. Massen et al. Temporal trends in endometriosis incidence and prevalence and symptom burden in England 2010-2020: A population-based cohort study. Currently under review - submitted to the Lancet

29. Is there any research that you feel would be needed to address uncertainties you are aware of in the evidence base?

-

Further Comments

30. Please add any further comments on your particular experiences or knowledge of the potential technologies for this assessment.

-

View results

Respondent

3 Anonymous

17:08

Time to complete

This questionnaire is only to be completed and submitted by Health and care practitioners

This questionnaire should be completed by those whose role is, or is directly related to, one of the specialisms below. For each assessment, we engage with professionals with expertise relevant to the topic under evaluation. By completing this questionnaire, you acknowledge and consent to being considered for the role of professional expert on this assessment.

Please indicate which option best describes your area of expertise. If there is no option which you feel relates to your role, please select 'Other' and let us know your role and why you think we should include your knowledge and expertise on the assessment.

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<https://techcommunity.microsoft.com/blog/microsoftformsblog/you-can-now-save-and-edit-your-survey-responses/3865033>

1. Please indicate which option best describes your area of expertise by selecting an option below. If your role is not listed but you feel it ought to be included, please select 'Other' and let us know your role and why you think we should include your knowledge and expertise on the assessment if not already listed.

- Consultant Gynaecologist with special interest in endometriosis
- Doctor of Obstetrics and Gynaecology
- Reproductive endocrinologists
- Endometriosis surgeon including advanced laparoscopic surgeon and consultant in endometriosis and minimal access surgery, thoracic surgeon specialised in minimally invasive surgery (VATS)
- GP with extended role in Women's Health / special interest in endometriosis
- Clinical nurse specialist in endometriosis, including advanced endometriosis practitioner
- Clinical psychologist, specialising in gynaecology / pelvic pain
- Radiologists specialised in endometriosis including Gynaecological radiologist and female pelvic imaging radiologist.
- Consultant in Anaesthesia and Pain Management with special interest in endometriosis / women's health / pelvic pain management.
- Physiotherapist, specialising in women's health, including pelvic floor physiotherapist.
- Other

2. Topic Title

HTE10082 Endometriosis

3. Name: *

Donna Ghosh

4. Job title *

Consultant Gynaecologist and Endometriosis specialist laparoscopic and robotic

surgeon

5. Organisation

Worcestershire Acute Hospitals

6. Professional organisation or society membership/affiliation

BSGE- Honorary Secretary

7. Nominated/ratified by (if applicable)

BSGE

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC 6143036

Consent to publish response

How NICE will use this information: The information that you provide on this form may be used to develop guidance on this topic.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Where relevant your name, job title, organisation and your responses, along with your declared interests may be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

Please note: if consent is not given, you will not be eligible for the role of professional expert on this assessment.

For more information about how we process your data please see our privacy notice.

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below: *

- Yes, I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above.
- No, I do not give my consent for the information in this questionnaire to be used and it may not be published on the NICE website as outlined above.
- Other

11. If you do not consent to us publishing your response, please explain why below:

No answer provided.

Contact confirmation

Please indicate if you would like to opt in to NICE contacting you regarding other technologies/treatments in the future for your advice, or if you would only like to be contacted regarding this specific technology:

12. Please select what NICE may contact you about: *

- NICE can use my details to contact me for advice on this and future assessments.
- NICE can use my details to contact me for advice on this topic only, but not for others.

13. Please select what the External Assessment Group (EAG) for the assessment may contact you about:(The EAG is an independent academic group who assess clinical and economic evidence and produce a report which is presented to the committee) *

- The EAG on this assessment can contact me for further information and advice on this assessment.
- The EAG on this assessment cannot contact me for further information and advice.

14. Date *

16/12/2025



Experience

Please answer the following questions as fully as possible to provide further information about the procedure/technologies and/or your experience

15. Please describe your level of experience with the procedure/technologies, for example:

- Are you familiar with the procedure or technologies which currently support diagnosis of endometriosis?
- Do you have any experience of : Endotest, DotEndo and Endosure?
- Please indicate your experience with these technologies, including how widely these are used within the NHS or private sector? If known, please describe the settings they are used in (primary / secondary) or who they are used by (clinicians in other specialities)
- Please highlight any other technologies you are aware of which propose to support rapid diagnosis of endometriosis for consideration in this assessment

Principle investigator - Study into the accuracy of a new non-invasive device (Endosure test, EndoSure, Inc) for the diagnosis of endometriosis (ADDEND study)

16. Please indicate your research experience relating to this procedure or technology (please choose one or more if relevant): (Please highlight your choice(s))

- I have done bibliographic research on this procedure or technology
- I have done research on this procedure or technology in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure or technology involving patients or healthy volunteers.
- I have published this research.
- I have had no involvement in research on this procedure or technology.
- trial underway

Current management

17. Please describe the current standard of care that is used in the NHS to diagnose endometriosis. Please note any clinical guidelines used routinely in the NHS which are relevant to the care pathway

Clinical assessment + imaging (USS/ MRI) and proceed to laparoscopy and treatment

18. Where would the technologies be most appropriate in the care pathway? Consider where they would be most value to the system. Please include what setting this would involve (primary care, general hospitals, specialist centres, women's health hubs).

Specialist centres/ Women health hubs/ Gynecologists with interest in pain

19. Do these technologies have the potential to replace current standard care, or would it be used as an addition to existing standard care?

In primary care, alongside history taking, clinical examination, in place of / alongside ultrasound imaging? In secondary care, used prior to repeat imaging or laparoscopy?

replace- patients may feel diagnosis is sufficient and may continue with medical treatment. Exclude patients with no endometriosis with pelvic pain and avoid surgery. Consider as a tool for adolescents/ patients with recurrent symptoms

20. Approximately how many people each year would be eligible for an intervention with these technologies. Please (give either as an estimated number, or a proportion of the target population) *Please state this in the context of the point in the pathway you feel it is best positioned.*

if used as a screening possibly 1/10

Potential patient benefits and impact on the health system

21. What do you consider to be the potential benefits to patients from using these technologies?

Are there any groups of patients who would particularly benefit from these technologies?

Are there any groups in which these technologies would be less effective or would be less likely to benefit?

Are there any potential equality issues that should be considered when assessing technologies for this condition?

1) avoid surgery in less severe disease
2) avoid repeat surgery in patients who have undergone previous endometriosis treatment
3) help reduce diagnostic laparoscopy

22. What do you consider to be the potential benefits to the system from using these technologies? Could it lead, for example, to a reduced number of appointments, reduced investigations, improved care pathway, more efficient NHS staff time use?

reduce costly theatre time. reduce admissions

23. What (if any) clinical facilities (or changes to existing facilities) are needed to implement this technology safely? What are the potential implementation challenges of these types of technologies in the pathway?

appropriate trained technician (could be HCA), facility to perform test, appropriate triaging and pathway to direct suitable patients to the test to allow benefits described above

24. Is any specific training needed in order to use these technologies with respect to efficacy or safety? Who would this training be required for?

No - non invasive test

Safety and efficacy of the procedure/technologies

25. What are the potential harms of the technologies? Please list any adverse events and potential risks you might consider with these technologies use (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Please list any uncertainties or concerns about the efficacy and safety of these technologies?

risk of false positive

26. Please list efficacy and safety outcomes that are key to be captured for these technologies. Please suggest the most appropriate method of measurement for these outcomes and timescales (where appropriate) and highlight any challenges to capturing these.

na

27. Are you aware of any additional issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS? This could include costs, resource, staffing for example.

cost of test would need to be evaluated against the potential cost of referral (capacity of secondary care) and treatment (surgery)

28. Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of which may be appropriate for consideration in this assessment.

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email:

samantha.baskerville@nice.org.uk

please do

29. Is there any research that you feel would be needed to address uncertainties you are aware of in the evidence base?

3. Nisenblat V, Prentice L, Bossuyt PMM, Farquhar C, Hull ML, Johnson N. Combination of the non-invasive tests for the diagnosis of endometriosis. Cochrane Database of Systematic Reviews 2016, Issue 7. Art. No.: CD012281. DOI: 10.1002/14651858.CD012281.
7. <https://www.endosure.com/>
8. Mathias JR, Franklin R, Quast DC, Fraga N, Loftin CA, Yates L, Harrison V. Relation of endometriosis and neuromuscular disease of the gastrointestinal tract: new insights. *Fertil Steril.* 1998 Jul;70(1):81-8.
9. Noar M. AI-derived threshold score of intraabdominal myoelectrical activity predicts presence and stage of endometriosis with 100% accuracy. *J Minim Invasive Gynecol.* 2022 Nov;29(11):S4-S5. DOI:<https://doi.org/10.1016/j.jmig.2022.09.026>.

Further Comments

30. Please add any further comments on your particular experiences or knowledge of the potential technologies for this assessment.

none

View results

Respondent

11 Anonymous

14:36

Time to complete

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- Consultant in Anaesthesia and Pain Management with special interest in endometriosis / women's health / pelvic pain management.
- Physiotherapist, specialising in women's health, including pelvic floor physiotherapist.
- Other

2. Topic Title

Technologies to support the rapid diagnosis of endometriosis

3. Name: *

Elisabeth Bean

4. Job title *

Consultant Gynaecologist

5. Organisation

Barking, Havering and Redbridge University Hospitals NHS Trust

6. Professional organisation or society membership/affiliation

GMC

7. Nominated/ratified by (if applicable)

BSGE

8. Registration number (e.g. GMC, NMC, HCPC) *

7090013

Consent to publish response

How NICE will use this information: The information that you provide on this form may be used to develop guidance on this topic.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Where relevant your name, job title, organisation and your responses, along with your declared interests may be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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- Other

11. If you do not consent to us publishing your response, please explain why below:

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Contact confirmation

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12. Please select what NICE may contact you about: *

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13. Please select what the External Assessment Group (EAG) for the assessment may contact you about:(The EAG is an independent academic group who assess clinical and economic evidence and produce a report which is presented to the committee) *

- The EAG on this assessment can contact me for further information and advice on this assessment.
- The EAG on this assessment cannot contact me for further information and advice.

14. Date *

05/01/2026



Experience

Please answer the following questions as fully as possible to provide further information about the procedure/technologies and/or your experience

15. Please describe your level of experience with the procedure/technologies, for example:

- Are you familiar with the procedure or technologies which currently support diagnosis of endometriosis?
- Do you have any experience of : Endotest, DotEndo and Endosure?
- Please indicate your experience with these technologies, including how widely these are used within the NHS or private sector? If known, please describe the settings they are used in (primary / secondary) or who they are used by (clinicians in other specialities)
- Please highlight any other technologies you are aware of which propose to support rapid diagnosis of endometriosis for consideration in this assessment

I have experience in advanced ultrasound for the diagnosis and mapping of endometriosis
I have published research on ultrasound diagnosis of endometriosis
I do not have any personal experience with Endotest, DotEndo or Endosure.
I have had discussions with the Endosure team about trialling the device in a clinic setting.
I am not aware that these technologies are funded, endorsed or used at all within NHS settings at present.

16. Please indicate your research experience relating to this procedure or technology (please choose one or more if relevant): (Please highlight your choice(s))

- I have done bibliographic research on this procedure or technology
- I have done research on this procedure or technology in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure or technology involving patients or healthy volunteers.
- I have published this research.
- I have had no involvement in research on this procedure or technology.
- Other

Current management

17. Please describe the current standard of care that is used in the NHS to diagnose endometriosis. Please note any clinical guidelines used routinely in the NHS which are relevant to the care pathway

Current standard of care = advanced ultrasound +/- MRI +/- laparoscopy (as per NICE guidance)

18. Where would the technologies be most appropriate in the care pathway? Consider where they would be most value to the system. Please include what setting this would involve (primary care, general hospitals, specialist centres, women's health hubs).

They could be utilised as a screening tool to direct patients to earlier and more appropriate clinical care pathways. They could be used by primary care, general hospitals and women's health hubs to triage patients to appropriate investigations and services

19. Do these technologies have the potential to replace current standard care, or would it be used as an addition to existing standard care?

In primary care, alongside history taking, clinical examination, in place of / alongside ultrasound imaging? In secondary care, used prior to repeat imaging or laparoscopy?

these tools could not replace advanced USS/MRI/laparoscopy as they do not map disease severity and location

20. Approximately how many people each year would be eligible for an intervention with these technologies. Please (give either as an estimated number, or a proportion of the target population) *Please state this in the context of the point in the pathway you feel it is best positioned.*

20% of women attending a gynaecology clinic have endometriosis, 1 in 10 women of reproductive age have endometriosis. Those with a suspected diagnosis might be eligible and therefore I estimate approximately 5-10% of all new gynaecology referrals in the UK are due to suspected endometriosis

Potential patient benefits and impact on the health system

21. What do you consider to be the potential benefits to patients from using these technologies?

Are there any groups of patients who would particularly benefit from these technologies?

Are there any groups in which these technologies would be less effective or would be less likely to benefit?

Are there any potential equality issues that should be considered when assessing technologies for this condition?

Earlier diagnosis and triage to specialist services (as requested by patients in the NCEPOD report)
Not sufficiently effective in diagnosing severity and location of disease

22. What do you consider to be the potential benefits to the system from using these technologies? Could it lead, for example, to a reduced number of appointments, reduced investigations, improved care pathway, more efficient NHS staff time use?

Improved care pathway and more efficient use of current resources. Reduced number of diagnostic laparoscopies and resulting effect on NHS Gynae elective waiting lists.

23. What (if any) clinical facilities (or changes to existing facilities) are needed to implement this technology safely? What are the potential implementation challenges of these types of technologies in the pathway?

This will be dependent on the test itself. My understanding is that Endosure is quite time consuming to perform and requires a clinical space for equipment set up. microRNA screening is quicker, does not require specialist facilities and can be easily integrated into an outpatient screening setting.

24. Is any specific training needed in order to use these technologies with respect to efficacy or safety? Who would this training be required for?

Yes. this would require training for implementation, analysis of results, explanation of results and planning patient care once the results are known.

Safety and efficacy of the procedure/technologies

25. What are the potential harms of the technologies? Please list any adverse events and potential risks you might consider with these technologies use (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Please list any uncertainties or concerns about the efficacy and safety of these technologies?

No known adverse results that I am aware of.

26. Please list efficacy and safety outcomes that are key to be captured for these technologies. Please suggest the most appropriate method of measurement for these outcomes and timescales (where appropriate) and highlight any challenges to capturing these.

pt feedback
clinician feedback
evidence to demonstrate how implementation has an effect on patient pathway, costs to NHS and patient experience

27. Are you aware of any additional issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS? This could include costs, resource, staffing for example.

Cost of implementation and these tests do not negate the requirement for more advanced imaging if positive results

28. Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of which may be appropriate for consideration in this assessment.

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email:

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Tanos P, Donders F, Massaro A, Philippe S, Karamelas S. Defining the Role of the Gastrointestinal Myoelectrical Activity (GIMA) Biomarker in the Diagnosis of Endometriosis. *Journal of Minimally Invasive Gynecology*. 2025 Nov 1;32(11):S23.

Ferrier C, Bendifallah S, Suisse S, Dabi Y, Touboul C, Puchar A, Zarca K, Durand Zaleski I. Saliva microRNA signature to diagnose endometriosis: A cost-effectiveness evaluation of the Endotest®. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2023 Mar;130(4):396-406.

Rogalska A, Brukało K. Diagnostic Tools for Endometriosis in Poland: A Comparative Assessment of Reliability and Out-of-Pocket Costs. *Journal of Clinical Medicine*. 2025 Jul 11;14(14):4935.

29. Is there any research that you feel would be needed to address uncertainties you are aware of in the evidence base?

cost analysis and qualitative assessment of patient care with implementation of non-invasive test

Further Comments

30. Please add any further comments on your particular experiences or knowledge of the potential technologies for this assessment.

No answer provided.

View results

Respondent

1 Anonymous

20:22

Time to complete

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<https://techcommunity.microsoft.com/blog/microsoftformsblog/you-can-now-save-and-edit-your-survey-responses/3865033>

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- Consultant Gynaecologist with special interest in endometriosis
- Doctor of Obstetrics and Gynaecology
- Reproductive endocrinologists
- Endometriosis surgeon including advanced laparoscopic surgeon and consultant in endometriosis and minimal access surgery, thoracic surgeon specialised in minimally invasive surgery (VATS)
- GP with extended role in Women's Health / special interest in endometriosis
- Clinical nurse specialist in endometriosis, including advanced endometriosis practitioner
- Clinical psychologist, specialising in gynaecology / pelvic pain
- Radiologists specialised in endometriosis including Gynaecological radiologist and female pelvic imaging radiologist.
- Consultant in Anaesthesia and Pain Management with special interest in endometriosis / women's health / pelvic pain management.
- Physiotherapist, specialising in women's health, including pelvic floor physiotherapist.
- Other

2. Topic Title

HTE10082 Endometriosis

3. Name: *

Felicity watson

4. Job title *

Consultant gynaecologist

5. Organisation

NHS Greater Glasgow and Clyde

6. Professional organisation or society membership/affiliation

MRCOG GMC

7. Nominated/ratified by (if applicable)

No answer provided.

8. Registration number (e.g. GMC, NMC, HCPC) *

7036960

Consent to publish response

How NICE will use this information: The information that you provide on this form may be used to develop guidance on this topic.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Where relevant your name, job title, organisation and your responses, along with your declared interests may be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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For more information about how we process your data please see our privacy notice.

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below: *

- Yes, I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above.
- No, I do not give my consent for the information in this questionnaire to be used and it may not be published on the NICE website as outlined above.
- Other

11. If you do not consent to us publishing your response, please explain why below:

No answer provided.

Contact confirmation

Please indicate if you would like to opt in to NICE contacting you regarding other technologies/treatments in the future for your advice, or if you would only like to be contacted regarding this specific technology:

12. Please select what NICE may contact you about: *

- NICE can use my details to contact me for advice on this and future assessments.
- NICE can use my details to contact me for advice on this topic only, but not for others.

13. Please select what the External Assessment Group (EAG) for the assessment may contact you about:(The EAG is an independent academic group who assess clinical and economic evidence and produce a report which is presented to the committee) *

- The EAG on this assessment can contact me for further information and advice on this assessment.
- The EAG on this assessment cannot contact me for further information and advice.

14. Date *

03/12/2025



Experience

Please answer the following questions as fully as possible to provide further information about the procedure/technologies and/or your experience

15. Please describe your level of experience with the procedure/technologies, for example:

- Are you familiar with the procedure or technologies which currently support diagnosis of endometriosis?
- Do you have any experience of : Endotest, DotEndo and Endosure?
- Please indicate your experience with these technologies, including how widely these are used within the NHS or private sector? If known, please describe the settings they are used in (primary / secondary) or who they are used by (clinicians in other specialities
- Please highlight any other technologies you are aware of which propose to support rapid diagnosis of endometriosis for consideration in this assessment

Yes awareness and understanding of noninvasive testing for endometriosis, primarily Endosure in private sector.

Also aware of new testing of proteins within endometrial lining for endometriosis which may has higher negative predictive value.

16. Please indicate your research experience relating to this procedure or technology (please choose one or more if relevant): (Please highlight your choice(s))

- I have done bibliographic research on this procedure or technology
- I have done research on this procedure or technology in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure or technology involving patients or healthy volunteers.
- I have published this research.
- I have had no involvement in research on this procedure or technology.
- Other

Current management

17. Please describe the current standard of care that is used in the NHS to diagnose endometriosis. Please note any clinical guidelines used routinely in the NHS which are relevant to the care pathway

Primarily pelvic ultrasound and diagnostic laparoscopy, often with significant delays due to waiting list pressures

18. Where would the technologies be most appropriate in the care pathway? Consider where they would be most value to the system. Please include what setting this would involve (primary care, general hospitals, specialist centres, women's health hubs).

Triage of need for diagnostic laparoscopy where uncertain diagnosis. Reduce need for secondary care referral or laparoscopy allowing earlier diagnosis/commencing treatment including specific treatments licensed only for endometriosis ie ryeqo and dienogest

Also facilitating earlier referral to other specialities/ waiting list management for overstretched Gyn lists and earlier appropriate referral to Gyn avoiding delayed diagnosis and reducing unwarranted investigations

19. Do these technologies have the potential to replace current standard care, or would it be used as an addition to existing standard care?

In primary care, alongside history taking, clinical examination, in place of / alongside ultrasound imaging? In secondary care, used prior to repeat imaging or laparoscopy?

Yes. Reduce no of diagnostic lap, particularly negative laps which come at cost to NHS and potential risk to patient. Saving of £800 per patient vs diag lap and likely quicker diagnosis. Reduced scarring and less frequent surgical procedures.

Triage of referrals straight to correct team from primary care to specialist team.

20. Approximately how many people each year would be eligible for an intervention with these technologies. Please (give either as an estimated number, or a proportion of the target population) *Please state this in the context of the point in the pathway you feel it is best positioned.*

100% of women referred as possible endometriosis reducing need for diagnostic laparoscopy in around 80% of these women

Potential patient benefits and impact on the health system

21. What do you consider to be the potential benefits to patients from using these technologies?

Are there any groups of patients who would particularly benefit from these technologies?

Are there any groups in which these technologies would be less effective or would be less likely to benefit?

Are there any potential equality issues that should be considered when assessing technologies for this condition?

Reducing need for surgical intervention for diagnosis and reducing time to commencement of appropriate treatment. Reassurance for patient regarding diagnosis.

22. What do you consider to be the potential benefits to the system from using these technologies? Could it lead, for example, to a reduced number of appointments, reduced investigations, improved care pathway, more efficient NHS staff time use?

Cost savings and reduced risks to patients. Reduced time to diagnosis and reduced surgical risks

23. What (if any) clinical facilities (or changes to existing facilities) are needed to implement this technology safely? What are the potential implementation challenges of these types of technologies in the pathway?

Limited for set up. Likely easy to set up parallel to Gyn clinic or as a hub. Small investment to set up vs cost of diagnostic laparoscopy

24. Is any specific training needed in order to use these technologies with respect to efficacy or safety? Who would this training be required for?

Yes for practitioner administering test

Safety and efficacy of the procedure/technologies

25. What are the potential harms of the technologies? Please list any adverse events and potential risks you might consider with these technologies use (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Please list any uncertainties or concerns about the efficacy and safety of these technologies?

Small false positive rate will result in over investigation for some.

26. Please list efficacy and safety outcomes that are key to be captured for these technologies. Please suggest the most appropriate method of measurement for these outcomes and timescales (where appropriate) and highlight any challenges to capturing these.

Relatively poor specificity

27. Are you aware of any additional issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS? This could include costs, resource, staffing for example.

No. Great alternative to lap in secondary care. Requires hub set up in primary care given specialist skills

28. Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of which may be appropriate for consideration in this assessment.

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email:

samantha.baskerville@nice.org.uk

No answer provided.

29. Is there any research that you feel would be needed to address uncertainties you are aware of in the evidence base?

No answer provided.

Further Comments

30. Please add any further comments on your particular experiences or knowledge of the potential technologies for this assessment.

No answer provided.

View results

Respondent

12 Anonymous

41:08

Time to complete

This questionnaire is only to be completed and submitted by Health and care practitioners

This questionnaire should be completed by those whose role is, or is directly related to, one of the specialisms below. For each assessment, we engage with professionals with expertise relevant to the topic under evaluation. By completing this questionnaire, you acknowledge and consent to being considered for the role of professional expert on this assessment.

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- Physiotherapist, specialising in women's health, including pelvic floor physiotherapist.
- Other

2. Topic Title

Endometriosis: diagnosis, long-term management and primary care pathways

3. Name: *

Irene Asamoah

4. Job title *

GP

5. Organisation

NHS/HCA International/Holiya

6. Professional organisation or society membership/affiliation

GMC, Primary Care Women's Health Society

7. Nominated/ratified by (if applicable)

No answer provided.

8. Registration number (e.g. GMC, NMC, HCPC) *

7490539

Consent to publish response

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14. Date *

06/01/2026



Experience

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15. Please describe your level of experience with the procedure/technologies, for example:

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- Please highlight any other technologies you are aware of which propose to support rapid diagnosis of endometriosis for consideration in this assessment

I have extensive experience managing patients with suspected and confirmed endometriosis in primary care, including early recognition, symptom management, referral decision-making, and coordination with secondary and tertiary services.

I am familiar with current diagnostic pathways for endometriosis, including symptoms-based assessment, pelvic ultrasound and MRI, and the role of laparoscopy as the current gold standard in secondary care. I regularly counsel patients on diagnostic uncertainty and on navigating existing NHS pathways.

I am aware of emerging non-invasive diagnostic technologies such as Endotest, DotEndo and Endosure. Whilst I do not personally deliver these tests, I am familiar with their use and discuss them with patients looking for alternatives to invasive investigation. I understand that these technologies are not yet widely embedded within NHS diagnostic pathways and are currently limited to research, pilot settings, and private provision.

From a primary care perspective, I can comment on the potential impact of such technologies on diagnostic delay, referral thresholds, patient expectations, and equity of access, as well as practical considerations for implementation within NHS pathways. I am also aware of broader developments including advanced imaging protocols and biomarker based approaches aimed at supporting earlier diagnosis.

16. Please indicate your research experience relating to this procedure or technology (please choose one or more if relevant): (Please highlight your choice(s))

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- I have done research on this procedure or technology in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure or technology involving patients or healthy volunteers.
- I have published this research.
- I have had no involvement in research on this procedure or technology.
- Other

Current management

17. Please describe the current standard of care that is used in the NHS to diagnose endometriosis. Please note any clinical guidelines used routinely in the NHS which are relevant to the care pathway

In the NHS the diagnosis of endometriosis is primarily based on clinical assessment, supported by imaging and specialist referral, in line with NICE guideline NG73 (Endometriosis: diagnosis and management).

Initial assessment typically occurs in primary care and includes a detailed history of symptoms such as dysmenorrhoea, dyspareunia, dyschezia and chronic pelvic pain; and their impact on the individual's quality of life. Validated tools such as the EHP-30/5 (Endometriosis Health Profile) for quality of life, the EIQ (Endometriosis Impact Questionnaire) are commonly used to facilitate this. Empirical management with analgesia and hormonal treatment is often started without a definitive diagnosis.

Pelvic ultrasound is frequently used as a first-line investigation to identify ovarian endometriomas or other pelvic pathology, however it has limited sensitivity for superficial disease. MRI can be used in secondary care where deep infiltrating endometriosis is suspected. Laparoscopy remains the gold standard for definitive diagnosis but it is increasingly reserved for cases with persistent symptoms, diagnostic uncertainty, or failure of medical management. Referral to secondary care gynaecology or specialist endometriosis centres frequently forms part of the pathway.

In spite of the pathways, diagnostic delay remains significant, with many patients experiencing prolonged symptom duration (on average 8-9 years in the UK), before confirmation of diagnosis.

18. Where would the technologies be most appropriate in the care pathway? Consider where they would be most value to the system. Please include what setting this would involve (primary care, general hospitals, specialist centres, women's health hubs).

Emerging non-invasive diagnostic technologies would be most valuable early on in the pathway; particularly at the interface between primary and secondary care.

In primary care or women's health hubs, these technologies could support earlier identification of patients with a high likelihood of endometriosis, reduce diagnostic uncertainty, and inform referral decisions. This would have the potential to shorten diagnostic delay and improve patient validation and engagement.

In secondary care and general hospitals, these technologies could be used to assist with triage, prioritise referrals, and support decision-making regarding further imaging or surgical investigation.

They are likely to complement, rather than replace, existing pathways, with the greatest system-level value seen where they help in reducing unnecessary referrals, optimise use of specialist services, and improve access to swifter diagnosis.

19. Do these technologies have the potential to replace current standard care, or would it be used as an addition to existing standard care?

In primary care, alongside history taking, clinical examination, in place of / alongside ultrasound imaging? In secondary care, used prior to repeat imaging or laparoscopy?

These technologies are unlikely to replace current standard care in the near term and would be best positioned as an adjunct to existing diagnostic pathways.

They could be used alongside history taking and clinical assessment in primary care, to support risk stratification and referral decisions, rather than as a replacement for ultrasound or clinical judgement. They may be particularly valuable where imaging is normal or inconclusive but clinical suspicion remains high.

In secondary care, such technologies could support triage and decision-making prior to repeat imaging or consideration of diagnostic laparoscopy, helping to prioritise patients most likely to benefit from further investigation.

Overall, I believe that their role is likely to be complementary, supporting earlier diagnosis and more efficient use of existing investigations rather than replacing ultrasound or laparoscopy at this stage.

20. Approximately how many people each year would be eligible for an intervention with these technologies. Please (give either as an estimated number, or a proportion of the target population) *Please state this in the context of the point in the pathway you feel it is best positioned.*

The relevant target population would be people of reproductive age presenting with symptoms suggestive of endometriosis, especially those with persistent pelvic pain or dysmenorrhoea despite initial empirical treatment.

Endometriosis is estimated to affect around 1 in 10 women of reproductive age, equating to approximately 1.5–2 million individuals in England, although only a percentage present for assessment in any given year.

At the most appropriate point in the pathway (patients with ongoing symptoms or normal first-line imaging being considered for referral), a reasonable estimate of the eligible population would be in the region of 50,000 to 150,000 patients per year in England, depending on how narrowly the technology is targeted.

If used earlier in primary care as a risk-stratification tool, the eligible population would be larger; if restricted to pre-secondary care triage, numbers would be smaller but still significant.

Potential patient benefits and impact on the health system

21. What do you consider to be the potential benefits to patients from using these technologies?

Are there any groups of patients who would particularly benefit from these technologies?

Are there any groups in which these technologies would be less effective or would be less likely to benefit?

Are there any potential equality issues that should be considered when assessing technologies for this condition?

These technologies may particularly benefit patients with persistent symptoms despite normal first-line imaging, those who are reluctant to undergo invasive investigations, and those who experience delays in access to specialist services (including those with disabilities and other constraints). Earlier diagnostic support would also likely improve patient engagement, shared decision-making, and confidence in care pathways.

The technologies may be less beneficial in patients with complex comorbid pelvic pain syndromes where symptoms are multifactorial, or in cases where disease severity or extent still requires imaging or surgical assessment.

With regard to equality, it would be important to ensure that access isn't limited to private or self-funded routes, as this risks widening existing health disparities. Careful consideration would be needed to ensure equitable access across different socioeconomic groups, ethnic backgrounds, abilities, and geographic areas, particularly given known disparities in diagnosis and care for endometriosis.

22. What do you consider to be the potential benefits to the system from using these technologies? Could it lead, for example, to a reduced number of appointments, reduced investigations, improved care pathway, more efficient NHS staff time use?

These technologies have the potential to support earlier and more appropriate triage of patients with suspected endometriosis, which may reduce repeated GP consultations, unnecessary referrals, and delays in accessing specialist care.

If used appropriately, they could help optimise the use of imaging and surgical investigation by supporting more targeted referral pathways and prioritisation of patients most likely to benefit from further assessment.

There may also be indirect benefits through improved patient confidence and reduced repeated presentations driven by unresolved symptoms, contributing to more efficient use of NHS resources.

23. What (if any) clinical facilities (or changes to existing facilities) are needed to implement this technology safely? What are the potential implementation challenges of these types of technologies in the pathway?

These technologies are likely to require minimal additional clinical facilities if designed for non-invasive use, and, depending on the modality, could be implemented within existing primary care, women's health hub, or outpatient settings.

Key implementation challenges are likely to be operational. These include integration into existing care pathways, clarity around clinical responsibility for acting on results, alignment with referral criteria, and avoiding duplication with existing investigations.

Other challenges may include variable access across regions, funding and commissioning decisions, and managing patient expectations where results are inconclusive or do not replace the need for further investigation.

24. Is any specific training needed in order to use these technologies with respect to efficacy or safety? Who would this training be required for?

Some training would be required to ensure safe and effective use, particularly around appropriate patient selection, interpretation of results, and communication of uncertainty.

This training would be relevant for clinicians using the technology in practice, including GPs, clinicians working in women's health hubs, and secondary care teams involved in triage or referral decision making.

Training requirements are likely to be modest but important to ensure consistent use, avoid over-reliance on test results, and support appropriate integration into existing diagnostic pathways.

Safety and efficacy of the procedure/technologies

25. What are the potential harms of the technologies? Please list any adverse events and potential risks you might consider with these technologies use (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Please list any uncertainties or concerns about the efficacy and safety of these technologies?

These technologies are likely to be minimally invasive or non-invasive compared with surgical diagnosis. Where biospecimen collection is required (for example blood or saliva), direct physical harms are likely to be low and comparable to routine blood sampling, with adverse events such as pain, bruising, or vasovagal symptoms expected to be uncommon (potentially 1-2%).

The main potential harms are indirect and relate to diagnostic uncertainty. False positive results may lead to anxiety, unnecessary referral, or over investigation, whilst false negative results may provide false reassurance and contribute again, to delayed diagnosis. The incidence of these harms is uncertain and would depend on real-world diagnostic accuracy, but even low false negative rates could have clinically meaningful impact given the high prevalence of endometriosis.

From clinical experience, managing uncertainty and patient expectations is already challenging in endometriosis care, and there is a theoretical risk of over reliance on test results in place of clinical judgement if technologies are used outside clearly defined pathways.

Key uncertainties include real world performance across different populations, effectiveness in patients with overlapping pelvic pain conditions, and downstream effects on clinical decision making rather than immediate adverse events.

26. Please list efficacy and safety outcomes that are key to be captured for these technologies. Please suggest the most appropriate method of measurement for these outcomes and timescales (where appropriate) and highlight any challenges to capturing these.

Key efficacy outcomes should include diagnostic accuracy compared with current standards, impact on time to diagnosis, and effects on referral patterns and subsequent investigations.

Patient reported outcomes are also important, especially symptom burden, quality of life, and patient confidence or reassurance within the diagnostic process.

Safety outcomes are likely to relate primarily to downstream effects, such as unnecessary referrals or investigations following false positive results, and delayed diagnosis due to false negative results.

These outcomes could be measured using diagnostic accuracy studies, routine pathway data, and patient reported outcome measures, with short term follow-up (months to 1 year) for pathway impact and medium to long term follow-up (1 year plus) to assess downstream consequences. A key challenge would be attributing changes in outcomes directly to the technology within complex and variable care pathways.

27. Are you aware of any additional issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS? This could include costs, resource, staffing for example.

Common barriers are cost and commissioning arrangements, workforce capacity, and uncertainty around who is responsible for requesting, interpreting, and acting on results.

Variation in local service configuration, lack of integration with existing referral criteria, and limited clarity on how results should influence decision making could also hinder uptake.

Without clear guidance and pathway alignment, there is a risk that these technologies could add complexity rather than streamline care.

28. Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of which may be appropriate for consideration in this assessment.

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email:

samantha.baskerville@nice.org.uk

I am aware that evidence for these technologies is emerging and includes early validation studies, pilot data, and conference abstracts, largely within research, innovation, and private sector contexts.

This includes pilot work relating to the Endosure test, as well as other biomarker-based approaches being explored to support earlier, less invasive diagnosis of endometriosis. These have been reported in early studies but remain at an early stage of evaluation.

I am not aware of large-scale UK real world implementation studies, registries, or mature randomised controlled trials currently informing routine NHS practice. Overall, the evidence base appears to be evolving, with further high quality data required to support widespread adoption within NHS diagnostic pathways.

29. Is there any research that you feel would be needed to address uncertainties you are aware of in the evidence base?

Further research is needed to establish real world diagnostic performance across different populations and care settings, especially within primary care. Studies evaluating the impact of these technologies on diagnostic delay, referral patterns, patient experience, and health inequalities would be particularly valuable.

Comparative studies assessing how these technologies perform alongside existing investigations, rather than in isolation, as well as longer-term follow-up to understand downstream consequences, would help address current uncertainties in the evidence base.

Further Comments

30. Please add any further comments on your particular experiences or knowledge of the potential technologies for this assessment.

My perspective is primarily from primary care, where most patients with endometriosis first present and where diagnostic delay is most acutely experienced.

I routinely support patients navigating prolonged diagnostic pathways, uncertainty following normal imaging, and the interface between primary, secondary, and specialist services. From this position, I am particularly interested in how emerging diagnostic technologies may support earlier recognition, improve patient experience, and integrate realistically within existing NHS pathways.

I would welcome consideration of primary care and pathway level implications when assessing these technologies, alongside technical performance.

View results

Respondent

4 Anonymous

09:58

Time to complete

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- Physiotherapist, specialising in women's health, including pelvic floor physiotherapist.
- Other

2. Topic Title

establishing consensus on how to assess the musculoskeletal structures of the pelvis in women with chronic pelvic pain

3. Name: *

Katie Gore

4. Job title *

Pelvic Specialist Physiotherapist

5. Organisation

Oxford Brookes University

6. Professional organisation or society membership/affiliation

CSP POGP

7. Nominated/ratified by (if applicable)

No answer provided.

8. Registration number (e.g. GMC, NMC, HCPC) *

PH89587

Consent to publish response

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- NICE can use my details to contact me for advice on this topic only, but not for others.

13. Please select what the External Assessment Group (EAG) for the assessment may contact you about:(The EAG is an independent academic group who assess clinical and economic evidence and produce a report which is presented to the committee) *

- The EAG on this assessment can contact me for further information and advice on this assessment.
- The EAG on this assessment cannot contact me for further information and advice.

14. Date *

18/12/2025 

Experience

Please answer the following questions as fully as possible to provide further information about the procedure/technologies and/or your experience

15. Please describe your level of experience with the procedure/technologies, for example:

- Are you familiar with the procedure or technologies which currently support diagnosis of endometriosis?
- Do you have any experience of : Endotest, DotEndo and Endosure?
- Please indicate your experience with these technologies, including how widely these are used within the NHS or private sector? If known, please describe the settings they are used in (primary / secondary) or who they are used by (clinicians in other specialities
- Please highlight any other technologies you are aware of which propose to support rapid diagnosis of endometriosis for consideration in this assessment

My expertise lies in musculoskeletal tests used in women with pelvic pain

16. Please indicate your research experience relating to this procedure or technology (please choose one or more if relevant): (Please highlight your choice(s))

- I have done bibliographic research on this procedure or technology
- I have done research on this procedure or technology in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure or technology involving patients or healthy volunteers.
- I have published this research.
- I have had no involvement in research on this procedure or technology.
- Other

Current management

17. Please describe the current standard of care that is used in the NHS to diagnose endometriosis. Please note any clinical guidelines used routinely in the NHS which are relevant to the care pathway

No answer provided.

18. Where would the technologies be most appropriate in the care pathway? Consider where they would be most value to the system. Please include what setting this would involve (primary care, general hospitals, specialist centres, women's health hubs).

In determining comorbid pain generating elements in the MSK system (pelvic floor, spine etc)

19. Do these technologies have the potential to replace current standard care, or would it be used as an addition to existing standard care?

In primary care, alongside history taking, clinical examination, in place of / alongside ultrasound imaging? In secondary care, used prior to repeat imaging or laparoscopy?

A standardised approach does not exist yet

20. Approximately how many people each year would be eligible for an intervention with these technologies. Please (give either as an estimated number, or a proportion of the target population) *Please state this in the context of the point in the pathway you feel it is best positioned.*

Every women with pelvic pain

Potential patient benefits and impact on the health system

21. What do you consider to be the potential benefits to patients from using these technologies?

Are there any groups of patients who would particularly benefit from these technologies?

Are there any groups in which these technologies would be less effective or would be less likely to benefit?

Are there any potential equality issues that should be considered when assessing technologies for this condition?

Stratifying women out into those who might benefit from conservative intervention such as physiotherapy to manage pain. Much like we do with back pain clinical pathways

22. What do you consider to be the potential benefits to the system from using these technologies? Could it lead, for example, to a reduced number of appointments, reduced investigations, improved care pathway, more efficient NHS staff time use?

Increased satisfaction rates for those who do need surgery as people who's pain isn't entirely endometrial disease generated will be directed to appropriate care first
Significant improvements for women with dyspareunia due to pelvic floor muscle pain who do not benefit from surgical intervention or who have endo optimised but are trying to conceive but cannot achieve penetration
Reduction in numbers of patients having surgical intervention for pain only symptoms

23. What (if any) clinical facilities (or changes to existing facilities) are needed to implement this technology safely? What are the potential implementation challenges of these types of technologies in the pathway?

Education of the standardised approach and recognition this approach in guidelines

24. Is any specific training needed in order to use these technologies with respect to efficacy or safety? Who would this training be required for?

GPS, gynaecologists, potentially nurses and physiotherapists treating this patient group

Safety and efficacy of the procedure/technologies

25. What are the potential harms of the technologies? Please list any adverse events and potential risks you might consider with these technologies use (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Please list any uncertainties or concerns about the efficacy and safety of these technologies?

No answer provided.

26. Please list efficacy and safety outcomes that are key to be captured for these technologies. Please suggest the most appropriate method of measurement for these outcomes and timescales (where appropriate) and highlight any challenges to capturing these.

No answer provided.

27. Are you aware of any additional issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS? This could include costs, resource, staffing for example.

No answer provided.

28. Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of which may be appropriate for consideration in this assessment.

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email:

samantha.baskerville@nice.org.uk

No answer provided.

29. Is there any research that you feel would be needed to address uncertainties you are aware of in the evidence base?

No answer provided.

Further Comments

30. Please add any further comments on your particular experiences or knowledge of the potential technologies for this assessment.

No answer provided.

View results

Respondent

16 Anonymous

32:10

Time to complete

This questionnaire is only to be completed and submitted by Health and care practitioners

This questionnaire should be completed by those whose role is, or is directly related to, one of the specialisms below. For each assessment, we engage with professionals with expertise relevant to the topic under evaluation. By completing this questionnaire, you acknowledge and consent to being considered for the role of professional expert on this assessment.

Please indicate which option best describes your area of expertise. If there is no option which you feel relates to your role, please select 'Other' and let us know your role and why you think we should include your knowledge and expertise on the assessment.

For expressions of interest and/or to share your lived experience please email pjp@nice.org.uk

Note:

Please ensure all necessary edits or amendments are completed on your questionnaire before the portal close date. A final submission pull will be conducted after closure, and the portal will then be locked. Any changes made after the closing date will not be included in the final submission.

<https://techcommunity.microsoft.com/blog/microsoftformsblog/you-can-now-save-and-edit-your-survey-responses/3865033>

1. Please indicate which option best describes your area of expertise by selecting an option below. If your role is not listed but you feel it ought to be included, please select 'Other' and let us know your role and why you think we should include your knowledge and expertise on the assessment if not already listed.

- Consultant Gynaecologist with special interest in endometriosis
- Doctor of Obstetrics and Gynaecology
- Reproductive endocrinologists
- Endometriosis surgeon including advanced laparoscopic surgeon and consultant in endometriosis and minimal access surgery, thoracic surgeon specialised in minimally invasive surgery (VATS)
- GP with extended role in Women's Health / special interest in endometriosis
- Clinical nurse specialist in endometriosis, including advanced endometriosis practitioner
- Clinical psychologist, specialising in gynaecology / pelvic pain
- Radiologists specialised in endometriosis including Gynaecological radiologist and female pelvic imaging radiologist.
- Consultant in Anaesthesia and Pain Management with special interest in endometriosis / women's health / pelvic pain management.
- Physiotherapist, specialising in women's health, including pelvic floor physiotherapist.
- GP

2. Topic Title

Assessment of technologies to support the rapid diagnosis of endometriosis (HTE10082)

3. Name: *

Sharon Dixon

4. Job title *

Dr

5. Organisation

Donnington Medical Partnership, Oxford Nuffield Department of Primary Care Health Sciences, University of

Oxford

6. Professional organisation or society membership/affiliation

MRCGP (RCGP college representative for safeguarding and women's health)

7. Nominated/ratified by (if applicable)

No answer provided.

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC 4322243

Consent to publish response

How NICE will use this information: The information that you provide on this form may be used to develop guidance on this topic.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Where relevant your name, job title, organisation and your responses, along with your declared interests may be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

Please note: if consent is not given, you will not be eligible for the role of professional expert on this assessment.

For more information about how we process your data please see our privacy notice.

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below: *

- Yes, I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above.
- No, I do not give my consent for the information in this questionnaire to be used and it may not be published on the NICE website as outlined above.
- Other

11. If you do not consent to us publishing your response, please explain why below:

No answer provided.

Contact confirmation

Please indicate if you would like to opt in to NICE contacting you regarding other technologies/treatments in the future for your advice, or if you would only like to be contacted regarding this specific technology:

12. Please select what NICE may contact you about: *

- NICE can use my details to contact me for advice on this and future assessments.
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13. Please select what the External Assessment Group (EAG) for the assessment may contact you about:(The EAG is an independent academic group who assess clinical and economic evidence and produce a report which is presented to the committee) *

- The EAG on this assessment can contact me for further information and advice on this assessment.
- The EAG on this assessment cannot contact me for further information and advice.

14. Date *

08/01/2026



Experience

Please answer the following questions as fully as possible to provide further information about the procedure/technologies and/or your experience

15. Please describe your level of experience with the procedure/technologies, for example:

- Are you familiar with the procedure or technologies which currently support diagnosis of endometriosis?
- Do you have any experience of : Endotest, DotEndo and Endosure?
- Please indicate your experience with these technologies, including how widely these are used within the NHS or private sector? If known, please describe the settings they are used in (primary / secondary) or who they are used by (clinicians in other specialities)
- Please highlight any other technologies you are aware of which propose to support rapid diagnosis of endometriosis for consideration in this assessment

I have read about these tests and I have encountered them through academic literature and presentations, and in discussion on social media. This includes through endometriosis academic meetings and also Femtech meetings. I have not as yet encountered them in my clinical role as a GP partner.

I have not personally encountered these specific testing technologies in my clinical role as a GP. I am not aware that they are being used locally in the NHS. The practice and PCN I work in as a GP serve a relatively socio-economically deprived population, and I do not encounter a significant amount of non-NHS care.

16. Please indicate your research experience relating to this procedure or technology (please choose one or more if relevant): (Please highlight your choice(s))

- I have done bibliographic research on this procedure or technology
- I have done research on this procedure or technology in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure or technology involving patients or healthy volunteers.
- I have published this research.
- I have had no involvement in research on this procedure or technology.
- I have conducted and published a public and patient partnership project exploring Femtech priorities, which identified better diagnostic tests and tre:

Current management

17. Please describe the current standard of care that is used in the NHS to diagnose endometriosis. Please note any clinical guidelines used routinely in the NHS which are relevant to the care pathway

The current standard that I am aware of which is used in the NHS is the NICE guidance, though I often also refer to the ESHRE guidance in my clinical practice, because this guideline has more detailed evidence about adolescents and menopause (for example). As a GP, when I see someone with symptoms suggesting possible endometriosis, I offer a trial of hormonal contraception medication or with non-steroidal anti-inflammatory medications. I actively offer and stress the importance of follow up and feedback after these trials of treatment. If these are not tolerated, helpful, or acceptable, or the person asks for referral, then I refer to specialist care. I would typically also arrange a pelvic ultrasound-scan and possibly other tests, for example to look for the possibility of anaemia. In my locality, referral is triaged in a community gynaecology service, and may not be accepted for onward care, or until other interventions are trialled. After specialist diagnosis, many people are discharged back to general practice for ongoing care, requiring re-referral for emergent concerns or symptoms (and typically through the whole triage route again).

If someone presents with concerns about fertility, then this may open a different referral route.

I would also note that sometimes we encounter people who are found to have imaging changes suggestive of possible endometriosis through investigations undertaken where this was not expected or not the primary reason for the imaging (for example, in gastrointestinal investigations or for peri-menopausal or HRT related bleeding) and there is not always a clear pathway or route for this support. This is perhaps an example of where the breadth of diagnosis needs to be framed in a breadth of guidance and support.

In general practice, where we see people with undifferentiated symptoms, meaning that referrals and diagnostic consideration can be complex. Calls from some advocating for making a 'clinical' diagnosis does not reflect the clinical reality of complex potential differential diagnosis when people with symptoms are seen in general practice, as opposed to specialist clinics. Throughout this, the challenges of long NHS waiting lists – notably in gynaecology – complicate referral for diagnosis at present.

I note the potential paradox in current guidance, whereby someone seeking referral for diagnosis is in a pathway which requires a trial of treatment before referral, with the medication which is the first line treatment for the both the symptom and the condition when diagnosed. There is also potential uncertainty about whether non-response to a trial of treatment does predict endometriosis, with a cohort study following up young people seen with marked dysmenorrhoea to adulthood finding that response to empirical treatment with hormonal therapy was associated with the likelihood of a diagnosis of adult endometriosis. However, non-response to a trial of treatment is evidence of persistent symptoms and a need for consideration of next steps for treatment and support to help meet ongoing care needs. What this will mean in a context of evolving diagnostic technologies may be worth considering.

Finally, I note that the evidence that underpins the existing NICE guidance is derived from participants who are not representative of the UK population as a whole, or the population seen in general practice, and mirrors the inequity in those who are diagnosed. A non-invasive test might offer scope to mitigate against this but needs care and consideration about where introduced.

18. Where would the technologies be most appropriate in the care pathway? Consider where they would be most value to the system. Please include what setting this would involve (primary care, general hospitals, specialist centres, women's health hubs).

Whether these tests are integrated into pathways for referral and diagnosis and used to stratify onward steps, or whether they are standalone diagnostic tests, will need to be informed by evidence – and this influences where in pathways then can be upon adoption, recognising that this may evolve with time and developing understanding.

This is a critical question, and I think would need to be under-pinned by evidence in and from whichever care pathway or setting they are deployed in. I would think that if there was evidence to support a diagnostic test in primary care which could make a diagnosis, or risk stratify for referral (reliably exclude), then this would be an important, impactful and useful test. However, I am not confident as yet that these tests have been trialled for use in this way, in an undifferentiated general practice population, and the challenge of potential confounding of test accuracy by co-morbidities and medications is a significant concern for me.

I think there is great potential for use of non-invasive diagnostic in general practice (+/- women's health hubs, which are heterogeneous in structure and function at present), but whether and how they are used needs RCT evidence and needs to address concerns about whether they can predict who might benefit from treatment, including surgical treatment (worth noting that if diagnosis is by laparoscopy, then treatment might happen at the same time). The population prevalence will influence the sensitivity and specificity of the test. This needs consideration. These tests could also have a place in secondary care, perhaps stratifying operative or imaging modalities, but if diagnosis needs affirmation, then the value of new tests is perhaps less certain. Wherever they are intended, anticipating test access and adoption in other parts of the pathway may well occur, which may be important to consider and anticipate, including potential impacts on services.

I think there is uncertainty, given the likely significant under-ascertainment of endometriosis according to current estimates, that this might drive rather than reduce pressures on diagnostic or clinical pathways, and again, this needs to not adversely impact on people with symptoms who do/may not have endometriosis. Arguably, this will generate evidence to drive clinical care improvements and capacity, and evidence, which is needed and would be welcome. But, it may take time.

Another question to reflect on, with easier access to non-invasive diagnostic tests, is whether we have knowledge and evidence about how to support people who are asymptomatic, or know how to answer questions about potential fertility, when evidence is currently largely developed from people presenting with persistent symptoms or concerns about fertility.

It is thought that some endometriosis lesions might regress (I have encountered estimates of up to a third of people), which creates an uncertainty about labelling and prognostication.

Finally, how the tests perform with other medications including hormonal treatments, including contraception and HRT, needs to be understood.

19. Do these technologies have the potential to replace current standard care, or would it be used as an addition to existing standard care?

In primary care, alongside history taking, clinical examination, in place of / alongside ultrasound imaging? In secondary care, used prior to repeat imaging or laparoscopy?

As above, I think there is potential at all of these sites, but needs to be underpinned by evidence in that site, with that population, and with the diagnostic test performing the intended role at that point in the pathway.

From my perspective as a GP, it would be helpful to use these tests to stratify referral for specialist care as well as for onward uses in specialist settings, for example to possibly to stratify laparoscopic surgery, if evidence supports these uses. A reliable rule out test would be helpful, as would a rule in. The question about whether they diagnose alone or assess likelihood of endometriosis will be important to clarify, with the cautions I list above.

I would think any diagnostic test needs to exist alongside clinical examination, history taken and care, and see these as an adjunctive addition alongside imaging (that is also often organised because when someone presents with symptoms, of dysmenorrhoea, heavy bleeding, dyspareunia or pelvic pain, to general practice, there are many possible explanations, of which endometriosis is one).

I understand the tests are predominantly binary (endometriosis yes/no), rather than offering a measure of disease activity, but if this evolved that could be valuable.

20. Approximately how many people each year would be eligible for an intervention with these technologies. Please (give either as an estimated number, or a proportion of the target population) *Please state this in the context of the point in the pathway you feel it is best positioned.*

Pelvic pain and menstrual pain are common and impactful. If these tests were situated in a primary care pathway, I would anticipate significant usage (though again note that I am not aware that they have been trialled in this population).

An estimated 10% of the female at birth population might have endometriosis, though there is significant (and unequitable) ascertainment of this. For example, 90% of adolescents experience dysmenorrhoea, and most are not seen or referred.

Wherever these tests sit in a pathway, if and when there is science to support one, there would be clinical need and significant interest.

Potential patient benefits and impact on the health system

21. What do you consider to be the potential benefits to patients from using these technologies?

Are there any groups of patients who would particularly benefit from these technologies?

Are there any groups in which these technologies would be less effective or would be less likely to benefit?

Are there any potential equality issues that should be considered when assessing technologies for this condition?

From qualitative research with people who have been diagnosed with endometriosis, documented advantages of receiving an endometriosis diagnosis include feeling that the diagnoses can legitimise symptoms, bring validation at home and the workplace, and can offer social community membership. However, I think it is vital that a new test does not disadvantage people with ongoing symptoms who do not have a positive test result, and that all pain is met with healthcare, social, and occupational compassion and validation.

If better understanding and increased ascertainment of diagnosis informed service provision, then this could enhance supportive, responsive and tailored care. The NCEPOD report highlighted challenges with ongoing care, and repeated referrals and call for endometriosis to be framed as a long-term condition. If this was recognised and supported, perhaps as diabetes care is, then we could democratise access to care, and try to reduce inequalities in care.

Easier access to testing and diagnosis could enable a development of epidemiological understanding and could enable more resonant and inclusive health research, information and evidence that could benefit all. However, this needs to be accompanied by systems and services which remain funded, including pelvic pain services if tests are negative.

Endometriosis holds historical inequities, and current pressures on systems risk exacerbating these. Any test introduced needs system support and to be made available in a framework that actively seeks to mitigate against these inequities.

Any new test that is predominantly available in the private sector might exacerbate these inequities. In my experience, there is also the risk that private testing can lead to increased requests for onward NHS referrals for care, and, if this happens, then this is another possible source of increasing inequalities.

22. What do you consider to be the potential benefits to the system from using these technologies? Could it lead, for example, to a reduced number of appointments, reduced investigations, improved care pathway, more efficient NHS staff time use?

If these tests can streamline access to specialist services – both for those with endometriosis (with a positive test) and also then for anyone with impactful symptoms – for the right treatment or service for them, then this could be beneficial for all. Easier routes to diagnosis might help shift the focus of care from diagnosis to treatment. There is widespread unease and dissatisfaction with healthcare services around the long and complex journeys to endometriosis diagnosis, with potential impacts on trust in services and on healthcare encounters. Smoother pathways to diagnosis and diagnostic tests could mitigate this, which would be beneficial to those delivering and using services.

Depending somewhat on whether they risk stratify or are standalone tests, these non-invasive tests might reduce appointments on the journey to diagnosis. If this were true, then this resource could be utilised to develop meaningful ongoing support and long-term condition pathways and resources for people with endometriosis.

Laparoscopies are not without risk, and reducing the number of people who have laparoscopies would be beneficial. Having a laparoscopy to explore long-term pelvic or menstrual pain and receiving a 'normal' (no endometriosis) result can be distressing and perhaps notably so when this occurs after waiting a long time for the test. If this time can be reduced, and the number of people who have laparoscopies which do not find endometriosis can be reduced, then this could be potentially beneficial for them and for services, and help enable theatre access, and staff capacity.

However, as above, the inherent uncertainties about endometriosis, including the lack of complete understanding of its heterogeneity and natural history or the impact of early treatment need to be considered in framing expectations. More accessible tests have potential to help develop this understanding, but this depends on their sensitivity and specificity in the populations and for the roles for which they are deployed.

23. What (if any) clinical facilities (or changes to existing facilities) are needed to implement this technology safely? What are the potential implementation challenges of these types of technologies in the pathway?

Capacity will be needed in the laboratory and clinical settings. There will need to be pathway capacity, including where the testing happens, consumables and equipment for the tests, and also for onward services or further testing, if that is how any non-invasive tests are integrated into pathways.

24. Is any specific training needed in order to use these technologies with respect to efficacy or safety? Who would this training be required for?

Anyone offering or delivering the test, advising people or counselling people about having the test, interpreting the results, or integrating the test into a local clinical pathway will need system and setting appropriate training and resources.

Any lab managing the test will need training, equipment, reporting guidance and audit training.

Safety and efficacy of the procedure/technologies

25. What are the potential harms of the technologies? Please list any adverse events and potential risks you might consider with these technologies use (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Please list any uncertainties or concerns about the efficacy and safety of these technologies?

Some potential harms are related to the accuracy (sensitivity and specificity) of the test in the setting and for the clinical purpose in which they are used. Both false negatives and false positives could have adverse impacts on people.

If non-invasive tests rule out endometriosis when it is in fact present and they do not have opportunities for earlier counselling, or surgery, then this is a risk.

If people have surgery that they might not have previously had, because the test is overly sensitive (false positive) then this is a potential harm.

If systems become overwhelmed, then this risks harm.

If there are inequalities in those included in the tests or the trials, this risks being potentiated in deployment and this is a potential harm.

There is a risk that these will be exacerbated if they are deployed in care-settings in which there is not evidence in that population (e.g. primary care).

False positives or ascertainment of cases that might not have presented symptomatically perhaps risk over-diagnosis and medicalisation. If there is extrapolation of incomplete information about the likelihood of clinical sequelae if guidance and patient information are derived from different patient cohorts than those who are now being diagnosed, then this is a risk, although one that easier and more accessible testing might in the longer-term actively mitigate against.

26. Please list efficacy and safety outcomes that are key to be captured for these technologies. Please suggest the most appropriate method of measurement for these outcomes and timescales (where appropriate) and highlight any challenges to capturing these.

Diagnostic measures should be tested in the population where their use is intended.

Active monitoring and implementation evaluation exploring intended and actual use, impacts on services and individuals, and evolving understanding and awareness.

27. Are you aware of any additional issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS? This could include costs, resource, staffing for example.

Cost and service capacity.

28. Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of which may be appropriate for consideration in this assessment.

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email:

samantha.baskerville@nice.org.uk

No answer provided.

29. Is there any research that you feel would be needed to address uncertainties you are aware of in the evidence base?

I have touched on my thoughts on the interface between non-invasive diagnostic testing and endometriosis research uncertainties. Pivotal in primary care is the question of who to consider endometriosis in, when, and how best to support them, while recognising the heterogeneity of endometriosis. Our qualitative research with GPs speaks to these uncertainties, including the lack of accurate long-term prognostication, the uncertainty as to whether earlier treatment changes long-term sequelae likelihood, and how best to support people whose symptoms do improve with empirical treatment. Balancing these against the risks of laparoscopy are an ever-present consideration. Non-invasive testing has potential to mitigate against these and to develop understanding that could improve our ability to offer evidence-based care and personalised advice. However, this means that the period after introduction will be complex.

This depends on implementation being informed by research conducted in the clinical care pathway and research conducted in primary care so sensitivity and specificity is correct.

Further Comments

30. Please add any further comments on your particular experiences or knowledge of the potential technologies for this assessment.

Non-invasive diagnostic testing has the potential to enable care for those with a positive test and to reduce people's long and difficult journeys through healthcare, but this must not disadvantage care for those with symptoms without a positive test.

View results

Respondent

8 Anonymous

52:58

Time to complete

This questionnaire is only to be completed and submitted by Health and care practitioners

This questionnaire should be completed by those whose role is, or is directly related to, one of the specialisms below. For each assessment, we engage with professionals with expertise relevant to the topic under evaluation. By completing this questionnaire, you acknowledge and consent to being considered for the role of professional expert on this assessment.

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<https://techcommunity.microsoft.com/blog/microsoftformsblog/you-can-now-save-and-edit-your-survey-responses/3865033>

1. Please indicate which option best describes your area of expertise by selecting an option below. If your role is not listed but you feel it ought to be included, please select 'Other' and let us know your role and why you think we should include your knowledge and expertise on the assessment if not already listed.

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- Reproductive endocrinologists
- Endometriosis surgeon including advanced laparoscopic surgeon and consultant in endometriosis and minimal access surgery, thoracic surgeon specialised in minimally invasive surgery (VATS)
- GP with extended role in Women's Health / special interest in endometriosis
- Clinical nurse specialist in endometriosis, including advanced endometriosis practitioner
- Clinical psychologist, specialising in gynaecology / pelvic pain
- Radiologists specialised in endometriosis including Gynaecological radiologist and female pelvic imaging radiologist.
- Consultant in Anaesthesia and Pain Management with special interest in endometriosis / women's health / pelvic pain management.
- Physiotherapist, specialising in women's health, including pelvic floor physiotherapist.
- Other

2. Topic Title

HTE10082 Endometriosis

3. Name: *

Sujata Gupta

4. Job title *

Consultant Gynaecologist

5. Organisation

Manchester Foundation Trust

6. Email Address

sujata.gupta@mft.nhs.uk

7. Professional organisation or society membership/affiliation

GMC, RCOG, BSGE, BIARGS, BritSPAG, BMS

8. Nominated/ratified by (if applicable)

BSGE

9. Registration number (e.g. GMC, NMC, HCPC) *

6047263

Consent to publish response

How NICE will use this information: The information that you provide on this form may be used to develop guidance on this topic.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Where relevant your name, job title, organisation and your responses, along with your declared interests may be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

Please note: if consent is not given, you will not be eligible for the role of professional expert on this assessment.

For more information about how we process your data please see our privacy notice.

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below: *

- Yes, I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above.
- No, I do not give my consent for the information in this questionnaire to be used and it may not be published on the NICE website as outlined above.
- Other

11. If you do not consent to us publishing your response, please explain why below:

No answer provided.

Contact confirmation

Please indicate if you would like to opt in to NICE contacting you regarding other technologies/treatments in the future for your advice, or if you would only like to be contacted regarding this specific technology:

12. Please select what NICE may contact you about: *

- NICE can use my details to contact me for advice on this and future assessments.
- NICE can use my details to contact me for advice on this topic only, but not for others.

13. Please select what the External Assessment Group (EAG) for the assessment may contact you about:(The EAG is an independent academic group who assess clinical and economic evidence and produce a report which is presented to the committee) *

- The EAG on this assessment can contact me for further information and advice on this assessment.
- The EAG on this assessment cannot contact me for further information and advice.

14. Date *

29/12/2025



Experience

Please answer the following questions as fully as possible to provide further information about the procedure/technologies and/or your experience

15. Please describe your level of experience with the procedure/technologies, for example:

- Are you familiar with the procedure or technologies which currently support diagnosis of endometriosis?
- Do you have any experience of : Endotest, DotEndo and Endosure?
- Please indicate your experience with these technologies, including how widely these are used within the NHS or private sector? If known, please describe the settings they are used in (primary / secondary) or who they are used by (clinicians in other specialities)
- Please highlight any other technologies you are aware of which propose to support rapid diagnosis of endometriosis for consideration in this assessment

I have explored Endosure test. The test is currently not available on the NHS but I am aware of the current feasibility study which has started recruiting recently. I am in the process of setting this up in private sector.

16. Please indicate your research experience relating to this procedure or technology (please choose one or more if relevant): (Please highlight your choice(s))

- I have done bibliographic research on this procedure or technology
- I have done research on this procedure or technology in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure or technology involving patients or healthy volunteers.
- I have published this research.
- I have had no involvement in research on this procedure or technology.
- Other

Current management

17. Please describe the current standard of care that is used in the NHS to diagnose endometriosis. Please note any clinical guidelines used routinely in the NHS which are relevant to the care pathway

We currently use ESHRE guideline in day to day clinical practice.

I summary diagnosis of endometriosis uses the following-

Clinical history and examination
Imaging- Ultrasound/ MRI
Laparoscopy- even if scans are negative due to false negative results on scans

18. Where would the technologies be most appropriate in the care pathway? Consider where they would be most value to the system. Please include what setting this would involve (primary care, general hospitals, specialist centres, women's health hubs).

Screening test by GPs in primary care
Women health hubs
General gynaecology clinics- to decide if patient needs to be seen by endometriosis specialists
Specialist endometriosis clinics- For monitoring and follow up ?

19. Do these technologies have the potential to replace current standard care, or would it be used as an addition to existing standard care?
In primary care, alongside history taking, clinical examination, in place of / alongside ultrasound imaging? In secondary care, used prior to repeat imaging or laparoscopy?

This test may provide early reassurance to many patients who currently wait for several months before seeing a gynaecologist/ endometriosis specialist.

Care can be focused on women with actual endometriosis.

The test has potential to reduce referral to secondary care, earlier and faster diagnosis , cutting on need and waiting times for laparoscopy.

20. Approximately how many people each year would be eligible for an intervention with these technologies. Please (give either as an estimated number, or a proportion of the target population) *Please state this in the context of the point in the pathway you feel it is best positioned.*

I estimate would be in 100s and certainly in patients with clinical symptoms of endometriosis but with negative scans.

Potential patient benefits and impact on the health system

21. What do you consider to be the potential benefits to patients from using these technologies?

Are there any groups of patients who would particularly benefit from these technologies?

Are there any groups in which these technologies would be less effective or would be less likely to benefit?

Are there any potential equality issues that should be considered when assessing technologies for this condition?

This test will allow for faster and earlier diagnosis. As the test is non-invasive, it would also reduce the need for laparoscopic and avoid any associated complications.

I feel that the adolescent group will benefit significantly as endometriosis in this group is often ill-understood and harder to diagnose even after laparoscopy.

Currently, patients can only access this as a private test or in research setting on the nhs, which is very limited. Hence, access to this test is unequal based on affordability.

22. What do you consider to be the potential benefits to the system from using these technologies? Could it lead, for example, to a reduced number of appointments, reduced investigations, improved care pathway, more efficient NHS staff time use?

Reduced referrals to secondary care
earlier diagnosis- better patient satisfaction- fewer complaints/ litigation
Better use of resources focused on patients with disease
Fewer laparoscopies, MRI scans
Fewer complications secondary to laparoscopies
Follow up in communities/ Women's health hubs

23. What (if any) clinical facilities (or changes to existing facilities) are needed to implement this technology safely? What are the potential implementation challenges of these types of technologies in the pathway?

This test can be done in primary care setting or women's health hub or local diagnostic centres without need active participation by a clinician.
The test report can be accessed by clinician like any other report.
The main limitation is cost, availability and data/ validation of test.

24. Is any specific training needed in order to use these technologies with respect to efficacy or safety? Who would this training be required for?

Clinician training will be needed to interpret test result.
Technician training is done by the company but if adopted by wider NHS, this will need to be assessed.

Safety and efficacy of the procedure/technologies

25. What are the potential harms of the technologies? Please list any adverse events and potential risks you might consider with these technologies use (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Please list any uncertainties or concerns about the efficacy and safety of these technologies?

False positive and false negative results- may lead to over diagnosis/ missed diagnosis
Allergic reaction to pads
Discomfort during test
Discomfort due to fasting before test

26. Please list efficacy and safety outcomes that are key to be captured for these technologies. Please suggest the most appropriate method of measurement for these outcomes and timescales (where appropriate) and highlight any challenges to capturing these.

Rates of false positives and negatives against current gold standard (laparoscopy)
RCTs comparing Endosure to laparoscopy are lacking.

27. Are you aware of any additional issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS? This could include costs, resource, staffing for example.

Cost
Research support- cost, staff

28. Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of which may be appropriate for consideration in this assessment.

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email:

samantha.baskerville@nice.org.uk

<https://doi.org/10.1016/j.jmig.2025.09.027>

(1)Noar M, Mathias J, Kolatkar A. Gastrointestinal Myoelectrical Activity (GIMA) Biomarker for Noninvasive Diagnosis of Endometriosis. J. Clin. Med. 2024, 13, 2866. <https://doi.org/10.3390/jcm13102866>

29. Is there any research that you feel would be needed to address uncertainties you are aware of in the evidence base?

We need larger studies to assess the accuracy of this test in predicting presence or absence of endometriosis.

Further Comments

30. Please add any further comments on your particular experiences or knowledge of the potential technologies for this assessment.

I am aware of current data available on this test along with the current on-going feasibility study.

As an endometriosis specialist, I feel a fast non-invasive test will reduce need for laparoscopy and provide earlier reassurance to hundreds of women, but it is important that the accuracy of the test is high.

As an expert in endometriosis and paediatric and adolescent gynaecology, I come across many teenage patients with significant dysmenorrhoea. This is a particularly challenging group and will benefit significantly from a non-invasive test.

I am currently in the process of setting up an endosure clinic for suspected endometriosis in Manchester.

HTE10082: Technologies for the rapid diagnosis of endometriosis

Final external assessment report

Produced by: Coreva Scientific GmbH & Co. KG

Authors: Anya Lissina, Senior Medical Writer, Coreva Scientific
Sita Saunders, Chief Operating Officer, Coreva Scientific
Kim Seemann, Consultant in Health Economics, Coreva Scientific
Juliane Hafermann, Senior Medical Writer, Coreva Scientific
Erica Ehrhardt, Medical Writer, Coreva Scientific
Tobias Münch, Consultant in Health Economics, Coreva Scientific
Virginie Mittard, Quality and Compliance Officer, Coreva Scientific
Rhodri Saunders, EAG Director and Chief Executive Officer at Coreva Scientific

Correspondence to: Rhodri Saunders, Coreva Scientific GmbH & Co. KG, Im Muehlenbruch 1, 53639 Koenigswinter, Germany, rhodri@coreva-scientific.com

Date completed: 28/04/2026

Contains confidential information: Yes

Number of attached appendices: 5

Purpose of the early use assessment report

The purpose of this external assessment report (EAR) by an external assessment group (EAG) for early use assessment is to review the evidence currently available for technologies within the decision problem and advise what further evidence should be collected to help inform future decisions on whether the technologies should be widely adopted in the NHS. NICE has commissioned this work and provided the template for the report. The report forms part of the papers considered by the Committee when it is making decisions about the early use assessment.

Declared interests of the authors

None

Acknowledgements

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Responsibility for report

The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

Confidential information

The confidential information and its source are summarised in **Table 1**.

Table 1 Summary of all confidential information and its source in report

Technology	Brief description	AIC/CIC/PI	Page numbers	Source
EndoSure (3PCM/Endosure)	Unpublished data from a pilot feasibility study	AIC	138, 151	Company RFE
DotEndo (DotLab)	EMPOWER Study dataset description, algorithm development methodology, model architecture, publication status information, and follow-up	AIC and CIC	13, 56, 139, 140, 151	Company RFE
DotEndo (DotLab)	Initiation information for a planned pilot study	AIC	140, 150, 150, 172	Company RFE

Abbreviations: AIC, Academic in confidence; CIC, Commercial in confidence; PI, Personal information; RFE, Request for evidence

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Abbreviations

Term	Definition
AI	Artificial intelligence
AIC	Academic in confidence
AIET	GIMA-derived 2 stage AI-determined threshold
AUC	Area under the receiver operator characteristic curve
CAP	College of American Pathologists
CE	Conformité Européenne
CI	Confidence interval
CIC	Commercial in confidence
CLIA	Clinical Laboratory Improvement Amendments
CrI	Credible interval
DTAC	Digital Technology Assessment Criteria
EAG	External assessment group
EAR	External assessment report
EGG	Electrogastrogram
EHP-5	Endometriosis Health Profile-5
EVG	Electroviscogram/Electroviscography/Electroviscerogram/Electroviscerography
FDA	Food and Drug Administration
GBP	Great British Pounds
GI	Gastrointestinal
GIMA	Gastrointestinal myoelectrical activity
GP	General practitioner
HCP	Healthcare professional
HR	Hazard ratio
ICER	Incremental cost-effectiveness ratio
IQR	Interquartile range
IVD	In vitro diagnostic
IVDR	In vitro diagnostic regulation
MAUDE	Manufacturer and User Facility Device Experience
MDD	Medical Devices Directive
MDR	Medical Device Regulation
MHRA	Medicines & Healthcare products Regulatory Agency
miRNA	Micro ribonucleic acid
MRI	Magnetic resonance imaging
N	Total study population
n	Subset of total study population
NCC	National Cost Collection (NHS)
NGS	Next generation sequencing

NHB	Net health benefit
NMB	Net monetary benefit
NPV	Negative predictive value
NR	Not reported
OWSA	One-way sensitivity analysis
PI	Personal information
PPV	Positive predictive value
PRISM A	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROM	Patient-reported outcome measure
PSA	Probabilistic sensitivity analysis
QALY	Quality-adjusted life year
QoL	Quality of life
rASRM	Revised American Society for Reproductive Medicine
RCT	Randomised controlled trial
RFE	Request for evidence
RFI	Request for information
RoB	Risk of bias
SPE	Superficial peritoneal endometriosis
TaUS	Transabdominal ultrasound
TvUS	Transvaginal ultrasound
UKCA	United Kingdom Conformity Assessed
US	United States (of America)
WLST	Water load satiety test

Executive summary

Background

Endometriosis is a chronic inflammatory condition affecting an estimated 1.5 million women and people with female reproductive organs in the UK. Despite its high prevalence, the average time from first presentation to diagnosis in the UK is 9 years and 4 months ([Endometriosis UK 2026](#)), driven by factors such as late initial presentation, non-specific symptoms, delays in referral pathways, and the requirement for laparoscopy as the gold-standard diagnostic test (see Section 1). Three non-invasive or minimally invasive diagnostic technologies have been evaluated as part of this early use assessment: EndoSure (a device measuring gastrointestinal myoelectrical activity using electroviscerography, manufactured by 3PCM/Endosure), DotEndo (a blood-based miRNA biomarker test manufactured by DotLab), and EndoTest (a saliva-based miRNA biomarker test manufactured by Ziwig) (see Sections 2 and 3). The technologies aim to provide clinicians with objective, non-invasive decision-support tools to guide treatment, referral, and investigation decisions for people with suspected endometriosis and inconclusive imaging, thereby reducing diagnostic delay. In this assessment, the three technologies were placed within primary care in the diagnostic pathway and were intended to be used on people designated female at birth who had recurrent symptoms suggestive of endometriosis, normal clinical examination findings, and negative or equivocal ultrasound results. Please refer to the assessment [scope](#) and [protocol](#) for more information.

Clinical evidence

A rapid literature search of six bibliographic databases and three clinical trial registries was conducted to gather clinical and health-economic evidence for this assessment. The review also considered evidence presented on company websites and supplied by the companies following requests for information or evidence by NICE (see Section 4.1). A total of 28 records were included in the clinical evidence review: 12 for EndoSure, four for DotEndo, and 12 for EndoTest; of these, 19 had available results (see Section 4.2) and nine were ongoing studies (see Section 8.1). Although a formal risk assessment was not performed, the risk of bias and applicability for the evidence for each technology was ranked from low to high according to four domains (patient population, index text, reference standard, flow and timing). Risk of bias and applicability concerns were judged high for all three technologies. The main applicability concerns are that no included study was conducted in a primary care UK NHS setting (where endometriosis prevalence is lower than in the studied populations selected for laparoscopy) or involved the population considered in the [scope](#) of this assessment (i.e., individuals with recurrent/enduring symptoms of endometriosis and a negative ultrasound result) (see Section 5.1). Consequently, the EAG notes that the extrapolation of published diagnostic accuracy estimates to the NHS diagnostic pathway requires caution.

The reported outcomes were grouped into clinical outcomes, patient- or clinician-reported outcome measures (see Section 5.2), and health-economic outcomes (see Section 6.1). Most (79%) of the included studies only reported diagnostic test accuracy data. No study assessed downstream clinical outcomes such as time to diagnosis, reduction in diagnostic laparoscopy rates, or patient quality of life. Two studies presented patient- or clinician-reported outcomes; however, only one of these (a survey of clinician attitudes towards EndoTest) was a full-text, peer-reviewed manuscript (Nigdelis et al. 2025).

Overall, EndoTest has the largest evidence base. The pivotal Bendifallah et al. 2025 study (N=971, 17 centres) reported overall sensitivity of 97% and specificity of 94% for the 109-miRNA saliva signature, with assessors blinded to imaging and surgery findings and independent data monitoring. Performance was consistent across endometriosis stages and subtypes, including superficial peritoneal disease, which is common yet challenging to diagnose with imaging alone. However, the studies were predominantly conducted in France, were company-funded (and , and involved study populations with high endometriosis prevalence (77%) not representative of NHS primary care.

EndoSure has a moderate evidence base, with published accuracy data from two peer-reviewed studies (Noar et al. 2024a, 2024b), reporting sensitivities of 91% to 96% and specificities of 95% to 96%. However, recent published and unpublished conference abstracts reported a very wide range of specificities (0% to 100%), in many cases because no or few people without endometriosis were evaluated. In these studies, high diagnostic accuracy was largely attributable to high sensitivity in surgical populations with very high endometriosis prevalence, limiting generalisability to the primary care NHS setting. Other limitations included the conflict of interest arising both studies being led by the technology developer, and the single-centre US-based design. Of note, EndoSure is currently the only device in use in the NHS (see Section 7), although potential implementation issues of this technology have been raised (see Section 3.2).

DotEndo has the most limited evidence, with a single-centre published US-based study (Moustafa et al. 2020, N=100) reporting a sensitivity of 83% and a specificity of 96% (90% balanced threshold for both) for the 6-miRNA biomarker panel related to the current commercial product (DotEndo 2, referred to as simply DotEndo in the body of the report). Although the study was not company-funded, it cannot be viewed as company-independent as the lead author is an option holder in DotLab.

The EAG note some differences in the diagnostic accuracies reported by company-sponsored vs independently validated studies. For EndoSure,

investigator-sponsored studies report higher sensitivity and specificity (91% to 100% and 85% to 100%, respectively) than independent studies, with specificity ranging widely in independent analyses (0% to 96% when including unpublished data, and 0% to 26% when excluding unpublished data). For DotEndo, no comparison is possible as accuracy data are available only from one study with notable conflict of interest (sensitivity 83%, specificity 96%; 90% balanced threshold for both). EndoTest shows comparable sensitivity across study types (97% for both) but lower specificity in independently validated studies (94%) compared with company-sponsored evidence (100%).

None of the included studies for any technology reported adverse events attributable to the tests themselves. The EAG considers the clinical risk of all three technologies to be low given their non-invasive or minimally invasive nature (see Section 5.3). For a more in-depth summary of the clinical evidence base, please refer to Section 5.4.

Economic evidence

A de novo early health-economic model was developed to assess the potential cost-effectiveness of introducing the three technologies within the NHS diagnostic pathway for endometriosis. Each new diagnostic test was considered individually, without any combined testing. People entering the model had symptoms suggestive of endometriosis but were only offered one of the new tests (in the intervention arm) if they had a previous ultrasound that failed to identify signs of endometriosis or if they had declined an ultrasound. The intervention arm was compared to the current care diagnostic pathway. The model compared current NHS care (without the new diagnostic test) with pathway scenarios incorporating each technology separately.

The population entering the model is critical to understanding model outcomes. People entering the model had symptoms suggestive of endometriosis but only 43% had endometriosis; this value was calculated from a previous health technology assessment submission for the NHS (Khan et al. 2018). The EAG found that people with endometriosis were most likely to benefit from the new diagnostic tests. In people without endometriosis, the tests could be considered as a rule out test for disease options within a differential diagnostic pathway. Some people with endometriosis have comorbid conditions with symptoms overlapping with those of endometriosis, which may complicate the diagnostic pathway.

Under base-case conditions, all three technologies were cost-effective, with EndoSure (-£58) and DotEndo (-£88) showing a slight decrease in cost and EndoTest an increase in cost (+£583). The use of all three tests resulted in an increase in QALYs of 0.10 to 0.11. Although there is an uncertainty in the accuracy of model inputs, both probabilistic sensitivity analyses and scenario analyses pointed to a high likelihood that the new technologies would be

considered cost-effective under the assumption that no major training costs or implementation costs (e.g., changing healthcare infrastructure) were required when adopting the new technologies. It was not possible for this early use assessment to consider major implementation barriers as it is not known how the tests will be adopted in primary care. Very few simulations in the sensitivity analysis were not cost-effective and it is not known whether these represent a meaningful and realistic combination of parameter values.

The average time to definitive diagnosis estimated by the model for the current care arm of 9 years and 8 months aligned with the 9 years and 4 months recently reported by [Endometriosis UK 2026](#). If the new diagnostic tests are implemented, the model predicts a decrease in the time to a definitive diagnosis of 0.97 to 1.22 years. When increasing the proportion of people with endometriosis that enter the model to 100% (from 42.5%), all three new technologies dominated current care. That is, the new diagnostic tests were cost-saving and resulted in QALY increases (+0.16 to +0.21), which is indicative of how adopting these technologies might potentially impact the quality of life of people with endometriosis. A detailed description of the model and results is provided in Section 6.

Evidence gap analysis

Critical evidence gaps exist for all three technologies. The most important gaps are: (1) the absence of diagnostic accuracy data from NHS populations (both secondary and primary care); (2) the absence of evidence on downstream clinical outcomes (e.g., reduction in time to diagnosis, reduction in laparoscopy rates, quality of life); and (3) the absence of NHS-specific cost-effectiveness data. For EndoSure, the additional gap of independent validation (free from technology developer conflict of interest) is a priority. For DotEndo, published data on the current commercial product (DotEndo 2) are needed. For EndoTest, as for the other two tests, the gap between the high-prevalence validation cohorts and the expected NHS primary care prevalence means that the real-world diagnostic accuracy data in NHS practice remains uncertain. Fully company-independent validation studies are needed for all three technologies.

Several ongoing studies may partially address these gaps (see Sections 8.1 and 8.2). The ADDEND study 2024 (UK NHS, N=78, results expected in 2026) will provide the first UK NHS data for EndoSure. A UK NHS pilot for EndoTest is ongoing (UK NHS, N=100, results expected in 2026). A UK NHS pilot for DotEndo is being planned ([REDACTED] [REDACTED]). The ENDOBEST study 2025 (France, EndoTest, N=2,500, results expected in 2027) will provide the first management impact data for EndoTest, albeit outside the UK NHS setting.

Key points for decision makers

1. The EAG considers the evidence for all three technologies to be early-stage, with no NHS diagnostic accuracy data or evidence on downstream clinical pathway impact available for any technology (see Section 8.3).
2. At present, EndoTest has the most robust and independent evidence base. The Bendifallah et al. 2025 study and subsequent unpublished subgroup analyses of the same population provide credible evidence of high diagnostic accuracy across endometriosis stages and patient subtypes (including superficial peritoneal disease and infertility). The key uncertainty is generalisability to NHS practice, given the high prevalence of endometriosis in these study populations compared to NHS primary care, and the non-UK setting.
3. EndoSure shows promising results but is subject to considerable conflict of interest risk, requiring independent validation. Moreover, the discrepant preliminary results from independent researchers raise questions about test performance consistency.
4. DotEndo has the weakest evidence base at present. However, publication of results from the EMPOWER study 2020 (N= approximately 740) is expected ■■■. The planned UK NHS pilot and the outcomes of the UKCA approval process will further influence adoption consideration.
5. Economic modelling estimates that the technologies remain largely cost-effective over a time horizon of 60 years in all scenarios tested but that there is considerable uncertainty in input parameters. The most important data missing are head-to-head comparisons of diagnostic tests used in the primary care patient population presenting with symptoms suggestive of endometriosis. Test sensitivities largely drive model outcomes and available data are not comparative. The most important data required to enhance the current analysis are the sensitivity of the new technologies in comparison to transvaginal ultrasound in the primary care setting.
6. Any early use of the three technologies should be accompanied by systematic prospective data collection on NHS-specific diagnostic accuracy, pathway impact (e.g., reduction in laparoscopy rate and/or time to diagnosis), and patient-reported outcomes, using standardised protocols and validated outcome measures consistent with the outcomes outlined in the [scope](#).

1 Decision problem

The decision problem is described in the [scope](#) and the EAG comments on the decision problem are presented in the [protocol](#). The EAG made no changes to the scope or the protocol; however, following the company request for evidence (RFE) submission by DotLab, the EAG became aware that two forms of DotEndo exist: DotEndo 1 (a questionnaire in the form of a digital assessment tool to triage people with suspected endometriosis) and DotEndo 2 (a blood-based miRNA biomarker diagnostic test for endometriosis). Only DotEndo 2 was included in the scope and will be considered in this early use assessment. In this report DotEndo 2 will be referred to as 'DotEndo' as in the [scope](#).

2 Technologies

A brief description of the technologies can be found in **Table 2**. Please see the [scope](#) for further details.

Table 2 Description of technologies

Technology	Test description	Indication for use	Result interpretation	UKCA/CE mark
<p>EndoSure (3PCM/Endosure) Previous/other name(s): electrogastrogram/EGG, electroviscogram/electroviscerogram/EVG, Tricorder-3L, e-Corder</p>	<p>The test measures GIMA using electrodes placed on the abdomen in a technique called electroviscography or electroviscerography. People with endometriosis show distinct abnormal electrical frequency patterns in the gut caused by prostaglandins released by endometriosis tissue. The test software analyses these patterns to determine whether the GIMA biomarker characteristic of endometriosis is present.</p>	<p>People of any sex or age with symptoms that may indicate a condition listed in the intended purpose statement, including endometriosis.</p>	<p>The test is intended to aid clinicians in diagnosing endometriosis; it is not intended as a standalone diagnostic or to replace clinical judgement.</p>	<p>The test is currently registered with the MHRA as a Class IIa device (which includes all components). A CE/MDD/MDR article 120 extension has been obtained and approval of the CE/MDR is expected in March 2026.</p>
<p>DotEndo (DotLab) Previous/other names: DotEndo 2</p>	<p>The in vitro diagnostic test quantifies the levels of six endometriosis-specific miRNA biomarkers in blood samples and inputs the clinical data into a validated machine-learning algorithm to generate a result indicative of the likelihood of endometriosis.</p>	<p>Women (and people assigned female at birth) of reproductive age (18 to 49 years of age) with unexplained pelvic pain and/or suspected endometriosis.</p>	<p>The result is intended to be used in conjunction with standard clinical assessment to aid in the evaluation of endometriosis and to inform clinical management and referral decisions. It is not intended to be used as a standalone diagnostic test.</p>	<p>Company RFE: For the UK/EU markets:</p> <ul style="list-style-type: none"> • Anticipated classification: Class C in vitro diagnostic medical device under UK IVDR and EU • IVDR (2017/746), reflecting the intended purpose of aiding the evaluation of endometriosis and informing clinical management. • UKCA and CE marking submissions are

Technology	Test description	Indication for use	Result interpretation	UKCA/CE mark
				<p>planned commencing 2026.</p> <ul style="list-style-type: none"> Based on anticipated submission timelines commencing in 2026, regulatory clearance is expected in late 2026 to early 2027, subject to approved body review timelines. DTAC assessment has not yet been initiated but is planned as part of UK market access activities.
<p>EndoTest (Ziwig)</p> <p>Previous/other name: "Salivary miRNA signature for endometriosis"</p>	<p>The laboratory diagnostic test detects the presence of a 109-miRNA biomarker signature of endometriosis based on an automated bioinformatic analysis of salivary miRNAs. Saliva is collected using a specific saliva collection and stabilisation kit.</p>	<p>Women (and people assigned female at birth) of reproductive age (18 to 43 years of age) with symptoms suggestive of endometriosis.</p>	<p>Medical management of the patient should be based on all of the symptoms and available clinical and biological data.</p>	<ul style="list-style-type: none"> The test obtained CE certification in April 2024 under IVDR. The CE certificate is recognised in the UK until 30 June 2030. The test is used with a stabilisation kit to collect the saliva samples: OMNIgene·ORAL, reference OME-505.005. It is class A under IVDR and it is a general IVD under UK MDR 2002.

Abbreviations: CE, Conformité Européenne; CAP, College of American Pathologists; CLIA, Clinical Laboratory Improvement Amendments; DTAC, Digital Technology Assessment Criteria; EVG, Electroviscogram/Electroviscography/Electroviscerogram/Electroviscerography; FDA, Food and Drug Administration;

GIMA, gastrointestinal myoelectrical activity; IVD, *In vitro* diagnostic; IVDR, *In vitro* diagnostic regulation; MDD, Medical Devices Directive; MDR, Medical Device Regulation; MHRA, Medicines & Healthcare products Regulatory Agency; RFE, Request for evidence; UKCA, UK Conformity Assessed

3 Clinical context

The visual summary of the endometriosis diagnostic pathway presented in **Figure 1** has been adapted from the [NICE guidelines for endometriosis](#) and their [visual summary](#). Please note that although this pathway is a simplified and generalised representation that appears more linear than real-world clinical practice, it incorporates feedback from clinical experts indicating that not all diagnostic modalities included are consistently available across the NHS and that access varies regionally. Consequently, the pathway reflects how people may move through different secondary-care routes depending on the specific services available in their local area.

The new minimally invasive diagnostic tests (referred to generically as “new test”) being evaluated in this early use assessment will sit within the primary care setting, in accordance with the [scope](#). It is assumed that the new test will be used in addition to current care (the comparator) and will not replace any existing imaging diagnostics. It is further assumed that only one type of new test is introduced into the current diagnostic pathway at a time and that the new tests are not used in combination at this stage. In this early use assessment, the EAG refers to primary care as general practice surgeries/clinics and intermediary services such as women’s health hubs. Meanwhile, secondary care encompasses services where the patient is seen by a specialist trained in diagnosing and treating endometriosis.

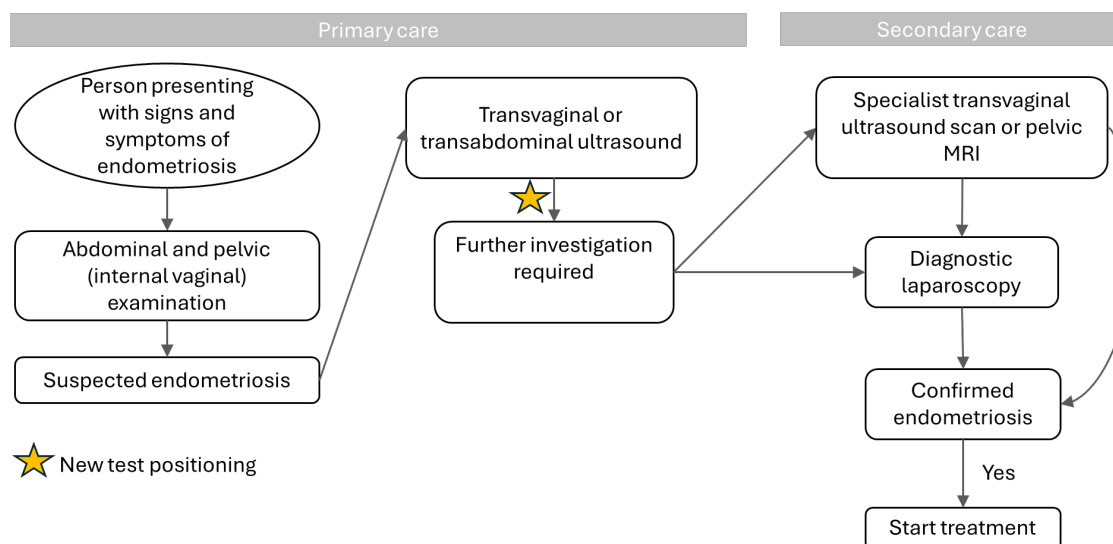


Figure 1. An overview of the endometriosis diagnostic pathway based on the [NICE guidelines for endometriosis](#). Abbreviations: MRI, magnetic resonance imaging.

3.1 Equality issues

The equality issues and considerations for this early use assessment are described in the [equalities impact assessment](#) accompanying the [scope](#). No additional equality issues have been identified during the assessment.

3.2 Potential implementation issues

Differences among the technologies being assessed (two in vitro diagnostic tests vs an electroviscography [EVG]-based test) and potential implementation issues were noted during the scoping workshop and during evidence review for this early use assessment.

Capacity limitations and organisational challenges may arise due to additional training requirements, staff workload, and infrastructure that accompanies the introduction of new treatment pathways. For instance, the EndoSure test not only requires specialist training of staff in EVG but also takes considerably longer (the total procedure time is approximately 45 minutes) to perform than a blood (DotEndo) or a saliva (EndoTest) test, both of which could feasibly be completed during a typical 10-minute general practitioner (GP) consultation. As such, EndoSure will likely have to be performed in an intermediary care setting such as a standard NHS hospital imaging department or a women's health hub. In the feedback provided to the EAG by clinical experts, there were concerns about how the long appointment time and the need for room space with trained primary care network staff required for EndoSure could be accommodated in primary care, given the existing pressures on general practice and the unequal national distribution of women's health hubs.

Meanwhile, unlike EndoSure, which generates the test results during the assessment visit, the two in vitro tests must have their results analysed by a certified laboratory. It is important to consider whether the NHS has the infrastructure to accommodate these additional processes. Clinical expert feedback implied that the blood and saliva tests could be requested through integrated laboratory systems at a GP appointment and then collected in a subsequent healthcare assistant or phlebotomy appointment (for DotEndo) or at home (for EndoTest) and dropped in at the general practice.

Discussions at the scoping workshop also highlighted differences in the indicated populations for the three tests. EndoSure is approved for use in individuals of all ages, whereas DotEndo (indicated for adults aged 18 to 49 years) and EndoTest (indicated for adults aged 18 to 43 years) have defined age restrictions. The assessment did not consider any potential off-label applications of these diagnostic tests but did consider whether test indications could be expanded in ongoing or future studies.

4 Clinical evidence

4.1 Search strategies and study selection

A rapid literature review of clinical and health-economic evidence for EndoSure, DotEndo, and EndoTest was performed on March 3rd, 2026. The search interrogated six bibliographic databases and three clinical trial databases, according to the methodology outlined in the [protocol](#). The review also considered references published on company websites and any evidence supplied by the companies following request for information (RFI) and RFE submissions to NICE. Additionally, a pragmatic search of reference lists of any included systematic literature reviews was conducted to capture any eligible studies that the database searches may have missed. Further details regarding the searches can be found in **Appendix A**.

4.2 Included and excluded studies

The PRISMA flow diagram is provided in **Appendix B**. A total of 2,100 records were identified in the database searches. Another 18 published records were identified from the company websites. After deduplication, 1,568 unique records were assessed for eligibility. Of these, 1,535 were excluded during abstract screening, and the remaining 33 records were selected for full-text review. 17 studies were excluded at full-text review stage; the reasons for their exclusion are provided in **Appendix C**.

In addition to the 16 full-text records retrieved from the literature search (six for EndoSure, two for DotEndo, and eight for EndoTest), 23 new records were submitted following the company RFE. Of these, 12 were included in the evidence review (six for EndoSure, two for DotEndo, and four for EndoTest) and the rest were excluded (see **Appendix C**). Screening of reference lists of retrieved systematic reviews yielded zero new records. Thus, in total, 28 records were included in the clinical evidence review; 12 for EndoSure, four for DotEndo, and 12 for EndoTest. A detailed overview of the 19 included studies with results (10 for EndoSure, one for DotEndo, and eight for EndoTest) is provided in **Table 3** below. A summary of the nine included ongoing studies (two for EndoSure, three for DotEndo, and four for EndoTest) is provided in Section 8.

Table 3 Description of key studies in the evidence base

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
EndoSure (3PCM/Endosure)	Noar 2022 Prospective open-label study (conference abstract) (Partial match to scope) USA	Participants: N=50 women aged 17 to 45 years with chronic abdominal pain, negative CT/MRI and GI endoscopy, scheduled for laparoscopy (Partial match to scope) Setting: Tertiary care centre, USA (No match to scope)	Intervention: EndoSure (EVG with WLST and AI-derived GIMA threshold scoring) (Full match to scope) Comparator: Diagnostic laparoscopy with biopsy as the reference standard (Partial match to scope)	Outcomes: EndoSure GIMA biomarker threshold scoring sensitivity, specificity (Full match to scope) No follow-up data reported	Literature review and company submission	<ul style="list-style-type: none"> • Conference abstract only, no peer-reviewed full-text • Modest* sample size • Single-centre study • Conflict of interest; authored by technology developer (M. Noar of 3PCM/Endosure); data require independent validation • Non-UK setting • No blinding
EndoSure (3PCM/Endosure)	Noar et al. 2024a Prospective open-label comparative study (Full match to scope) USA	Participants: N=154 women aged ≥18 years; Cohort 1: n=62 non-endometriosis controls; Cohort 2: n=43 with histologically confirmed endometriosis;	Intervention: EndoSure (EVG with WLST and GIMA biomarker threshold scoring using AI-derived algorithm). (Full match to scope)	Outcomes: EndoSure sensitivity, specificity, NPV, C-statistic (Full match to scope) No follow-up data reported	Literature review and company submission	<ul style="list-style-type: none"> • Multicentre, prospective study • Conflict of interest; lead author is EndoSure developer • Modest* sample sizes per cohort • Non-UK setting • No blinding

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
		<p>Cohort 3: n=49 with abdominal pain and negative imaging scheduled for laparoscopy. Existing treatments unchanged. (Full match to scope)</p> <p>Setting: Tertiary care centre and routine outpatient centre, USA (No match to scope)</p>	<p>Comparator: Diagnostic laparoscopy with biopsy as the reference standard (Partial match to scope)</p>			
EndoSure (3PCM/Endosure)	Noar et al. 2024b Prospective, open-label, multi-ethnic, multicentre validation study (Full match to scope) USA	<p>Participants: N=50; women aged 27 to 55 years, n=25 with endometriosis, n=25 without endometriosis (controls) (Partial match to scope)</p> <p>Setting: Tertiary care centre and</p>	<p>Intervention: EndoSure (EVG with WLST and GIMA biomarker threshold scoring). (Full match to scope)</p> <p>Comparator: Laparoscopic surgery/histology as</p>	<p>Outcomes: EndoSure sensitivity, specificity, PPV, NPV (Full match to scope)</p> <p>No follow-up data reported</p>	Literature review and company submission	<ul style="list-style-type: none"> • Interim data, full results pending • Modest* sample size • Conflict of interest: lead author is technology developer • Non-UK setting • No blinding

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
		routine outpatient centre, USA (No match to scope)	the reference standard (Partial match to scope)			
EndoSure (3PCM/Endosure)	Tanos et al. 2025 Prospective comparative study (conference abstract) (Partial match to scope) Belgium	Participants: N=100 adult females (aged 18 to 65 years) with suspected endometriosis, enrolled December 2024 to May 2025 (Partial match to scope) Setting: Specialised endometriosis tertiary care centre, Belgium (No match to scope)	Intervention: EndoSure device plus MRI or TvUS; people with positive EndoSure results but negative imaging also underwent diagnostic laparoscopy (Full match to scope) Comparator: MRI (n=35), TvUS (n=45), or laparoscopy (n=12) as the reference standard (Partial match to scope)	Outcomes: EndoSure sensitivity, specificity, accuracy, patient acceptance (Full match to scope) No follow-up data reported	Literature review and company submission	<ul style="list-style-type: none"> • Conference abstract only, no peer-reviewed full publication available • Preliminary data • Non-UK setting • Modest* sample size but only 12 patients had laparoscopy as reference standard • No blinding
EndoSure (3PCM/Endosure)	Andres et al. 2025	Participants: N=43 women aged 18 to 45 years;	Intervention: Non-invasive EVG/EndoSure	Outcomes: EndoSure sensitivity,	Literature review and	<ul style="list-style-type: none"> • Conference abstract only, no peer-reviewed full publication available

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
	Prospective validation study (conference abstract) (Partial match to scope) Brazil	(Partial match to scope) Setting: Two tertiary hospitals, Brazil (No match to scope)	(Full match to scope) Comparator: TvUS (n= 30) and/or laparoscopy (n=13) as the reference standard (Partial match to scope)	specificity, accuracy, PPV (Full match to scope) No follow-up data reported	company submission	<ul style="list-style-type: none"> • Non-UK setting • Small* sample size; only 13 patients had laparoscopy as reference standard • Surgeons and sonographers blinded to EVG test results
EndoSure (3PCM/Endosure)	Unpublished, structured, open-label, validation study by Tadpole Women's Centre (Partial match to scope) UK	Participants: N=10 adolescent females (aged 9 to 18 years) with endometriosis and elevated activity index scoring during EVG (Partial match to scope) Setting: NHS secondary care centre, UK (Partial match to scope)	Intervention: EndoSure test pre and post Ryeqo therapy (Partial match to scope) Comparator: None (No match to scope)	Outcomes: EndoSure sensitivity, specificity, PPV, NPV (Full match to scope) Follow-up with repeat EndoSure test 2 to 4 months after initiation of medication	Company submission	<ul style="list-style-type: none"> • UK setting • Independent study • Small* sample size • Subjects were blinded to EVG results • No comparator • No peer-reviewed publication available

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
EndoSure (3PCM/Endosure)	Unpublished, structured, non-randomised, comparative, open enrolment study by Sheba Hospital Medical Centre (Partial match to scope) Israel	Participants: N=55; people (aged 18 to 65 years) designated female at birth with endometriosis undergoing planned laparoscopic surgery (n=35) or people (aged 18 to 65 years) designated female at birth with no known endometriosis undergoing planned laparoscopic surgery for benign gynaecological disease (n=20, control group) (Partial match to scope) Setting: Tertiary care centre, Israel (No match to scope)	Intervention: EndoSure test (Full match to scope) Comparator: None. (No match to scope)	Outcomes: EndoSure sensitivity, specificity, accuracy, (Full match to scope) No follow-up data reported	Company submission	<ul style="list-style-type: none"> • Non-UK setting • Independent study • Modest* sample size • Surgeons were blinded to EVG results • No comparator • No peer-reviewed, publication available

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
EndoSure (3PCM/Endosure)	Unpublished, structured, randomised, blinded, surgical validation study by M. Noar et al. (Partial match to scope) Country unknown (presumed USA based on study sponsor)	Participants: N=286 people designated female at birth (aged 9 to 81 years) with (n=233) or without (n=53) endometriosis (Partial match to scope) Setting: Tertiary treatment centre, USA (No match to scope)	Intervention: EndoSure test (Full match to scope) Comparator: None. (No match to scope)	Outcomes: EndoSure sensitivity: 94.7%, specificity: 85.48%, accuracy: 91.54% (Full match to scope) No follow-up data reported	Company submission	<ul style="list-style-type: none"> • Setting uncertain • Conflict of interest: lead author is technology developer • Large* sample size • No peer-reviewed, publication available • No comparator • EVG technicians were blinded to surgical or diagnostic results
EndoSure (3PCM/Endosure)	Unpublished, structured, non-randomised, surgically validated study by Nezhat Minimally Invasive Surgery Institute (Partial match to scope) USA	Participants: N=9; n=7 people designated female at birth (aged 18 to 65 years) with endometriosis; n=2 women without endometriosis (controls) (Partial match to scope)	Intervention: EndoSure test (Full match to scope) Comparator: Unclear, diagnostic laparoscopy, possibly also transvaginal ultrasound as the reference standard	Outcomes: EndoSure sensitivity, accuracy (Full match to scope) No follow-up data reported	Company submission	<ul style="list-style-type: none"> • Non-UK setting • No peer-reviewed, publication available • Small* sample size • Surgeon blinded to EVG results before surgery • EVG technicians blinded to subjects' endometriosis status

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
		Setting: Tertiary treatment centre (No match to scope)	(Partial match to scope)			
EndoSure (3PCM/Endosure)	Unpublished, structured, non-randomised, surgically validated study by Mercy Hospital Gynaecological Surgery (Partial match to scope) USA	Participants: N=8 people assigned female at birth (aged 17 to 65 years) with pelvic pain suspected of endometriosis (Partial match to scope) Setting: Tertiary treatment centre, USA (No match to scope)	Intervention: EndoSure test (Full match to scope) Comparator: Diagnostic laparoscopy as the reference standard (Partial match to scope)	Outcomes: EndoSure sensitivity, specificity, accuracy (Full match to scope) No follow-up data reported	Company submission	<ul style="list-style-type: none"> • Non-UK setting • No peer-reviewed publication available • Small* sample size • Surgeon blinded to EVG results before surgery • EVG technicians blinded to subjects' endometriosis status
DotEndo (DotLab)	Moustafa et al. 2020 Prospective, case-control, independent validation diagnostic accuracy study	Participants: N=100 people designated female at birth (aged 18 to 49 years) with symptoms suggestive of endometriosis.	Intervention: 6-miRNA random forest classifier (miR-125b-5p, miR-150-5p, miR-342-3p, miR-451a,	Outcomes: miRNA classifier Sensitivity, specificity (Full match to scope) No follow-up data reported.	Literature review and company submission	<ul style="list-style-type: none"> • Non-UK setting • Modest* sample size • Diverse ethnic population • Independent validation cohort included

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
	(Full match to scope) USA	Following exploration by laparoscopy, patients were classified into two groups n=41 with endometriosis and n=59 without endometriosis (negative controls). The model was tested in an independent validation cohort (n=48). (Partial match to scope) Setting: Tertiary treatment centre, USA (No match to scope)	miR-3613-5p, let-7b) (Partial match to scope) Comparator: Standard clinical assessment, with diagnostic laparoscopy plus visual/histological confirmation as the reference standard (Partial match to scope)			<ul style="list-style-type: none"> • Not DotLab-funded but study lead is an option holder in DotLab • Blinded analysis
EndoTest (Ziwig)	Bendifallah et al. 2022d Prospective single-centre development	Participants: N=200 women (aged 18 to 43 years) with signs and symptoms suggestive of	Intervention: EndoTest (Full match to scope)	Outcomes: EndoTest sensitivity, specificity (Full match to scope)	Literature review and company submission	<ul style="list-style-type: none"> • Non-UK setting • Development/discovery cohort (internal cross-validation only); external validation required

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
	study (Reporting data from ENDOmiRNA study 2021; NCT04728152) (Full match to scope) France	endometriosis. Following exploration by laparoscopy and/or imaging, patients were classified into two groups: n=153 with endometriosis, n=47 without endometriosis (negative controls). (Partial match to scope) Setting: Tertiary care centre, France (No match to scope)	Comparator: Laparoscopic diagnosis with histology and/or MRI as the reference standard (Partial match to scope)	No follow-up data reported		<ul style="list-style-type: none"> • Funded by Ziwig • Large* sample size • Predominantly (48%) stage III/IV disease • Prevalence of endometriosis (77%) higher than general symptomatic population • No blinding
EndoTest (Ziwig)	Bendifallah et al. 2023 Prospective multicentre external validation study; interim analysis (Reporting data	Participants: N=200 women (aged 18 to 43 years) with formal endometriosis diagnosis or suspected endometriosis.	Intervention: EndoTest (Full match to scope) Comparator: Diagnostic laparoscopy with	Outcomes : EndoTest sensitivity, specificity, NPV (Full match to scope) No follow-up data reported	Literature review and company submission	<ul style="list-style-type: none"> • Interim analysis only; full results of same cohort published in Bendifallah et al. 2025 • Non-UK setting • External validation study

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
	from ENDOmiRNA Saliva Test study 2022; NCT05244668) (Full match to scope) France	Following exploration by laparoscopy and/or imaging, patients were classified into two groups: n=159 with endometriosis, n=41 without endometriosis (negative controls). (Partial match to scope) Setting: Four tertiary care centres and one secondary care centre, France (No match to scope)	histology and/or MRI as the reference standard (Partial match to scope)			<ul style="list-style-type: none"> • Funded by Ziwig but externally validated by Monitoring Force • Lead author consultant for Ziwig and company medical board member • Large* sample size • No overlap with development cohort • High endometriosis prevalence (80%) may not reflect typical diagnostic pathway • No blinding
EndoTest (Ziwig)	Bendifallah et al. 2025 Prospective multicentre external validation study; full results (Reporting data	Participants: N=971 women (aged 18 to 43 years) with signs and symptoms suggestive of endometriosis. Following exploration by	Intervention: EndoTest (Full match to scope) Comparator: Diagnostic laparoscopy with	Outcomes: EndoTest sensitivity, specificity, PPV, NPV, accuracy, misclassification rate (Full match to scope)	Literature review and company submission	<ul style="list-style-type: none"> • Largest validation study for EndoTest to date; published in <i>NEJM Evidence</i> (high-impact journal) • Non-UK setting

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
	<p>from ENDOmiRNA Saliva Test study 2022; NCT05244668) (Full match to scope) France (16 centres) and Canada (1 centre)</p>	<p>laparoscopy and/or imaging, patients were classified into two groups: n=749 with endometriosis, n=222 without endometriosis (negative controls) (Partial match to scope)</p> <p>Setting: 17 tertiary or secondary care centres (nine university hospitals, five general hospitals and clinics, two medical imaging centres, and one gynaecology practice), mostly in France (No match to scope)</p>	<p>histology and/or MRI/TvUS as the reference standard (Full match to scope)</p>	<p>No follow-up data reported</p>		<ul style="list-style-type: none"> • Funded by Ziwig but externally validated by Monitoring Force • Lead author consultant for Ziwig and company medical board member • High endometriosis prevalence (77%) not representative of general population • Assessors were blinded to imaging/surgery findings

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
EndoTest (Ziwig)	Ferrier et al. 2023 Cost-effectiveness analysis (Full match to scope) France	Participants: Women with chronic pelvic pain (Partial match to scope) Setting: French healthcare system (Partial match to scope)	Intervention: EndoTest incorporated into three diagnostic strategies: 1. All patients have EndoTest 2. People with negative ultrasound have an EndoTest 3. People with negative ultrasound and negative MRI have an EndoTest (Full match to scope) Comparator: Standard French diagnostic algorithm (ultrasound with/without MRI or with/without laparoscopy) (Partial match to scope)	Outcomes: EndoTest sensitivity/specificity (secondary data), cost, ICERs (Full match to scope) No follow-up data reported	Literature review and company submission	<ul style="list-style-type: none"> Economic modelling study based on diagnostic performance from development cohort (Bendifallah et al. 2022d) French healthcare costs; not directly applicable to UK NHS setting Indicates potential economic value of EndoTest when used alongside standard imaging Independent study, although one author is employed by Ziwig

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
EndoTest (Ziwig)	Nigdelis et al. 2025 Open web-based survey study (Partial match to scope) Germany	Participants: N=141/190 respondents (>75% completion), members of German gynaecological endoscopy (AGE), endometriosis (AGEM) societies and endometriosis research foundation (SEF) (No match to scope) Setting: Online survey of healthcare providers, Germany (No match to scope)	Intervention: EndoTest (Full match to scope) Comparator: None (No match to scope)	Outcomes: Clinician-reported outcomes, EndoTest cost (Partial match to scope) No follow-up data reported	Literature review	<ul style="list-style-type: none"> • Survey only, not a diagnostic accuracy study • Provides evidence on clinical adoption barriers and healthcare provider attitudes in a European but non-UK setting • Very few respondents had experience with the test (n=21/141, 15%)
EndoTest (Ziwig)	Rogalska and Brukała 2025 Desk-based comparative market assessment	Participants: Data collected in September 2024 from Polish private healthcare market	Intervention: Comparative assessment of commercially available endometriosis	Outcomes: EndoTest sensitivity/specificity (secondary outcomes) and cost (Full match to scope)	Literature review	<ul style="list-style-type: none"> • Desk-based market analysis, not a diagnostic accuracy study • None of the blood-based tests in Poland achieved sensitivity or specificity

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
	(Partial match to scope) Poland	(No match to scope) Setting: N/A (market analysis) (No match to scope)	diagnostic tests in Poland: two imaging techniques (TvUS, MRI) and three blood-based tests, including EndoTest (Partial match to scope) Comparator: Compliance assessed against 2022 ESHRE guidelines (No match to scope)	No follow-up data reported		>90%, which is contradictory to the EndoTest results reported in cited study (Bendifallah et al. 2022d) <ul style="list-style-type: none"> • By contrast, imaging techniques met the >90% sensitivity and specificity criteria • Provides context on availability and cost in Polish private market; not necessarily generalisable to NHS
EndoTest (Ziwig)	Moawad 2026a Unpublished conference abstract accepted for presentation at the Society of Gynaecologic Surgeons (SGS) 52 nd Annual	Participants: N=556 women (aged 18 to 43 years) with symptoms suggestive of endometriosis (n=332 patients with SPE, n=216 negative controls) (Partial match to scope)	Intervention: 109-miRNA panel (EndoTest) (Full match to scope) Comparator: Diagnostic laparoscopy with histology and/or MRI/TvUS as the reference standard	Outcomes: EndoTest sensitivity, specificity, accuracy. (Full match to scope) No follow-up data reported	Company submission	<ul style="list-style-type: none"> • This is a subgroup analysis of the ENDOmiRNA Saliva Test study 2022 focusing on the performance of EndoTest in the diagnosis of SPE, a common, yet challenging to diagnose endometriosis phenotype • EndoTest outperformed conventional imaging in

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
	Scientific Meeting (Partial match to scope) France	Setting: Tertiary and secondary care centres, France (No match to scope)	(Full match to scope)			<p>sensitivity while preserving high specificity</p> <ul style="list-style-type: none"> Other points as for ENDOmiRNA Saliva Test study 2022 entry
EndoTest (Ziwig)	Moawad 2026b Unpublished conference abstract accepted for presentation at the American and Global College of Endometriosis Specialists (AGCES) Annual meeting (Partial match to scope) France	Participants: N=1,000 women (aged 18 to 43 years) with signs or symptoms suggestive of endometriosis; Three subgroups evaluated: 1. Infertile endometriosis patients vs all control 2. Infertile endometriosis patients vs nulliparous controls 3. Infertile endometriosis patients with SPE phenotype only or with SPE and deep	Intervention: 109-miRNA panel (EndoTest) (Full match to scope) Comparator: Diagnostic laparoscopy with histology and/or MRI/TvUS as the reference standard (Full match to scope)	Outcomes: EndoTest sensitivity, specificity, accuracy. (Full match to scope) No follow-up data reported	Company submission	<ul style="list-style-type: none"> This is a subgroup analysis of the ENDOmiRNA Saliva Test study 2022 focusing on the performance of EndoTest in the diagnosis of endometriosis in infertile patients. EndoTest maintained accuracy regardless of fertility status and could reliably discriminate between infertile women with endometriosis from those without endometriosis. In this setting the prevalence of endometriosis ranged from 21% to 66% (considerably lower than previous EndoTest)

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcome measures and follow-up	Source	EAG comments
		<p>endometriosis phenotype vs controls. (Partial match to scope)</p> <p>Setting: Tertiary and secondary care centres, France (No match to scope)</p>				<p>diagnostic validation studies)</p> <ul style="list-style-type: none"> • Other points as for ENDOmiRNA Saliva Test study 2022 entry

*Common working definitions of samples sizes: small = <50, moderate = 50 to 200, large= >200

Abbreviations: AI, artificial intelligence; AIET, GIMA-derived 2 stage AI-determined threshold; ESHRE, European Society of Human Reproduction and Embryology; EVG, electroviscerography/electroviscography; GIMA, gastrointestinal myoelectrical activity; ICER, incremental cost-effectiveness ratio; miRNA, micro RNA; MRI, magnetic resonance imaging; NPV, negative predictive value; PPV, positive predictive value; SPE, superficial peritoneal endometriosis; TvUS, transvaginal ultrasound; WLST, water load satiety test

5 Clinical evidence review

5.1 Quality appraisal of studies

A formal risk of bias assessment was not undertaken, as this is not a requirement for an early use assessment (see [protocol](#)). However, the main quality concerns across the included studies for each technology were informally assessed by loosely using the [QUADAS-2](#) framework. QUADAS-2 is a tool used for assessing risk of bias in diagnostic test accuracy studies. It assesses risk of bias in the following four domains:

- Patient selection: risk of inappropriate exclusions, case-control design, or spectrum bias
- Index test: risk of unblinded interpretation, threshold setting on training data, or conflict of interest
- Reference standard: risk from non-laparoscopic or differential verification
- Flow and timing: risk from incomplete follow-up, inappropriate intervals, or missing data. Applicability concerns reflect whether the study populations, index tests, and reference standards match the NHS endometriosis diagnostic pathway.

Applicability concerns (i.e., the extent to which the study populations, index tests, and reference standards correspond to the decision problem outlined in the [scope](#)) were also assessed for each domain. A summary of the quality appraisal results is provided in **Appendix D**. The main quality concerns across the included studies for each technology are summarised narratively below.

EndoSure

Out of the five published studies included in this early use assessment for EndoSure, the two studies with more complete reporting (Noar et al. 2024a, 2024b) were the primary basis for the quality assessment; the three conference abstracts provided insufficient methodological detail for appraisal.

Patient selection: Noar et al. 2024a and Noar et al. 2024b reported a multicentre prospective blinded design (N=154 and N=50, respectively), recruiting participants with suspected endometriosis pending laparoscopy. While the studies describe prospective enrolment, the extent to which consecutive or random sampling was employed is not clearly reported. The restriction to people already scheduled for laparoscopy creates a risk of verification bias (occurs when a gold-standard test is only applied to a subset of people based on their index test results), as only those with sufficiently severe symptoms to warrant surgery were tested. The risk of bias in this domain is judged unclear

for Noar et al. 2024a and Noar et al. 2024b. The applicability concern is judged high for both studies, as they were conducted exclusively in US specialist women's health centres, recruiting a surgical population. In the present assessment, EndoSure is positioned as a pre-referral, pre-laparoscopy triage tool for people with suspected endometriosis and negative imaging in primary care; this population will have a substantially lower endometriosis prevalence (43% prevalence was calculated from data presented in Table 6 of Khan et al. 2018) than the highly selected surgical cohort studied.

Index test: The EVG result was interpreted using an AI-derived algorithmic threshold score; Noar et al. 2024a and Noar et al. 2024b report that clinicians and EVG technicians were blinded to each other's results and to surgical findings at the time of the EVG assessment. This reduces the risk of bias from the non-blinded interpretation of the index test. However, a major concern is the conflict of interest: in both studies, the lead author (M. Noar) is disclosed as the founder of 3PCM/Endosure (the technology manufacturer). This represents a considerable source of performance bias that affects all published EndoSure diagnostic accuracy data. No external, manufacturer-independent validation study has been published. The risk of bias in this domain is judged high for both studies. The applicability concern is also judged high for the two studies, as the performance of EndoSure has not been evaluated using assessors without a commercial conflict of interest.

Reference standard: Both studies used diagnostic laparoscopy with visual identification of endometriosis and histological biopsy as the reference standard, which is the accepted gold standard for the target condition. Laparoscopy was performed by high-volume endometriosis surgeons and included complete peritoneal evaluation. The risk of bias from the reference standard is judged low. The applicability concern is also judged low for both studies as diagnostic laparoscopy is the accepted gold standard for endometriosis in NHS clinical practice.

Flow and timing: The included studies report that EVG was performed prior to laparoscopy. The interval between EVG and surgery is not explicitly quantified but is described as occurring in the preoperative period. All enrolled people appear to have received both the index test and the reference standard, and no information is provided on withdrawals. The risk of bias in this domain is judged unclear.

DotEndo

One peer-reviewed diagnostic accuracy study is included for DotEndo (Moustafa et al. 2020, N=100).

Patient selection: The study recruited women with a clinical indication for gynaecological surgery from a single academic medical centre in the USA. People were selected based on the presence of symptoms rather than by consecutive sampling, which introduces a risk of selection bias. The study used a case-enrichment approach in a surgical population; however, the endometriosis prevalence in the study was 41%, which is more representative of a surgical referral population in NHS primary care (43% calculated from data presented in Table 6 of Khan et al. 2018) than the studies included for the other two technologies. The risk of bias in this domain is judged unclear. The applicability concern is judged unclear for this study, because although the prevalence of endometriosis is similar to that expected in a primary care NHS population, the control group (predominantly people with uterine leiomyoma) does not reflect the range of differential diagnoses (e.g., large symptom overlap with adenomyosis) typically encountered in the NHS diagnostic pathway.

Index test: Serum miRNA levels were measured by researchers blinded to surgical findings. The classifier algorithm was developed using a random forest model applied to the same dataset, with internal validation by random subsampling cross-validation and an independent hold-out set. However, the threshold for the classifier was determined using the training data, introducing optimism bias in the reported accuracy estimates. No independent, prospective validation in a new patient cohort (separate from the development data) has been published for the current DotEndo product. Although the study did not receive company funding, the lead author is an option holder in the company. The risk of bias in this domain is judged high due to internal algorithm development. The applicability concern is judged high as the miRNA panel and AI classifier were developed and validated in the same cohort using internal cross-validation.

Reference standard: Laparoscopy with visual confirmation and pathology was used as the reference standard. The reference standard was determined by the surgical team, and miRNA analysis was performed blinded to surgical findings. The risk of bias from the reference standard is judged low. The applicability concern is also judged low as diagnostic laparoscopy is the accepted gold standard in NHS practice.

Flow and timing: Serum samples were collected prior to surgery. All 100 enrolled people appear to have received both the index test and the reference standard. The risk of bias in this domain is judged low.

EndoTest

Three diagnostic accuracy studies are included for EndoTest: the development cohort (Bendifallah et al. 2022d, N=200), the interim external validation (Bendifallah et al. 2023, N=200), the full external validation (Bendifallah et al.

2025, N=971). This narrative description of the quality assessment focuses primarily on Bendifallah et al. 2025, which is the most methodologically complete and largest study; the quality assessment summaries for the other EndoTest studies are presented in **Appendix D**.

Patient selection: Bendifallah et al. 2025 recruited people aged 18 to 43 years with signs and symptoms suggestive of endometriosis from 17 centres in France and Canada between November 2021 and January 2023. The prospective, multicentre design and the use of diverse medical settings (gynaecology, general medicine, specialist endometriosis centres) reduce the risk of spectrum bias relative to the EndoSure and DotEndo studies. The inclusion criteria were applied consistently across sites. Patients with a history of prior surgery for endometriosis were excluded, which limits applicability to treatment-naïve people but reduces the risk of differential verification. The primary applicability concern is the high prevalence of endometriosis in the study population (77%), which is substantially higher than the expected prevalence in NHS primary or early secondary care (43% calculated from data presented in Table 6 of Khan et al. 2018) and would inflate the positive predictive value (PPV) and reduce the negative predictive value (NPV) reported in the study relative to what would be expected in the intended NHS pathway. The risk of bias in this domain is judged low for the Bendifallah et al. 2025 study, however, the applicability concern regarding prevalence is judged high.

Index test: The saliva miRNA signature was assessed blinded to people's endometriosis status as determined by imaging, laparoscopy, and/or histology. In the reference standard assessment, practitioners were blinded to the miRNA signature results. The threshold for the random forest classifier was pre-specified from the development cohort (Bendifallah et al. 2022d) and applied without modification to the external validation cohort, reducing the risk of threshold optimism. Independent oversight of data integrity was provided by [Monitoring Force](#), an independent entity mandated by the sponsor. The study was funded by Ziwig (the manufacturer), which represents a conflict of interest. In addition, the lead author on all three EndoTest publications (S. Bendifallah) received consultancy fees from Ziwig for the 2023 and 2025 studies and is a member of the Medical Board of the company. The use of independent data monitoring, investigator blinding, and academic authorship team partially mitigates this concern relative to fully company-run studies. The risk of bias in this domain is therefore judged unclear for Bendifallah et al. 2025. The applicability concern is judged low for (Bendifallah et al. 2023) and (Bendifallah et al. 2025) but judged high for (Bendifallah et al. 2022d) (the development study).

Reference standard: Patients in the control group all underwent laparoscopy with visual confirmation and histology as the reference standard. Among people

classified as having endometriosis, those with imaging evidence of endometrioma or colorectal deep endometriosis (as determined by MRI/ultrasound, confirmed by a multidisciplinary committee) did not all undergo laparoscopy; this was justified by reference to Cochrane evidence on imaging accuracy for these subtypes. This introduces a differential verification concern as not all people received the same reference standard, which could affect estimates of sensitivity and specificity, particularly for deep infiltrating and ovarian endometriosis. The risk of bias in this domain is judged unclear. The applicability concern is judged unclear across all three studies as a mixed reference standard was used and not all people underwent laparoscopy verification.

Flow and timing: Saliva samples were collected in the preoperative or pre-imaging period. The interval between saliva collection and the reference standard procedure is not precisely quantified. The study reports 971 people in the final analysis; the number of people enrolled but not included in the final analysis is not clearly stated. The risk of bias in this domain is judged unclear.

Cross-cutting applicability concerns

Risk of bias was judged high across all three technologies. The most significant applicability concern is that no included study was conducted in a primary care UK NHS setting, and the study populations (recruited from specialist surgical or gynaecology centres with a clinical indication for laparoscopy) do not reflect the expected patient mix in NHS primary care or early secondary care, where endometriosis prevalence (and potentially symptom severity) will be lower. All three technologies are intended as decision-support tools for people with suspected endometriosis and equivocal or unavailable imaging; however, none of the included studies enrolled people in this specific NHS diagnostic pathway context. At lower endometriosis prevalences, the published PPVs and NPVs are likely to be less favourable. The extrapolation of published diagnostic accuracy estimates to the NHS diagnostic pathway therefore requires caution.

5.2 Results from the evidence base

The results from the evidence base are summarised in **Tables 4 to 6** by technology and outcome domain. A narrative synthesis of the key findings is provided below and in Section 6.1; a comprehensive summary and interpretation of the evidence is provided in Section 5.4.

5.2.1 Population and subgroups

The study population typically consisted of women, or people assigned female at birth, presenting with signs or symptoms suggestive of endometriosis. In

most cases study participants formed part of a surgical population, which had a high (77% to 80%) prevalence for endometriosis.

The test validation nature of the included studies and the age restrictions listed in the indications for DotEndo and EndoTest also meant that there was limited evidence relating to many of the subgroups listed in the [scope](#). Two studies submitted as unpublished conference abstracts by EndoTest reported subgroup analyses for individuals with superficial peritoneal endometriosis (SPE) or infertility (see **Table 18** in Section 8). Three ongoing studies (two for EndoSure and one for EndoTest) considered the utility of the diagnostic tests in adolescents (see **Table 3**, **Table 17**, and **Table 19**). No data were available for the following subgroups: perimenopausal and postmenopausal people, people with higher body mass index, and people who find a transvaginal ultrasound (TvUS) unacceptable.

5.2.2 Clinical outcomes

Clinical outcomes are presented in **Table 4**. The majority of the included studies (15/16, 94%) only reported diagnostic accuracy data. No studies reported the following clinical outcomes listed in the [scope](#): time taken from initial presentation to referral to specialist services, impact of false positives, time taken to diagnosis, time taken to starting treatment, number of hospital attendances (including admissions and emergency department attendances), and number of primary care consultations.

For EndoSure, diagnostic accuracy data were available from five studies, consisting of two peer-reviewed published full-text articles (Noar et al. 2024a, 2024b) and three published conference abstracts (Andres et al. 2025; Tanos et al. 2025; Noar 2022). The published studies reported high sensitivity (91% to 100%) and specificity (95% to 100%) for the detection of endometriosis using gastrointestinal myoelectrical activity (GIMA) biomarkers. The C-statistic exceeded 99% and 98% for the two age subgroups evaluated in Noar et al. 2024a, and a sensitivity, specificity, PPV, and NPV of 96% (for all) are reported in the interim Noar et al. 2024b study. However, two of the three conference abstracts reported markedly lower specificity (0% and 5%), with a diagnostic accuracy of 96%, driven primarily by high sensitivity (100% for both) in a population with a very high prevalence of endometriosis, suggesting that these data may reflect early-stage studies with different methodology or patient selection criteria. Five unpublished abstracts submitted by the company following the RFE and originating from the USA (three studies), Israel, and UK, also reported consistently high sensitivities (92% to 100%) but a wide range of specificities (0%, 5%, 67%, 85%, and 96%). The three studies by Noar et al. reported that hormonal therapy (Noar 2022), surgical stage, pain score (Noar

et al. 2024a), and age (Noar et al. 2024b) did not affect diagnostic accuracy. Information on the effect of these parameters on test accuracy was not available for the remaining studies.

For DotEndo, a single peer-reviewed study (Moustafa et al. 2020, N=100) reported a sensitivity (83%; 90% balanced threshold sensitivity) and a specificity (96%; 90% balanced threshold specificity) for a six-miRNA serum panel, which is used in the current commercial DotEndo (specifically DotEndo 2) product. Subgroup analysis revealed that neither phase of the menstrual cycle nor use of hormonal medication had a significant impact on the expression levels of the miRNAs used in the algorithm.

For EndoTest, five diagnostic accuracy studies were included: the development cohort (Bendifallah et al. 2022d, N=200), interim external validation data (Bendifallah et al. 2023, N=200), full external validation results (Bendifallah et al. 2025, N=971), which essentially supersedes the interim study, and two unpublished conference abstracts presenting subgroup analysis results from the same validation cohort for people with SPE (Moawad 2026a) or infertility (Moawad 2026b). The largest published study (Bendifallah et al. 2025) reported an overall sensitivity of 97.3%, specificity of 94.1%, PPV of 98.2%, and NPV of 91.3% for the 109-miRNA saliva signature on which EndoTest is based. Subgroup analyses suggested consistently high performance across endometriosis stages (including stage I/II), age groups, and people on hormonal therapy. The test also performed well in detecting SPE (sensitivity=96% and specificity=95%) and endometriosis in people with infertility (sensitivity=97% and specificity=94%).

A survey study of >100 German gynaecologists (75% of whom considered themselves endometriosis experts) (Nigdelis et al. 2025) was also included in the evidence base as it provided insights on the attitudes of clinicians towards EndoTest. Although this study did not report primary clinical outcomes, it did give an indication of how EndoTest could impact laparoscopy referral practices, with most respondents agreeing that they would initiate medical treatment in case of symptoms suggestive of endometriosis, independent of the result of the test.

Two studies included in the clinical evidence review (Ferrier et al. 2023; Rogalska and Brukało 2025) reported secondary diagnostic accuracy data for EndoTest, with the primary data for both originating from Bendifallah et al. 2022d. As such, these studies are not listed in **Table 4** (reporting clinical outcomes) but are instead presented in **Table 6** (reporting resource use and cost outcomes) in Section 6.1.

Table 4 Summary of clinical outcomes reported in the included studies

Technology (manufacturer)	Study	Publication status	Diagnostic accuracy	Test sensitivity	Test specificity	PPV / NPV	Referrals for laparoscopy	Other outcome/Comments
EndoSure (3PCM/Endosure)	Noar 2022	Published (abstract only)	100%	100%	100%	NR	NR	<ul style="list-style-type: none"> • AIET scores ranged from 0.52 to 8.9 (threshold >0.5). • Hormonal suppression did not affect diagnosis.
EndoSure (3PCM/Endosure)	Noar et al. 2024a	Published	NR	95%/91% (age subsets ≤35/≥36 years)	96%/95% (age subsets ≤35/≥36 years)	PPV: 95%/91% NPV: 96%/95% (age subsets ≤35/≥36 years)	NR	<ul style="list-style-type: none"> • C-statistic >99%/98% for age subsets. • Hormonal therapy, surgical stage and pain score did not affect diagnostic accuracy.
EndoSure (3PCM/Endosure)	Noar et al. 2024b	Published	NR	96%	96%	PPV: 96% NPV: 96%	NR	<ul style="list-style-type: none"> • C-statistic 100%, regardless of age or pain scores. • Hormonal therapy, surgical stage, age, and pain score did not affect diagnostic accuracy.

Technology (manufacturer)	Study	Publication status	Diagnostic accuracy	Test sensitivity	Test specificity	PPV / NPV	Referrals for laparoscopy	Other outcome/Comments
EndoSure (3PCM/Endosure)	Tanos et al. 2025	Published (abstract only)	96% (preliminary, May 2025)	100%	5%	NR	12/100 patients underwent diagnostic laparoscopy (positive EndoSure + negative MRI/TvUS). Unknown whether they referred based on EndoSure result.	The company has updated their request for information submission to say that the 5% specificity figure presented in the published abstract should have been 'unquantifiable' as no normal cases were evaluated in the study.
EndoSure (3PCM/Endosure)	Andres et al. 2025	Published (abstract only)	Vs laparoscopy: 92% Vs TvUS: 47%	Vs laparoscopy: 100% Vs TvUS: 82%	Vs laparoscopy: 0% Vs TvUS: 26%	Vs laparoscopy, PPV: 92% Vs TvUS, PPV: 39%	NR	EVG demonstrated high sensitivity but low specificity when compared to both laparoscopy and ultrasound. Its best performance was observed in high-prevalence settings.
EndoSure (3PCM/Endosure)	Study by Tadpole Women's Centre	Unpublished	NR	100%	67%	PPV: 88% NPV: 100%	NR	None
EndoSure (3PCM/Endosure)	Study by Sheba Hospital Medical Centre	Unpublished	98%	92%	96%	NR	NR	None

Technology (manufacturer)	Study	Publication status	Diagnostic accuracy	Test sensitivity	Test specificity	PPV / NPV	Referrals for laparoscopy	Other outcome/Comments
EndoSure (3PCM/Endosure)	Study by M. Noar et al.	Unpublished	92%	95%	85%	NR	NR	None
EndoSure (3PCM/Endosure)	Study by Nezhat Minimally Invasive Surgery Institute	Unpublished	100%	100%	100% (only two normal cases evaluated)	NR	NR	Company updated the numbers in the RFE submission
EndoSure (3PCM/Endosure)	Study by Mercy Hospital Gynaecological Surgery	Unpublished	100%	100%	100% (only one normal case evaluated)	NR	NR	Company updated the numbers in the RFE submission
DotEndo (DotLab)	Moustafa et al. 2020	Published	NR	83% (specificity-optimised) (90% balanced threshold)	96% (specificity-optimised) (90% balanced threshold)	NR	NR	<ul style="list-style-type: none"> AUC 0.939 (6-miRNA serum algorithm). Individual miRNA AUCs: 0.68 to 0.92. Validation set n=48 Subgroup analysis revealed that neither phase of the menstrual cycle or use of hormonal medication had a significant impact on the

Technology (manufacturer)	Study	Publication status	Diagnostic accuracy	Test sensitivity	Test specificity	PPV / NPV	Referrals for laparoscopy	Other outcome/Comments
								expression levels in the miRNAs used in the algorithm.
EndoTest (Ziwig)	Bendifallah et al. 2022d	Published	NR	97%	100%	NR	NR	<ul style="list-style-type: none"> AUC 98.3% (range: from 79.9% to 98.4% across 10 cross-validation datasets). Internal validation only.
EndoTest (Ziwig)	Bendifallah et al. 2023 (Interim analysis; final results in Bendifallah et al. 2025)	Published	>92% (across all centres)	96% (95% CI 94% to 97%)	95% (95% CI 85% to 99%)	PPV: 95% (95% CI 85% to 99%) NPV: 87% (95% CI 78% to 90%)	NR	PLR 19.7 (95% CI 6.3 to 108.8); NLR 0.04 (95% CI 0.03 to 0.07); AUC 0.96 (95% CI 0.92 to 0.98).
EndoTest (Ziwig)	Bendifallah et al. 2025	Published	97% (95% CI 95% to 98%)	97% (95% CI 96% to 98%)	94% (95% CI 91% to 96%)	PPV: 98% (95% CI 97% to 99%) NPV: 91% (95% CI 88% to 93%)	NR	<ul style="list-style-type: none"> PLR 16.6 (95% CI 10.8 to 26.9); NLR 0.03 (95% CI 0.02 to 0.04). Multicentre (n=14 centres). Subgroup*: rASRM I/II sensitivity 95.1%, specificity 94.1%.

Technology (manufacturer)	Study	Publication status	Diagnostic accuracy	Test sensitivity	Test specificity	PPV / NPV	Referrals for laparoscopy	Other outcome/Comments
								<ul style="list-style-type: none"> The performance of the saliva miRNA signature did not appear to be influenced by age, hormonal treatment, or analgesia treatment.
EndoTest (Ziwig)	Nigdelis et al. 2025	Published	NR	97% (cited from Bendifallah et al. 2022d)	100% (cited from Bendifallah et al. 2022d)	NR	Survey of 141 German gynaecologists#: 25% would use before laparoscopy; 34.0% laparoscopy only if pronounced symptoms; 7.8% laparoscopy in all cases; 45.4% laparoscopy only if pronounced symptoms (pre-op testing).	Survey study of clinician attitudes to test use; no primary diagnostic accuracy data.
EndoTest (Ziwig)	Moawad 2026a (SGS abstract)	Unpublished	Overall: 96.0% (95% CI 94% to 98%)	Overall: 97% (95%)	Overall: 94% (95%)	Overall PPV: 96.4% (95% CI	NR	Subgroup analysis of individuals with SPE using data from

Technology (manufacturer)	Study	Publication status	Diagnostic accuracy	Test sensitivity	Test specificity	PPV / NPV	Referrals for laparoscopy	Other outcome/Comments
			In confirmed SPE subgroup: 95% (95% CI 92% to 97%),	CI 95% to 98%) In confirmed SPE subgroup: 96% (95% CI 90% to 99%)	CI 92% to 96%) In confirmed SPE subgroup: 95% (95% CI 93% to 96%)	95% to 98%) NPV: 95% (95% CI 93% to 97%) In confirmed SPE group: PPV: 88% (95% CI 82% to 90%) 99% (95% CI 96% to 100%)		ENDOMiRNA Saliva Test study 2022
EndoTest (Ziwig)	Moawad 2026b (AGCES abstract)	Unpublished	Overall [§] : 95% (95% CI: 93% to 97%)	Overall [§] : 96.7% (95% CI: 94% to 96%)	Overall [§] : 94% (95% CI: 92% to 96%)	Overall [§] : PPV: 93% (95% CI: 90% to 95%) NPV: 97% (95% CI: 95% to 99%)	NR	Subgroups analysis of individuals with infertility using data from ENDOMiRNA Saliva Test study 2022

* The accuracies of the saliva miRNA signature and imaging examination by TvUS and/or MRI, as calculated from the study data, are reported for the overall surgical population (n=591), for a subgroup with rASRM stage I and II (n=446), and for a subgroup of complex diagnostic cases (n=284)

Situation 1: If a person presents with endometriosis symptoms (e.g., dysmenorrhoea) and a positive EndoTest result, 34% recommended laparoscopy only if the symptoms were pronounced; 8% recommended laparoscopy in all cases. Situation 2: If a person presents with endometriosis symptoms (e.g., dysmenorrhoea), a normal ultrasound result, and a negative EndoTest result, 45% recommended laparoscopy only if the symptoms were pronounced; 2.8% recommended laparoscopy in all cases.

§ Diagnostic accuracy data for two other sub-analyses also available.

Abbreviations: AIET, GIMA-derived 2 stage artificial-intelligence-determined threshold; AUC, area under the receiver operator characteristic curve; CI, confidence interval; EVG, electroviscerography/electroviscography; GIMA, gastrointestinal myoelectrical activity; ICER, incremental cost-effectiveness ratio; miRNA, micro RNA; MRI, magnetic resonance imaging; NLR, negative likelihood ratio; NPV, negative predictive value; NR, not reported; PLR, positive likelihood ratio; PPV, positive predictive value; rASRM, revised American Society for Reproductive Medicine; RFE, Request for evidence; SPE, superficial peritoneal endometriosis; TvUS, transvaginal ultrasound

5.2.3 Patient- and clinician-reported outcomes

Two studies presented patient- or clinician-reported outcomes (**Table 5**). Only one study, a conference abstract, reported patient-reported outcome measures (PROMs), stating that 60% of patients preferred EndoSure over TvUS (Tanos et al. 2025). Clinician-reported outcomes were not listed within the [scope](#) but included under the provision that any additional outcomes relevant to the decision problem may be considered by the EAG (see Table 1 of the [protocol](#)).

The second study (Nigdelis et al. 2025), a peer-reviewed full-text publication, reported clinician attitudes towards EndoTest. Clinician feedback indicated generally limited support for adopting the test; however, the results should be interpreted with caution as only 15% of the respondents reported having conducted the test in clinical practice, which likely contributed to scepticism and reluctance to change established clinical practices. Most respondents felt that the cost of the test was prohibitive (especially if insurance coverage was limited), did not believe that the test could replace standard diagnostic tools, and considered that EndoTest could neither confirm nor screen for endometriosis. The reluctance to adopt EndoTest stemmed from a combination of factors. Many clinicians cited a lack of robust external validation studies, especially outside of France, and questioned the generalisability of the test's results to their patient populations. However, the Nigdelis et al. 2025 study was conducted based on findings from Bendifallah et al. 2023 and before the full results of the Bendifallah et al. 2025 study became available. There were also concerns about the lack of evidence for use in specific subgroups, such as adolescents, those with infertility, or people of different ethnicities. A considerable proportion of clinicians were unsure how to interpret test results or how these results should influence management, particularly in the absence of clear guidelines. This uncertainty was heightened by the fact that most had not used the test themselves. Some respondents worried that the test could lead to overdiagnosis, unnecessary anxiety, or overtreatment, especially if used as a screening tool in asymptomatic people. There was also concern that a positive test would not necessarily change the therapeutic approach, as most clinicians would still rely on symptoms and imaging. Opinions on where the test fits in the diagnostic pathway were split, though many felt it might be useful only under specific circumstances, such as in adolescents or when ultrasound or MRI results were negative (the latter of which is in line with the scope for this early use assessment). Less experienced gynaecologists were more open to test adoption than experts, and among the small proportion with hands-on experience, most reported positive patient feedback. Overall, few clinicians had used the test, and most did not anticipate changing current clinical practice. Moreover, clinical expert feedback gathered during this early use assessment highlighted that, as this study was a survey of specialist gynaecologists, the

findings may not be extrapolatable to primary care, where the test is intended to sit.

No PROM data are available for DotEndo or EndoTest and no studies reported the following outcomes that were listed in the scope: pain, symptom burden, quality of life (QoL), level of daily function, ease of use or acceptability for patients and carers.

Table 5 Patient- or clinician-reported outcome results from included studies

Technology (manufacturer)	Study	Publication status	Patient or clinician experience	Other patient/clinician-reported outcomes/comments
EndoSure (3PCM/Endosure)	Tanos et al. 2025	Published (abstract only)	60% of patients (N=100) preferred EndoSure over TvUS; 1% preferred TvUS.	None
EndoTest (Ziwig)	Nigdelis et al. 2025	Published	<ul style="list-style-type: none"> • 96% of surveyed clinicians found test costs high (63% found them too high) • 84% did not believe test replaces standard diagnostic tools • Responses were evenly divided on the subject of test placement (initially, before laparoscopy, before initiating therapy, on suspicion on recurrence, before initiating fertility treatment) • The majority (50%) found that the test should be used under specific circumstances • Most (58%) said that the test could not be used to confirm the diagnosis of endometriosis and 69% said that the test could not be used as a screening tool for endometriosis • The majority (48%) said that they would conduct the test if the patient had a negative ultrasound or MRI result for endometriosis 	<ul style="list-style-type: none"> • Conclusions: German healthcare providers would likely not change current clinical practice, even though they acknowledged that the test could be used under specific circumstances (e.g., in adolescents). • Only 15% of participants reported actually having experience with the salivary test.

			<ul style="list-style-type: none"> • 86/141 (61%) supported using the test in adolescents • Less experienced gynaecologists were more positive about test adoption than experts • Most (18%) clinicians who had used the test said that their patients had a positive experience with the test (vs 2% who said their patients had a negative experience). 	
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Abbreviations: MRI, magnetic resonance imaging; TvUS, Transvaginal ultrasound

5.2.4 Resource use and cost outcomes

Evidence from studies identified in the literature search that reported resource use and cost outcomes is presented in Section 6.1.

5.3 Adverse events and clinical risk

None of the included clinical studies for any of the three technologies reported adverse events directly attributable to the diagnostic test itself as an outcome. No safety signals, device-related incidents, field safety corrective actions, or product recalls have been identified in a search of publicly available regulatory and vigilance databases (including the Medicines and Healthcare products Regulatory Agency [MHRA], the US Food and Drug Administration Manufacturer and User Facility Device Experience [FDA MAUDE], and Swissmedic) for EndoSure, DotEndo, or EndoTest and related terms.

As non-invasive or minimally invasive diagnostic tests, the clinical risk profile of all three technologies is expected to be low. EndoSure involves the placement of abdominal surface electrodes and oral ingestion of water; no tissue is collected, and no reported physical adverse events are attributable to the procedure. DotEndo requires standard venepuncture for blood collection, which carries the risks associated with routine phlebotomy (bruising, haematoma, vasovagal response); no additional clinical risks are introduced by the test itself. EndoTest requires collection of a saliva sample, which is entirely non-invasive and associated with no physical risk.

The primary clinical risks for all three technologies relate to diagnostic errors rather than device-related harms. False-negative results could delay diagnosis and appropriate treatment for endometriosis, while false-positive results could lead to unnecessary further investigation (including invasive diagnostic laparoscopy). All three manufacturers specify that their tests are intended as adjuncts to clinical assessment, not standalone diagnostics, and provide explicit guidance that a negative result does not exclude endometriosis. These risk mitigations are consistent with their use as decision-support tools within a broader clinical pathway. Were these technologies to be used in the NHS during early adoption, clear clinical governance frameworks would need to be established to ensure appropriate clinical decision-making alongside test results, particularly for borderline or discordant findings.

No technical failures were identified in the published literature or company submissions for any of the three technologies.

5.4 Clinical evidence summary and interpretation

Summary of the evidence

The clinical evidence base for the three technologies under assessment is early-stage, with diagnostic accuracy as the primary outcome across all included studies. No primary care or UK NHS data are available for any technology, and no studies have evaluated the downstream impact of test use on other clinical outcomes included in the scope (e.g., time to diagnosis, diagnostic laparoscopy rates, hospital stay) or PROMs.

EndoSure has published diagnostic accuracy data from two peer-reviewed studies (Noar et al. 2024a, 2024b) [Click or tap here to enter text.](#), both originating from the US and led by the technology developer. The reported diagnostic accuracy is high (sensitivity 91% to 96%, specificity 95% to 96%) but is subject to risk of bias due to the conflict of interest, single-centre US origin, and lack of independent validation. The preliminary independent results from Andres et al. 2025 and Tanos et al. 2025 (both published as conference abstracts), which reported EndoSure specificities of 0% (vs laparoscopy) and 5%, respectively, (with sensitivity of 100% for both), highlight uncertainty about performance consistency across settings. Although the company-submitted unpublished abstracts for five more diagnostic accuracy studies (one of which originated from the UK), none of these have been peer reviewed and can only be considered as preliminary evidence. Similarly to Andres et al. 2025 and Tanos et al. 2025, these studies reported a wide range of specificities, which were not entirely consistent with the high specificity reported by the published full-text validation studies or the Noar 2022 published conference abstract. Two UK-NHS-based studies are ongoing (see **Table 19**).

The evidence base for DotEndo consists of a single published diagnostic accuracy study (Moustafa et al. 2020). Results from the large-scale EMPOWER study 2020 are expected [REDACTED]. A UK NHS pilot study is planned, subject to UKCA approval (see **Table 19**).

EndoTest has the largest evidence base, with three published, peer-reviewed diagnostic accuracy studies, two survey-based studies, and two company-submitted unpublished conference abstracts. The full external validation study (Bendifallah et al. 2025) demonstrated consistently high sensitivity (97%) and specificity (94%) across endometriosis subtypes and patient subgroups, including in people with the challenging to diagnose SPE phenotype and in those with infertility. The evidence is strengthened by independent data monitoring and assessor blinding. However, studies were predominantly conducted in France (with one centre based in Canada), and the high prevalence of endometriosis in study populations (77% to 80%) substantially limits the predictive value estimates and generalisability to primary or early secondary care in the NHS. A study in the UK NHS setting is ongoing (see **Table 19**).

Evidence interpretation

Across all three technologies, the evidence base is at an early stage. All included diagnostic accuracy studies were conducted outside the UK NHS, and none evaluated downstream outcomes such as time to diagnosis, reduction in laparoscopy rates, or QoL. The EAG notes that the absence of these outcomes means it is not possible to determine from the current evidence whether use of any of the three technologies in clinical practice would translate into meaningful patient benefit within the NHS diagnostic pathway for endometriosis. The EAG is therefore unable to draw conclusions about clinical effectiveness beyond the diagnostic accuracy data available.

Regarding safety, no adverse events attributable to any of the three tests were reported in the included studies, which is consistent with their non-invasive or minimally invasive nature. The EAG notes that the primary uncertainties regarding clinical risk relate to the downstream consequences of test results, specifically, the potential for false-negative results to delay diagnosis and for false-positive results to lead to unnecessary further investigation. The impact of test results on clinical decision-making in the NHS pathway has not been evaluated in any included study. All three manufacturers specify that their tests are intended as adjuncts to clinical assessment rather than standalone diagnostics; the EAG views this as an important contextual consideration for any future use of these technologies. A detailed description of evidence gaps and proposed evidence generation strategies is provided in Section 8.

6 Economic evidence

6.1 Existing economic evidence for the new technologies

The rapid literature search described in Section 4 identified three studies (all for EndoTest) reporting resource use and cost outcomes, all of which were included in the health-economic evidence review (**Table 7**).

Only one cost-effectiveness study (for EndoTest) was included in the review: a decision-tree model conducted from the perspective of the French healthcare system (Ferrier et al. 2023). As the only health-economic study, this study helped inform the health-economic analysis described below. The study compared four diagnostic strategies in women with chronic pelvic pain:

- Strategy I (current French algorithm: ultrasound with/without MRI with/without laparoscopy)
- Strategy II (EndoTest for all patients)
- Strategy III (ultrasound first, followed by EndoTest if no endometrioma is detected on ultrasound scan; this strategy is most aligned with the [scope](#) of this early use assessment)
- Strategy IV (ultrasound and MRI first, followed by EndoTest if both ultrasound and MRI were negative).

The primary effectiveness outcome was the proportion of people correctly diagnosed. At an EndoTest price of €750, the cost per correctly diagnosed case was €1,542 (Strategy I), €990 (Strategy II), €919 (Strategy III), and €1,000 (Strategy IV). Strategy I was dominated by all three strategies incorporating EndoTest, meaning EndoTest strategies were both more accurate and less costly than the current French algorithm. Strategy III (US then EndoTest) was the preferred strategy at a willingness-to-pay threshold of €473 to €4,670 per correctly diagnosed case, while Strategy II (EndoTest for all) was preferred above €4,670. Strategy IV was preferred only below €473. Results were directionally similar at test prices of €500 and €1,000, with Strategy I remaining the least cost-effective in all scenarios. A probabilistic sensitivity analysis using Monte Carlo simulations supported the robustness of these findings. No published economic analyses were available for EndoSure or DotEndo.

The other two studies reported EndoTest cost in the Polish and German markets, respectively (Rogalska and Brukało 2025; Nigdelis et al. 2025). Rogalska and Brukało 2025 conducted a desk-based analysis of endometriosis diagnostic tests available on the Polish private healthcare market, identifying three commercially available blood-based tests for endometriosis. None of the blood-based tests identified met the threshold of greater than 90% for both

sensitivity and specificity, in contrast to imaging tests (ultrasound and MRI), which did. The out-of-pocket costs of blood tests on the Polish private market ranged from €21 to €468. The cost for EndoTest in the private Polish market was reported as €535. Nigdelis et al. 2025 reported the cost of EndoTest in the German market as €800.

Table 6 Summary of costs and resource use outcome results from included studies

Technology (manufacturer)	Study	Publication status	Costs of equipment	Costs of staff and associated training	Cost of testing (incl. time requesting, reviewing and communicating results)	Cost of follow-up appointments (incl. further investigations, further treatment)	Costs of appointments, investigations and treatments avoided
EndoTest (Ziwig)	Ferrier et al. 2023	Published	<ul style="list-style-type: none"> • EndoTest test cost modelled at €750 baseline (sensitivity analyses at €500 and €1,000; commercial test price of approximately €780). • Cost of NGS estimated at €500. • Equipment costs not modelled separately from test unit cost. 	<ul style="list-style-type: none"> • NR • French healthcare payer perspective only; staff and training costs not included in model. • Only direct reimbursed costs were modelled. 	<ul style="list-style-type: none"> • EndoTest: €750 (baseline model; approximately €780 commercial test price). • Comparator test costs (French public insurance reimbursement): TvUS €70, pelvic MRI €314, physician consultation €25, specialist consultation €46, medical hormonal treatment €50/year 	<ul style="list-style-type: none"> • Diagnostic laparoscopy hospitalisation (median) cost: €1,522 • In EndoTest strategies, patients with positive EndoTest underwent subsequent TvUS (€70) and/or MRI (€314) as needed • Specialist follow-up consultation cost: €46 	NR

Technology (manufacturer)	Study	Publication status	Costs of equipment	Costs of staff and associated training	Cost of testing (incl. time requesting, reviewing and communicating results)	Cost of follow-up appointments (incl. further investigations, further treatment)	Costs of appointments, investigations and treatments avoided
EndoTest (Ziwig)	Nigdelis et al. 2025	Published	NR	NR	<ul style="list-style-type: none"> • Test cost approximately €800 cited in German survey • No unit cost breakdown or staff/training cost data reported 	NR	NR
EndoTest (Ziwig)	Rogalska and Brukała 2025	Published	NR	NR	<ul style="list-style-type: none"> • EndoTest (private market, Poland): approximately €535 • Comparator blood tests available privately: €21.1 to €467.77 	NR	NR

Abbreviations: MRI, magnetic resonance imaging; NGS, next generation sequencing; NR, not reported; TvUS, transvaginal ultrasound

6.2 Available economic models for endometriosis diagnosis

In addition to the literature search described in Section 4, previous economic evidence relevant to the [scope](#) was captured by performing a structured search in PubMed on March 23rd, 2026. The search string, inclusion/exclusion criteria, and PRISMA diagram are provided in **Appendix E**. In total, 40 articles were retrieved and screened using [PICO Portal](#) by one researcher; of the four articles for full-text review, all were included. For one model, published in Khan et al. 2018, additional information was identified in Appendix K of the [NICE Endometriosis diagnosis and management guidelines](#).

The aim of this smaller search was to identify available models that evaluated any element of the diagnostic care pathway in any country, regardless of whether they included one of the new technologies. These were reviewed to assess whether they could inform the economic analysis in this early technology assessment. Four economic models were considered related to this early use assessment and are summarised in **Table 8**.

Khan et al. published an NHS (UK) health technology assessment in 2018 including a cost-effectiveness analysis to answer the question of whether including MRI for diagnoses is cost-effective for people suffering with chronic pelvic pain (Khan et al. 2018). As the analysis was provided for the NHS, it was highly relevant. One of the major model inputs was taken from Khan et al., which was the 42.5% of people entering the model with symptoms who were disease positive (Khan et al. 2018). Although utilities were selected from an alternative source, as this analysis did not have all utilities required, the baseline utility for people with symptoms of endometriosis was very similar to what was used as a model input (**Table 14**). Beyond some useful information, Khan et al. considered a different research question to this early use assessment and did not focus on endometriosis (Khan et al. 2018).

Leonardi et al. published a diagnostic pathway that compared the inclusion of specialised deep endometriosis ultrasound into the standard care pathway while replacing a basic TvUS (Leonardi et al. 2019). The diagnostic pathway was comparable with the model structure developed by the EAG (**Figure 2**) for secondary care. The other difference is that Leonardi et al. only considered the diagnostic pathway within a single public tertiary gynaecology clinic where they did not include diagnostic options within primary care. The EAG did select the same time period of 1 month for transitioning between states in the Markov model (Leonardi et al. 2019). Results showed that a more accurate TvUS diagnosis method led to a decrease in care costs and a 50% reduction in surgical intervention (Leonardi et al. 2019).

As already introduced in Section 6.1, a cost-effectiveness analysis from Ferrier et al. compared different sequences of diagnostic tests (TvUS, MRI, and EndoTest) within a time horizon of 1 year from a French healthcare payer perspective (Ferrier et al. 2023). This model design was not useful for assessing the full pathway of diagnosis in the NHS and did not consider waiting times or times to diagnosis. Laparoscopy was not considered. Model parameters were not useful for the model developed by the EAG.

Xu et al. presented a US-based cost-utility analysis on the societal impact of offering a screening application to people suffering from symptoms of endometriosis before presenting to healthcare providers (Xu et al. 2026). The application suggests whether a person should see their healthcare provider based on their completed survey. As the focus of their work was people assessing their symptoms prior to first presentation, the diagnostic pathway was modelled simply with treatment being offered only after a diagnosis of endometriosis. The model considered menopause separately as a state where symptoms of endometriosis were resolved (Xu et al. 2026).

Table 7. Relevant economic models developed prior to this early use assessment

Reference	Model design	Country, perspective and care setting	Population	Intervention	Comparison
Khan et al. 2018	Cost-effectiveness model based on decision trees with a 6-month time horizon	UK, NHS perspective	People with chronic pelvic pain (at least 6 months)	MRI for diagnosing causes of chronic pelvic pain (one of which includes endometriosis)	Diagnostic laparoscopy
Leonardi et al. 2019	Cost analysis using a Markov model with a 1-year time horizon	Using data from a public, tertiary gynaecology clinic in Sydney Australia with high disease prevalence with a payer perspective of the Australian national healthcare service	People with symptoms of endometriosis and no previous diagnosis	Transvaginal ultrasound specialised to the detection of deep endometriosis in addition to other standard of care diagnostics and treatments	Basic transvaginal ultrasound with the additional standard of care including MRI, laparoscopic diagnosis and treatment and medical treatment in both comparison arms
Ferrier et al. 2023	Cost-effectiveness analysis using decision trees with a 1-year time horizon and no discounting	French healthcare payer, care setting was not specified	People in who accessed the healthcare system for a diagnosis for chronic pelvic pain.	Transvaginal ultrasound, MRI, and EndoTest for diagnosing endometriosis	Compares different test sequences for achieving a diagnosis of endometriosis
Xu et al. 2026	Cost-utility analysis using a Markov model supported by decision trees with 5-, 10-, and 20-year time horizons	General US healthcare system from a societal perspective including primary care and gynaecologists	People with symptoms of endometriosis	Symptom checking app to be used prior to first presentation in primary care	Simplified pathway for endometriosis diagnosis using cumulative accuracy of primary care and gynaecologist assessments over multiple visits

MRI, magnetic resonance imaging.

6.3 Early economic model

None of the abovementioned previous economic models allowed for the evaluation of all new technologies within the [scope](#) of this early use assessment. The most prominent reason was that none of the previous publications captured the diagnostic care pathway that was agreed on by clinical experts, patient representatives, and existing NICE guidelines ([NICE Endometriosis diagnosis and management guidelines](#)). The agreement was that the new technologies should be offered to people with symptoms suggestive of endometriosis in primary care after having received a negative ultrasound imaging result (no sign of endometriosis). Therefore, a de novo, early health-economic model was developed.

The primary objective of the developed model was to quantify the cost-effectiveness (specifically cost-utility) of adopting EndoSure, DotEndo, or EndoTest to complement the existing NHS diagnostic pathway for endometriosis. The secondary objectives were to explore the potential impact of adopting the new diagnostic technologies on time to diagnosis and the use of healthcare resources. The model was also built to assess important drivers and to explore uncertainties around input parameters— thus helping to identify key data gaps.

Endometriosis is a chronic, inflammatory, and systemic disease that can substantially impact QoL. This is best evaluated using a cost-utility model with an extended time horizon. The model supports a time horizon of up to 60 years, which is the base case in the model. A cohort model was chosen as an established health-economic approach to assess the population with access to the NHS in the UK. As per [NICE technology appraisal and highly specialised technologies guidance](#), a discount rate of 3.5% was applied and costs were inflated to 2025 British Pounds. The NHS and Personal Social Services perspective was modelled.

The analysis estimated costs, health outcomes, and the incremental cost-effectiveness ratio (ICER), calculated as the cost per quality-adjusted life year (QALY) gained, in accordance with [NICE technology appraisal and highly specialised technologies guidance](#).

The model is provided as a standalone Microsoft Excel file with development and reporting following the [NICE HealthTech programme manual](#).

6.3.1 Population

The modelled population comprised a hypothetical cohort of people presenting in primary care to NHS services within the UK with (recurring or enduring) symptoms suggestive of endometriosis. The cohort entering the model was defined by an average age. Age is used to inform all-cause mortality, which is

applied throughout the model using [UK national life tables 2022-2024 data](#) (published December 10th, 2025).

The cohort of people designed female at birth included individuals with endometriosis and those without. Those without endometriosis presented with symptoms that overlap with the symptom profile of endometriosis ([NICE Endometriosis diagnosis and management guidelines](#)). A proportion of people with endometriosis was assumed to have multimorbidity, meaning the presence of an additional condition that may mimic or overlap with endometriosis symptoms. This reflects real-world diagnostic complexity and the potential for delayed diagnosis due to symptom management or the treatment of alternative conditions. Within the model, outcomes for the group with endometriosis and the group without endometriosis (non-endometriosis) were calculated separately. The same underlying model structure was used for both groups and the majority of model inputs used were also the same. Diagnostic tests for endometriosis were defined by their sensitivities in the endometriosis group and by their specificities in the non-endometriosis group. The opposite was true for diagnostic tests used for the differential diagnosis of other conditions that present with symptoms similar to those of endometriosis.

As a hypothetical cohort model, no individual-level health information was processed or evaluated during this early use assessment, meaning that no ethical, data-sovereignty, or -data security concerns apply.

6.3.2 Care pathway

The endometriosis diagnostic care pathway is highly complex with extensive waiting times for both treatment and diagnosis with most recent data estimating an average time to diagnosis of 9 years and 4 months for the UK ([Endometriosis UK 2026](#)). It was noted by the clinical experts consulted during this early use assessment that there was no single current pathway implemented across the UK. For the purposes of this early use assessment, a pragmatic, current care pathway was developed that captures all treatment and diagnosis options provided in the NICE guidelines for endometriosis ([NICE Endometriosis diagnosis and management guidelines](#)) while considering input from clinical field experts and patient representatives. The modelled pathway (**Figure 1**) was split into the primary and secondary care settings. Each health state in the model was associated with a symptom and diagnosis state. Throughout the model the following terminology was used:

- Symptoms could be either:
 - **None:** The person had no symptoms of endometriosis at this point in time.
 - **Managed:** The person had symptoms of endometriosis at this point in time but they were well managed by treatment.

- **Unmanaged:** The person had symptoms of endometriosis at this point in time and they were either not being treated or the prescribed treatment was ineffective.
- **Diagnosis:**
 - **No (endometriosis) diagnosis:** The person had not been diagnosed with endometriosis. Any treatment received was under a different diagnostic code.
 - **Presumptive diagnosis:** The person was thought to have endometriosis (a positive outcome for any non-surgical diagnostic tests is sufficient for a presumptive diagnosis in the model) but the diagnosis had not been confirmed by laparoscopy.
 - **Definitive diagnosis:** The person had the presence of endometriosis confirmed by laparoscopy. The differentiation between a definitive and presumptive diagnosis was taken from the literature as only diagnostic laparoscopy is considered to provide a definitive diagnosis as the current 'gold standard' (Allaire et al. 2023).

The modelled diagnostic pathway (**Figure 2**) began with people who had symptoms suggestive of endometriosis. People first presented to a GP in primary care where they underwent a physical examination and were offered initial treatment to manage their symptoms (starting with Line 1 treatment, [BMJ best practice guidance](#) (Solnik, MJ and Sanders, A 2025)). The GP could then directly refer the person for ultrasound imaging of the pelvic area. Alternatively, the person could be managed initially in the primary care setting and only later referred for an ultrasound scan. The first ultrasound was provided within the primary care setting (including a women's health hub that is not considered secondary care) and most people will undergo a TvUS. People who declined a TvUS opted for a transabdominal ultrasound (TaUS); however, it was possible for a person to decline both ultrasound options.

If signs of endometriosis were detected in primary care, a presumptive diagnosis was made. A key characteristic of the diagnostic pathway is that treatment options were offered at first presentation with symptoms, which meant that treatment efforts did not wait until endometriosis was diagnosed (see [NICE Endometriosis diagnosis and management guidelines](#)). A proportion of people (both with and without a diagnosis) could experience a (temporary) reduction in symptoms after treatment. Because endometriosis is considered a chronic disease, the model did not consider that people could be cured; however, a proportion of people could achieve a state considered as having no symptoms requiring medical intervention (**long-term resolution of symptoms**). Recurrence of endometriosis with subsequent treatment is important for the burden of disease and overall societal impact but less relevant

to the diagnosis of endometriosis and therefore considered out of [scope](#) of this early use assessment.

The GP could refer the person to secondary care when there was a need for further investigation, both with and without a presumptive diagnosis of endometriosis. When a presumptive diagnosis was made, it was assumed that the investigation was more informed, meaning less effort was required on **differential diagnostics** where further tests for other related conditions were possible. The modelled care pathway allowed for a small number of people to be referred to diagnostic laparoscopy without the need for further imaging diagnostics in secondary care. Diagnostic laparoscopy could be performed with or without treatment laparoscopic surgery. However, most people underwent a further diagnostic imaging assessment performed by specialists in secondary care. This consisted of TvUS, TaUS, MRI, or a combination of these options. After completing the imaging assessment, people were offered treatment by the specialist, which was either specific to endometriosis (Line 2 or Line 3 treatment, [BMJ best practice guidance](#) (Solnik, MJ and Sanders, A 2025)) or for a different condition. In the absence of optimised treatment for the underlying disease, symptoms were assumed to recur, leading to repeated presentations in primary care.

After diagnostic laparoscopy, the people in the model with endometriosis were given a definitive diagnosis and were offered further **treatment and follow-up**. Their diagnostic pathway ended either after diagnostic laparoscopy and long-term follow-up or in a **long-term resolution** state where people who no longer have symptoms reside. Menopause was not treated separately in this pathway because, although some people may still have symptoms after menopause, these people can reach **symptom resolution** along with others who no longer need medical treatment.

Further details of how the care pathway was modelled are described in Section 6.3.3. In the following sections, the described care pathway is referred to as the **current care** diagnostic pathway, despite generalisation challenges.

6.3.3 Intervention and comparison

An early economic model for the three technologies within [scope](#) was developed. Each technology tests for the presence of endometriosis in a non-invasive manner (see **Table 2**). The key resource and structural changes required to carry out each of the tests that the EAG identified as being relevant for the economic assessment are described below:

- **EndoSure**: EndoSure must be used by a medical professional or technician trained and experienced in EVG techniques in detecting and measuring gastric, gastrointestinal, and GIMA signal data. The technology requires a quiet room with a reclining chair or exam table,

water, and computer access. The test takes around 45 minutes with results available immediately and there is an initial 2- to 3-minute internal equipment test. This is followed by a 10-minute baseline data collection period after which the person is instructed to drink water until they feel completely full. A 30-minute data collection period then begins. The software lets the user know when the test is complete. Primary care appointments with the GP do not usually exceed 10 minutes, therefore, this test requires a special dedicated service with an alternative healthcare provider (e.g., a nurse) in primary care that can offer it (see Section 3.2). An additional GP visit is required to discuss the results.

- **DotEndo:** A blood (or saliva) specimen is collected and analysed centrally by the manufacturer DotLab with results returned to the healthcare provider within 3 days. Results can support empirical treatment and referral decisions. The GP needs to introduce the test, get consent, and organise a sample to be taken. An additional visit is required to discuss the results.
- **EndoTest:** A saliva sample is collected by a technician or the clinician and sent off to a central laboratory service provided by the manufacturer, Ziwig. Clinicians receive a diagnostic result that can be incorporated into the management plan to be discussed in an additional visit to the healthcare provider. The GP needs to introduce the test, get consent, and organise a sample to be taken. An additional visit is required to discuss the results.

The model was developed with four comparator arms, with one arm per test and one arm for the current care diagnostic pathway. As per the [scope](#), each test was to be positioned in the existing care pathway after a person received a negative ultrasound result (i.e., a normal evaluation) or declined an ultrasound examination. In the model, the new technologies do not replace any existing diagnostic tests. Currently it is unknown whether structural changes may be required to integrate the new test into existing NHS services, therefore, this early use assessment used only training and direct resource use costs required to perform the tests.

6.3.4 Model structure

A cohort-based cost-utility model was developed based on two data-analysis structures. First, a Markov model was used to capture the different pathway options a person may experience from first presentation until a potential diagnosis (**Figure 2**). Second, separate decision trees were used to determine the outcomes for proportions of people undergoing a single or multiple diagnostic tests (**Figure 3** and **Figure 4**). The developed model essentially combined three models in one, where the adoption of each new technology

could be compared with the current care diagnostic pathway (from the results page in the Excel model) and inputs, results, and sensitivity analyses could be presented separately. Unless specifically indicated, however, all three models shared common clinical, utilities, and resource use input parameter values in the base case.

The model adopted a disease-based approach, as it was 'known' within the model which people or cohort proportions had the condition in question, and which did not. As such, the appropriate diagnostic test statistic to use was the sensitivity (for people with endometriosis) and specificity (for people without endometriosis). The alternative design for evaluating a diagnostic device is a test-based approach. In a test-based approach a mixed population (i.e., people with and without endometriosis) enters the model and the NPV and PPV are used to split the mixed population into true positives (people with endometriosis and a positive test result), false positives (people without endometriosis and a positive test result), true negatives (people without endometriosis and a negative test result), and false negatives (people with endometriosis and a negative test result). The test-based approach was not chosen for the following reasons:

- It requires accurate prevalence data for endometriosis in the population presenting in primary care and although data was available, its accuracy is uncertain.
- It requires the proportion of tests that return positive and negative results in the population presenting in primary care, and this was not available.

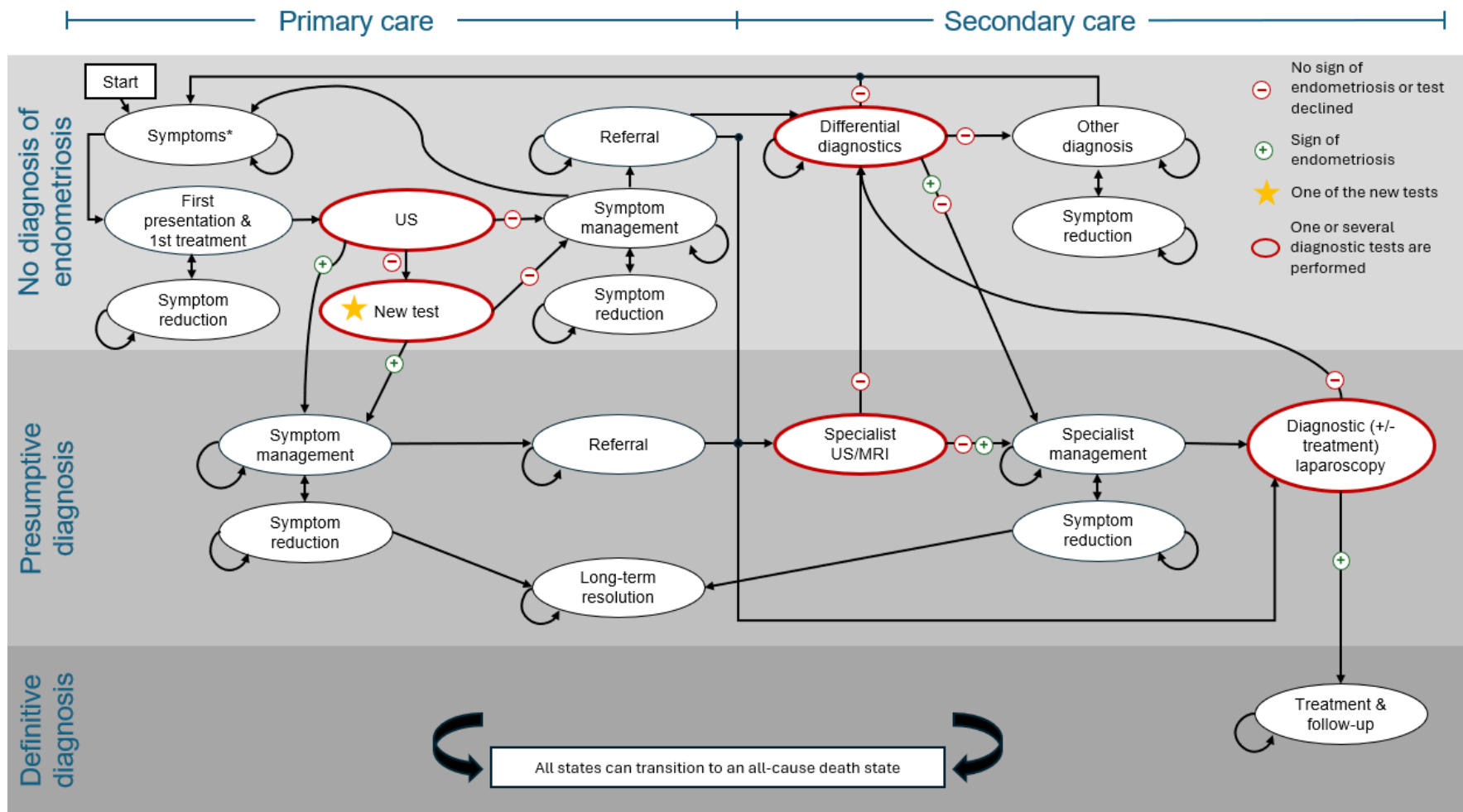


Figure 2 Model structure: Markov model of the endometriosis diagnostic care pathway. In each Markov model arm, either none or only one of the new diagnostic tests is offered; no combination of new tests was assessed. *Symptoms suggestive of endometriosis.

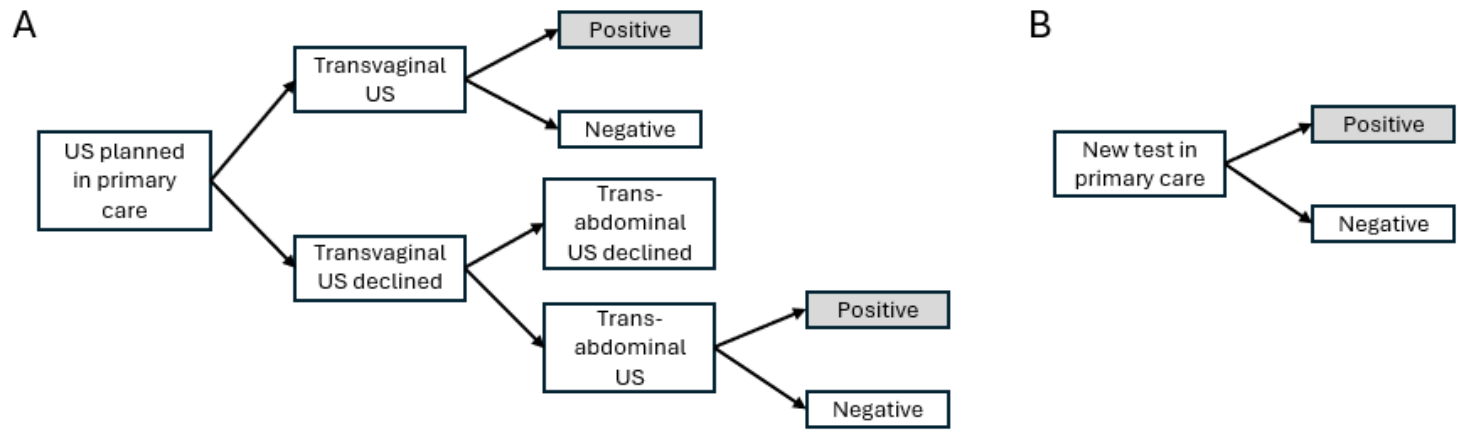


Figure 3 Embedded decision trees for the diagnostic Markov states in primary care. Ultrasound (US) and one new test per intervention arm (A). If endometriosis was detected, the outcome was positive; otherwise, it was negative (B).

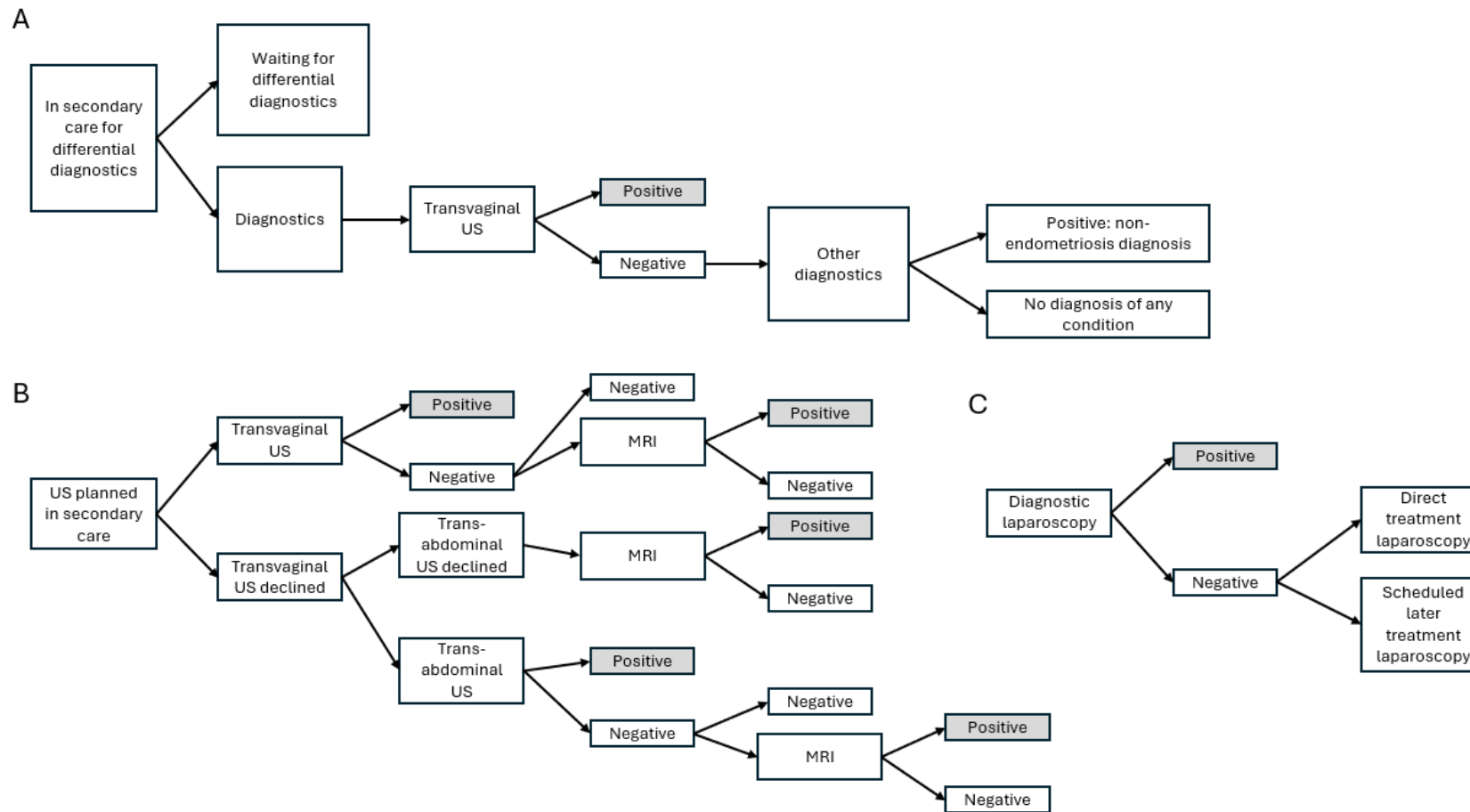


Figure 4. Embedded decision trees for the diagnostic Markov states in secondary care. Differential diagnostics (A), specialist ultrasound (US) and/or magnetic resonance imaging (MRI; B), and diagnostic laparoscopy with or without treatment laparoscopy (C). If endometriosis was detected, the outcome was positive; otherwise, it was negative.

6.3.4.1 Markov model

Each “health state” in the model was associated with probabilities and costs for resource use specific to that health state and its associated symptoms and diagnosis (see Section 6.3.3). Costs for unplanned visits to a primary caregiver, costs for unplanned visits to an emergency department for unmanaged and severe symptoms, and QoL utilities were included in each state. The Markov model had 21 mutually exclusive health states:

- **Symptoms:** People enter the model in a state where they have symptoms suggestive of endometriosis, and they can remain here until they decide to get medical support for their symptoms.
- **First presentation and treatment:** A person presents to their GP where their symptoms are assessed; they are offered an abdominal and pelvic examination and are prescribed first-line treatment options.
- **Symptom reduction without diagnosis in primary care:** First-line treatment may result in a reduction in symptoms where a person may remain in this state for several months until they present back to their GP with ongoing symptoms.
- **Ultrasound:** A GP will offer an ultrasound examination, which may need a referral to a primary care facility that offers ultrasound examinations. A person may decline a TvUS and opt for a TaUS or decline any ultrasound.
 - If the person tested is from the non-endometriosis group, then the diagnostic’s specificity is used to determine whether the person receives a ‘true negative’ or ‘false-positive’ result.
 - If the person tested is from the endometriosis group, then the diagnostic’s sensitivity is used to determine whether the person receives a ‘true positive’ or ‘false-negative’ result.
- **New diagnostic test:** One of the new tests are offered as described in Section 6.3.3 The new diagnostic test cannot be accessed in the current care arm of the model, this health state is only accessible within the intervention arm of the model.
 - If the person tested is from the non-endometriosis group, then the new diagnostic’s specificity is used to determine whether the person receives a ‘true negative’ or ‘false-positive’ result.
 - If the person tested is from the endometriosis group, then the new diagnostic’s sensitivity is used to determine whether the person receives a ‘true positive’ or ‘false-negative’ result.
- **Symptom management without diagnosis in primary care:** If there was no sign of endometriosis in the performed diagnostic tests or the person declined diagnostic tests, then they can be offered first and second-line treatment options to manage their symptoms.

- **Symptom reduction without diagnosis after ultrasound in primary care:** Treatment may result in a reduction of symptoms where people can stay in this health state for several months until they decide to revisit their GP due to ongoing or a worsening of symptoms.
- **Referral to secondary care without a diagnosis:** The GP has the option of referring people to secondary care at a monthly rate. A person can be referred to specialists for differential diagnostics or a person may bypass further imaging diagnostics and directly have a laparoscopy in secondary care. People stay in the referral state as regulated by a waiting-time input before transitioning.
- **Differential diagnostics:** When a person enters secondary care without any of the diagnostic tests showing signs of endometriosis, it is assumed that the healthcare provider may need to test for conditions beyond endometriosis that overlap in their symptom profile. Since people can wait in this state for several months, not everyone is offered diagnostic tests every month and only transvaginal ultrasound is explicitly modelled for a presumptive diagnosis of endometriosis. Ultrasound can also detect other conditions; therefore, it is followed by further diagnostics that can end in a diagnosis that is not endometriosis to calculate the number of people moving to the “other diagnosis” state. It was necessary to simplify this state because of the large number of possible options and to focus only on endometriosis, other, or no diagnoses. An average cost is associated with this state for the additional testing burden rather than costing out specifics. Examples of other tests possible are cervical culture test, MRI, cystoscopy, potassium chloride sensitivity test, hysteroscopy (Solnik, MJ and Sanders, A 2025).
- **Other diagnosis:** A diagnosis other than endometriosis does not rule out the presence of endometriosis but may mean that the person is treated for the confirmed condition. Symptoms of endometriosis may still need medical attention and the assumption in the model is that people return to primary care to the “**symptoms**” state and start the process again. People entering the model who do not have endometriosis as the underlying cause of their symptoms do not return to the “**symptoms**” state.
- **Symptom reduction with other diagnosis:** When on or after treatment for the other diagnosis, people can enter a health state where symptoms are reduced as is resource use with increased QoL.
 - If the person is from the endometriosis group, then a relative risk is applied (base case value 0.5) to account for the possibility that people are less likely to respond to treatment if they are misdiagnosed.
- **Symptom management with presumptive diagnosis in primary care:** People having received a positive outcome from any diagnostic

test enter a health state of symptom management with line 1 and line 2 treatment options.

- **Symptom reduction with presumptive diagnosis in primary care:** People may have a reduction of their symptoms when on or after treatment in primary care. When symptoms become problematic, they return to symptom management associated with increased resource use where they can access a referral to secondary care.
 - If the person is from the non-endometriosis group then a relative risk is applied (base case value 0.5) to account for the possibility that people are less likely to respond to treatment if they are misdiagnosed.
- **Referral with presumptive diagnosis to secondary care:** The GP can refer a person to secondary care at a monthly rate. When the GP refers a person with a presumptive diagnosis to secondary care, they can refer the person to specialist ultrasound and/or MRI imaging or the person bypasses additional imaging in secondary care and a laparoscopy is performed directly. People stay in the referral state according to a waiting-time input.
- **Specialist ultrasound or MRI with a presumptive diagnosis:** A transvaginal ultrasound is offered and if declined, the person declining will be offered a transabdominal ultrasound. If both are declined, the person will be referred to MRI. A proportion of people may undergo both an ultrasound and MRI investigation: Because this model focusses only on diagnosis, an MRI is only modelled for people with a negative (normal) ultrasound outcome even though MRI may be offered to further investigate the type of endometriosis in positive ultrasound outcomes. It is assumed that a presumptive diagnosis with endometriosis uses fewer resources in this health state than when looking for a differential diagnosis.
 - If the person tested is from the non-endometriosis group, then the diagnostic's specificity is used to determine whether the person receives a 'true negative' or 'false-positive' result.
 - If the person tested is from the endometriosis group, then the diagnostic's sensitivity is used to determine whether the person receives a 'true positive' or 'false-negative' result.
- **Specialist management in secondary care:** Specialist treatment options become available beyond what was previously tried if these were not successful.
- **Symptom reduction with specialist management:** when on or after treatment, symptoms may be reduced with lower resource use and better QoL.
 - If the person is from the non-endometriosis group, then a relative risk is applied (base case value 0.5) to account for the possibility

that people are less likely to respond to treatment if they are misdiagnosed.

- **Long-term resolution of symptoms:** It is assumed that symptoms become no longer clinically relevant with a high QoL. The EAG did not specifically model menopause but a proportion of those people may enter **long-term resolution of symptoms** if they no longer have symptoms after menopause. It is possible, however, for a person to still be suffering from endometriosis symptoms after menopause and therefore this was not considered an exit avenue for the diagnostic pathway as has been proposed by previous work (Xu et al. 2026).
- **Diagnostic (with and without treatment) laparoscopy:** People in this health state will undergo a diagnostic laparoscopy to the extent that after this laparoscopy there will be a definitive outcome (endometriosis was identified or not). A proportion of people will also undergo simultaneous laparoscopic surgical removal of endometrial-type tissue.
- **Treatment and follow-up after laparoscopy:** A proportion of people will undergo further surgical treatment.
- **Death:** Due to the long time horizon, an all-cause mortality is implemented where death can occur at any time—from any state—in the model. Death is an absorbing state and the only one in the model.

All people entered the model in the **symptoms** state and transitioned between health states in monthly cycles. Two separate cohorts of people entered the model for each comparator arm: one with endometriosis and one without. Pharmaceutical treatment for endometriosis was simplified into three treatment tiers, informed by the [BMJ best practice guidance](#) (Solnik, MJ and Sanders, A 2025). The treatment lines were only used to estimate treatment costs and did not impact symptom reduction or QoL in the model. The three treatment lines were:

- **Line 1:** Pain relief (e.g., paracetamol, non-steroidal anti-inflammatory drugs [NSAIDs]) ± the contraceptive pill as before the first ultrasound appointment in primary care.
- **Line 2:** Danazol could be applied after the first ultrasound appointment in primary care.
- **Line 3:** Hormonal-based therapy in secondary care with treatments from lines 1 and 2 also available.

6.3.4.2 Diagnostic testing and decision trees

Diagnostic health states incorporate embedded decision trees to manage cohort proportions receiving different diagnostic tests and reflect accuracies and diagnostic outcomes of each test. The decision trees for performing a non-specialist ultrasound (part A) or one of the new tests in the intervention arm (part B) in primary care are shown in **Figure 3**. The decision trees for the

differential diagnostics (part A), ultrasound and/or MRI diagnostic (part B), and diagnostic laparoscopy (part C) in secondary care are shown in **Figure 4**.

For each diagnostic test, the person could receive a true-positive, false-negative, true-negative, or false-positive result depending on whether they had endometriosis (known in the model) and the sensitivity and specificity of the test.

- **Sensitivity** determines the probability that a person with endometriosis receives a positive test result.
- **Specificity** determines the probability that a person without endometriosis receives a negative test result.

As depicted by the positive and negative symbols in **Figure 2**, people with positive test results could move into health states reflecting a presumptive or definitive diagnosis and subsequent management. People with negative or inconclusive results could continue symptom management, undergo further diagnostic assessment, or re-enter the **symptoms** state. This reflects flexibility in the guidelines and physician judgement to consider other factors beyond the diagnostic tests.

In the differential diagnostics state, people with multimorbidity could receive an alternative diagnosis. Treatment for an alternative diagnosis could then lead to symptom reduction but did not treat underlying endometriosis if the individual did not have the condition. Symptoms were assumed to recur over time, causing the person to re-enter the **symptoms** state.

6.3.5 Clinical parameters

The model was parameterised with over 150 input parameters, reflecting the highly complex care pathway. Key base-case values for cohort clinical parameters are listed in **Table 9**, with the diagnostic performance clinical parameters listed in **Table 10**. The cohort characteristics remained the same for each technology assessed, as did the diagnostic performance of TvUS, TaUS, MRI, and laparoscopy. The only clinical change made in the model between the assessment of different technologies was the sensitivity and specificity of each specific technology.

Table 8 Main clinical parameters

Variable	Value (SD or 95% CI or range)	Source	EAG commentary on availability, quality, reliability and relevance of the source/s
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Age at presentation	22 years	Zhang et al. 2025; Husby et al. 2003; Kok et al. 2025	Data are consistently in the early 20s in studies identified: midpoint of 20-24 from Zhang et al. 2025; 21.2 years from Norway (Husby et al. 2003); and 23.7 Netherlands (Kok et al. 2025). An age of 22 years was taken as the midpoint of these values.
People with symptoms that have endometriosis	42.5%	Khan et al. 2018 Table 6 (page 22)	The source is a previous health technology assessment for the NHS UK and is, therefore, considered an accepted source. The value was calculated from a single study: of 287 people assessed 71 had superficial and 40 had deep endometriosis, with a further 11 having endometriosis of the ovary. In total, 122 of 287 (42.5%) people presenting had endometriosis. The value closely aligns with the 40% used in the model of Ferrier et al. 2023, taking a French national healthcare system perspective.
Endometriosis and other comorbid diseases	25%	McGrath et al. 2025	Analysis of the UK biobank looked at co-existence of endometriosis with other conditions. Of comorbid codes identified, 25% were for genitourinary diagnosis.
Waiting time for first presentation	8.9 months	(National Confidential Enquiry into Patient Outcome and Death 2024)	From 840 patient survey responses, 50% of respondents had visited their GP by 9 months due to the appearance of symptoms (Figure 3.4, page 25 of the report).
Ultrasound after first presentation	90%	Expert opinion	The percentage of people that are scheduled for an ultrasound directly after first presentation.
Waiting time for differential diagnostics (from GP)	3.40 months	Elective Recovery Tracker published by Royal College of Obstetricians & Gynaecologists (RCOG) (February 2026)	The Royal College of Obstetricians & Gynaecologists (RCOG) publish a dynamic Elective Recovery Tracker that reports an average (median) waiting time of 14.8 weeks for England (February 2026) with a range of 10.5 to 18.2 weeks across different regions of the UK. Using a conversion factor of 4.35 from weeks to months, the calculations for mean and range was: 14.8/4.35=3.40 months 10.5/4.35=2.41 months (lower bound) 18.2/4.35=4.35 months (upper bound)

			The limitation of this source is that it only has data for England and only reports the median, which is likely underestimating the mean time needed for the model.
Waiting time after referral to secondary care with presumptive diagnosis (from GP)	3.40 months	Elective Recovery Tracker published by RCOG (February 2026)	<p>The Royal College of Obstetricians & Gynaecologists (RCOG) publish a dynamic Elective Recovery Tracker that reports an average (median) waiting time of 14.8 weeks for England (February 2026) with a range of 10.5 to 18.2 weeks across different regions of the UK. Using a conversion factor of 4.35 from weeks to months, the calculations for mean and range was:</p> <p>14.8/4.35=3.40 months 10.5/4.35=2.41 months (lower bound) 18.2/4.35=4.35 months (upper bound)</p> <p>The limitation of this source is that it only has data for England and only reports the median, which is likely underestimating the mean time needed for the model.</p>
Waiting time for laparoscopy	13.57 months	Freedom of Information (Scotland) Act 2002. Response to correspondence dated 6 October 2025. Request: Laparoscopy Waiting Times Reference: IGTFOISA25912	With no peer-reviewed data identified, grey literature was used. In October 2025, NHS Scotland released information on wait times for diagnostic laparoscopy. The average was 59 weeks, with the maximum wait being 188 weeks.
Declined transvaginal ultrasound in primary care	21.7%	(National Confidential Enquiry into Patient Outcome and Death 2024)	A transvaginal ultrasound scan was undertaken in 332/424 (78.3%) people. Expert input ranged from 15% to 30%. The inverse 21.7% was used as an assumption that these people declined transvaginal ultrasound. The report later reports people having an MRI with the following reasons given. Direct quote: "MRI is not recommended as a first-line investigation and so reasons for having an MRI may have been due to the person declining ultrasound, examination and/or ultrasound not being feasible, or potentially a

			differential diagnosis requiring another imaging modality.”
Declined transvaginal ultrasound secondary care	9.8%	(Friedman et al. 2013)	1349 pregnant people were included to be offered universal transvaginal ultrasound to assess cervical length. Transabdominal ultrasound was used first to measure the cervix before including the person in the study. 132/1349 (9.8%) declined transvaginal ultrasound after the initial transabdominal ultrasound.
Symptom reduction in primary care	36.56%	(National Confidential Enquiry into Patient Outcome and Death 2024) and expert opinion	Of the 733/941 (77.9%) survey respondents prescribed hormonal treatments, only 363/687 (52.8%) had any improvement in symptoms. 7.1% had resolution of symptoms, leaving 45.7% (as presented in Table 5.2) with reduction. We assume a reduction of 20% on this for primary care (36.56%). This fits with expert opinion: 5% and 40-50%, the range is 5% to 50% for sensitivity analyses.
Symptom reduction in specialist management	45.70%	(National Confidential Enquiry into Patient Outcome and Death 2024) and expert opinion	Of the 733/941 (77.9%) survey respondents prescribed hormonal treatments, only 363/687 (52.8%) had any improvement in symptoms. 7.1% had resolution of symptoms, leaving 45.7% (as presented in Table 5.2) with reduction. This fits with expert opinion: 20-25% and 50-60%, the range is 20% to 60% for sensitivity analyses.
People achieving symptom resolution in primary care	5.68%	(National Confidential Enquiry into Patient Outcome and Death 2024)	7.1% was reported as the percentage of respondents for whom hormone treatment was successful in easing endometriosis symptom-related pain in secondary care. A 20% reduction on this value is assumed for primary care.
People achieving symptom resolution in secondary care	7.10%	(National Confidential Enquiry into Patient Outcome and Death 2024)	Reported as the percentage of respondents for whom treatment was successful in easing endometriosis symptom-related pain.

Table 9 Diagnostic sensitivity and specificity

Variable	Value (SD or 95% CI or range)	Source	EAG commentary on availability, quality, reliability and relevance of the source/s
Transvaginal ultrasound sensitivity, primary care	25% (12.7% to 41.2%)	Fraser et al. 2015	Expert opinion is that transvaginal ultrasound in primary care can be less accurate than in specialist care. No data were identified for the UK, used here are data from 114 Canadian people with surgically confirmed endometriosis, 2006-2013. The value used is for a non-specialist performing the ultrasound.
Transvaginal ultrasound specificity, primary care	93% (78.0% to 99.0%)	Appendix 2 of NICE Endometriosis diagnosis and management guidelines	The study by Fraser et al. 2015 In the original documentation this value is identified as transabdominal ultrasound, the references supporting it are all using transvaginal ultrasound and so it is used here for transvaginal ultrasound.
Transabdominal ultrasound sensitivity	20% (10.2% to 32.9%)	Fraser et al. 2015	Expert opinion is that transabdominal ultrasound is less accurate for a presumptive diagnosis of endometriosis than transvaginal ultrasound but no value for this input could be found. Used here are data from 114 Canadian people with surgically confirmed endometriosis, 2006-2013. The value used is for a non-specialist performing the ultrasound, though it is still transvaginal ultrasound. We took 80% of the transvaginal ultrasound sensitivity to align with expectations from experts.
Transabdominal ultrasound specificity	93% (78.0% to 99.0%)	Appendix 2 of NICE Endometriosis diagnosis and management guidelines	Due to a lack of data, assumed as specific as transvaginal ultrasound.
EndoSure sensitivity	96%	Company RFI and Noar et al. 2024a	Data are not from primary care and so the tested population may not reflect the use case in this early use

			assessment. Sensitivity in primary care may vary from that used here.
EndoSure specificity	95%	Company RFI and Noar et al. 2024a	Data are not from primary care and so the tested population may not reflect the use case in this early use assessment. Specificity in primary care may vary from that used here.
DotEndo sensitivity	90.0%	Moustafa et al. 2020	Data are not from primary care and so the tested population may not reflect the use case in this early use assessment. Sensitivity in primary care may vary from that used here.
DotEndo specificity	90%	Moustafa et al. 2020	Data are not from primary care and so the tested population may not reflect the use case in this early use assessment. Specificity in primary care may vary from that used here.
EndoTest sensitivity	97.3% (96.4% to 98.0%)	Instructions of use document supplied by company and Bendifallah et al. 2025	Data are not from primary care and so the tested population may not reflect the use case in this early use assessment. Sensitivity in primary care may vary from that used here.
EndoTest specificity	94.1% (91.0% to 96.4%)	Instructions of use document supplied by company and Bendifallah et al. 2025	Data are not from primary care and so the tested population may not reflect the use case in this early use assessment. Specificity in primary care may vary from that used here.
Specialist transvaginal ultrasound sensitivity	83.3% (62.3% to 95.3%)	Bailey et al. 2024	A retrospective diagnostic test study following a change in practice at a tertiary London hospital. The study showed that diagnosis of superficial endometriosis has lower sensitivity than for deep endometriosis. The value used is the sensitivity for deep endometriosis.
Specialist transvaginal ultrasound specificity	97.4% (90.8% to 99.7%)	Bailey et al. 2024	A retrospective diagnostic test study following a change in practice at a tertiary London hospital. The study showed that diagnosis of superficial endometriosis has lower sensitivity than for deep endometriosis. The value used is the specificity for deep endometriosis.

MRI sensitivity	90.3%	Solnik, MJ and Sanders, A 2025; Bazot et al. 2004 BMJ best practice	Data in this area are relatively old, more modern technology might provide better clarity and thus diagnostic insight.
MRI specificity	91%	Solnik, MJ and Sanders, A 2025; Bazot et al. 2004 BMJ best practice	Data in this area are relatively old, more modern technology might provide better clarity and thus diagnostic insight.
Laparoscopy sensitivity	97%	Walter et al. 2001; Solnik, MJ and Sanders, A 2025 BMJ best practice	Currently laparoscopy is the gold standard, high sensitivity is expected. Age of data might lack relevance to current clinical practice; however, sensitivities may not have changed.
Laparoscopy specificity	77%	Walter et al. 2001; Solnik, MJ and Sanders, A 2025 BMJ best practice	The specificity is substantially lower than all the other diagnostics above—it is possible that the difference in the underlying population being tested is the driver of this difference and not actual test specificities on an identical population. Age of data might lack relevance to current clinical practice; however, specificities may not have changed.

6.3.6 Resource use and cost parameters

In the scoping workshop, physician and emergency department visits were identified as cost and resource use for consideration in the analysis. As little evidence on frequency of visits was identified in the literature, these inputs were sourced from clinical experts (see **Table 11**). In addition, the costs of the new technologies are provided in **Table 12**; the other cost data are presented in **Table 13**.

Table 10 Resource use parameters

Unplanned visits per month	No symptoms	Managed symptoms	Unmanaged symptoms
GP visits for people with no endometriosis diagnosis	0.00 (0, 0)	0.17 (0.25, 0.08)	0.63 (0.5, 0.75)
GP visits for people with a	0.03 (0.05, 0)	0.18 (0.2, 0.17)	0.53 (0.4, 0.67)

presumptive endometriosis diagnosis			
GP visits for people with a definitive endometriosis diagnosis	0.01 (0.02, 0)	0.07 (0.1, 0.04)	0.42 (0.25, 0.58)
ED visits for people with no endometriosis diagnosis	0.00 (0, 0)	0.03 (0.05, 0)	0.15 (0.1, 0.21)
ED visits for people with a presumptive endometriosis diagnosis	0.00 (0, 0)	0.02 (0.03, 0)	0.10 (0.08, 0.13)
ED visits for people with a definitive endometriosis diagnosis	0.00 (0, 0)	0.01 (0.02, 0)	0.07 (0.05, 0.08)

Table populated from expert opinion from two clinical experts; inputs presented as model input averaged from (expert input 1, expert input 2). The expert inputs were used as lower and upper bounds for the probabilistic sensitivity analyses unless both estimates were zero. In these cases the upper or lower bound was adjusted by 0.05 for GP visits and 0.01 for ED visits to allow for sensitivity analyses to be performed. Abbreviations: ED, emergency department; GP, general practitioner.

Table 11 Key cost parameters

Parameter	Cost of implementation	Cost per person or user	Source	Comment
EndoSure	Capital £70.83 Training £4.17	£350	Company submission	Consideration of the capital costs within a cost-utility analysis is complex as the cost is not per use. In a conservative approach, it is assumed that the £8,500 capital cost is split over 120 uses, the minimum user volume for £350 per person cost). The same approach was used for training costs.
DotEndo	None	£400	Company submission	-

EndoTest	None	£1,381	Company submission	-
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No variances were provided by the companies, therefore, the default of $\pm 30\%$ was used for the probabilistic sensitivity analyses.

Table 12 Other cost parameters

Parameter	Value [SD or 95% CI or range]	Source	EAG commentary on availability, quality, reliability and relevance of the source/s
HCP time per hour	£196.00	Unit Costs of Health and Social Care 2024 (Jones et al. 2025) Manual (page 72)	Cost per hour for a GPs patient contact time. without other staff costs and without qualification costs. This cost is taken to represent the patient contact time of any diagnostic performed.
GP visit	£37.00	Unit Costs of Health and Social Care 2024 (Jones et al. 2025)	Table 9.4.2 unit costs for a GP provides a cost of £37 for a 10 minute consultation without qualification costs. The range is £33 to £45 is qualification costs and staff time are included/excluded.
Specialist visit	£239.90	Row 1037 of NCC 24/25 Summary: outpatient procedure in gynaecology	NHS data for specialist visits, data are not endometriosis-specific.
Emergency department visit	£291.17	NHS walk-in Row 27. Emergency care, Row 50 (Cat 3 investigation with Cat 4 treatment) NCC national schedule 24/25	NHS data, data are not endometriosis-specific.
Line 1 treatment	£13.36	Khan et al. 2018	Priced as ibuprofen 400 mg taken three times per day and 50% of people receiving a combined oral contraceptive. Prices in the reference are inflated to 2025 GBP.
Line 2 treatment	£38.44	Khan et al. 2018	Danazol (£86.63 for 3 months, £28.88 per month) inflated to 2025 GBP.
Line 3 treatment	£104.74	Khan et al. 2018	GnRH antagonists cost £236 for 3 months. Prices in the reference are inflated to 2025 GBP

Transvaginal ultrasound, primary care	£110.22	Diagnostic imaging, Rows 61, 107 NCC national schedule 24/25	NHS costs, not endometriosis-specific.
Transvaginal ultrasound, secondary care	£220.17	Outpatient procedure, Row 568, 107 NCC national schedule 24/25	NHS costs, not endometriosis-specific.

Abbreviations: CI, confidence interval; GP, general practitioner; GBP, Great British Pound, inflated to 2025 where necessary; HCP, healthcare professional; NCC, National Cost Collection.

6.3.7 Health state utilities

Generic QoL measures were preferred in the analysis to allow comparison of cost-utility. EQ-5D data were identified in multiple studies, but only a single study provided all inputs required. The utilities and disutilities used are provided in **Table 14**. The utility values were combined in a multiplicative approach rather than in an additive approach. Dependent on each symptom or diagnosis state, a disutility is applied to the baseline utility. A positive disutility decreases QoL and a negative disutility increases QoL. All utilities/disutilities were taken from a single French study (Aubry et al. 2017). Although these values may not be generalisable to the UK NHS population, they all come from a single study rather than from different studies and populations. In addition, the baseline utility of 0.56 extracted from Aubry et al. was the same as the one reported in a UK-based study for the NHS health technology assessment that used MRI for the diagnosis of endometriosis (Khan et al. 2018). The UK study was not used because not all the required utilities/disutilities were reported.

Table 13 Health state utilities

Variable	Value (SD or Range)*	Source	EAG commentary on availability, quality, reliability and relevance of the source/s
Baseline utility	0.5900 (±0.2800)	Aubry et al. 2017	This prospective, observational study in France enrolled 253 consecutive women with diagnosed endometriosis. It examined performance of EQ-5D-3L and the Endometriosis Health Profile-5 (EHP-5) quality of life questionnaires. The visual analogue EQ-VAS at baseline was 0.563. This matches well to the 0.56 reported by Khan et al. 2018, NHS data. The EQ-5D-3L

			data are used for utilities in the model.
No diagnosis disutility	0.0625	Aubry et al. 2017	People without a diagnosis are expected to have symptoms and Endometriosis UK found that 79% of respondents reported an improved QoL after receiving a diagnosis. As an assumption, we assume the disutility for people reporting symptoms (pain > 7, dysmenorrhoea >7, pelvic pain >5, painful defecation moderate-severe) applies to 'no diagnosis'. This is a mean difference of -0.0625.
Presumptive diagnosis disutility	0.0000 (-0.0500 to 0.0500)	Aubry et al. 2017	Assumed as baseline in study as all people enrolled had a pre-surgical diagnosis of endometriosis.
Definitive diagnosis disutility	-0.0625	Aubry et al. 2017	The value used is informed by EQ-5D-3L data presented by Aubry et al. 2017. The assumption is that a definitive diagnosis gives the same quality of life increment as a presumptive diagnosis.
Unmanaged symptoms disutility	0.0625	Aubry et al. 2017	People reporting symptoms (pain > 7, dysmenorrhoea > 7, pelvic pain >5, painful defecation moderate-severe) had a mean QoL of 0.5275, which differs from population mean by 0.0625.
Managed symptoms disutility	-0.0750	Aubry et al. 2017	People reporting milder symptoms (pain <= 7, dysmenorrhoea >=7, pelvic pain <=5, painful defecation none-mild) had a mean QoL of 0.665. Difference to population mean of 0.075.
No symptoms disutility	-0.2400	Aubry et al. 2017	Patients who reported they were better at follow-up had an EQ-5D-3L of 0.83, difference to baseline 0.24

EQ-5D: Euro-QoL 5 dimensions; VAS: Visual analogue scale; Disutilities: Dependent on symptoms or diagnosis state, a disutility is applied to the baseline utility. A positive disutility decreases quality of life and a negative disutility increases quality of life. All EQ-5D-3L

utilities/disutilities were taken from a single French study that may deviate from an NHS population. However, the advantage is that they all come from a single study rather than from different studies and populations. *For inputs that have nothing in brackets, no variation was reported.

6.3.8 Key model assumptions

The key assumptions driving the model structure, development, and/or parameterisation are listed in **Table 15**, alongside direct or indirect feedback provided by the clinical experts and patient representatives. For this early use assessment, assumptions around input parameters were either based on published literature (e.g., data from secondary care was used in a primary care setting) or educated guesses. If literature-based uncertainty measures around assumptions were not available, they were parameterised by expert input (if possible) or by using a fixed uncertainty range of $\pm 20\%$ and $\pm 30\%$ for clinical and cost inputs, respectively.

Table 14 Key model assumptions including responses from experts if provided

Assumption name	Assumption details	Feedback from experts
Diagnosis status	<p>Having a presumptive diagnosis increases treatment effectiveness and quality of life, which is again increased after a definitive diagnosis—for the average person suffering from endometriosis. A single positive outcome from any diagnostic test in the model is sufficient for a presumptive diagnosis because all people already have symptoms suggestive of endometriosis.</p>	<p>“Having a diagnosis is meaningful and important for people and clinicians. I think there is a question about the incremental accumulation with transitioning from presumptive to confirmed”</p>
Symptom status	<p>On average, there are more unplanned primary care visits and emergency department visits when symptoms are unmanaged in comparison to having reduced symptoms during treatment and there are no endometriosis-related visits when symptoms are no longer clinically relevant. In addition, quality of life improves on average when symptoms are managed with treatment.</p>	<p>“Symptoms are a key driver of healthcare use in general practice, as are concerns about health impacts, for example worry about risk of potential future events, side effects of treatment, or evolving priorities which can include questions about fertility. BUT I agree that at the core is informed approaches to managing symptoms and that unmanaged symptoms (which can include symptoms that are not explained or under investigation) are a key driver of GP attendance”</p>
Imaging diagnostic	<p>Every person going through secondary care diagnostics will have at least one imagine diagnostic performed. A person can decline ultrasound and will then have an MRI instead.</p> <p>Clarification in response to expert feedback: Ultrasound in primary care is included. Not all people will receive additional imaging in secondary</p>	<p>“This is true if you include the US [ultrasound] done in primary care”</p> <p>“They will all have had an USS [ultrasound scan] arranged from general practice. If this was done in the hospital or a specialist setting, then in secondary care this may not be repeated and MRI arranged instead?”</p>

	care, with 2.5% of those referred going on to laparoscopy without additional imaging.	
New test application rate 100% of people eligible within the scope receive the test, no one declines the test who is eligible	No one declines the new test in the model in each new-test arm.	“Think that may be less certain for the EndoSure. There may be some concerns about perceived alternative storage of genetics and saliva? But, I anticipate that for people with symptoms, for a non-invasive test, the decline rate is likely to be low but not nil.”
Treatment options	Treatment is offered as soon as the initial presentation and is continued to be offered until symptom resolution. Before the first ultrasound visit, people are offered first-line treatment and after the first ultrasound it is possible to progress to second-line treatment. Specialist treatment is only available in secondary care. See clinical inputs for a details on first-line, second-line and specialist treatment.	“I absolutely agree all should/will be offered treatment at first and hopefully each encounter. I think people have often tried OTC medications and may have either tried or elected to try hormonal contraception before. These are often/can be used together. I also observe a cohort who do not want treatment before/until they have a diagnosis. I do not think Ryeqo or GnRH analogues would be used typically in primary care without a diagnosis and secondary care input.”
Referral to secondary care 90% are referred	Not all people are referred to secondary care in the model. A proportion of people may remain with options for treatment in primary care without ever having surgical treatment. The referred proportion is informed by expert input.	“I would anticipate, noting the prevailing discourse about endometriosis, that the vast majority of people with signs of endometriosis on USS [ultrasound scan] or a positive test would expect to be referred to specialist care, and that this is what most GPs would do. Countering this, if the tests were negative, and the symptoms were ongoing, I think guidance would still suggest referral for further evaluation.”

<p>Resolution of symptoms in primary care 5.68%</p>	<p>No suitable data were identified here. In the (National Confidential Enquiry into Patient Outcome and Death 2024) it was reported that 7.1% of people achieve symptom resolution with hormone therapy in secondary care. We assume a 20% reduction on this value for primary care.</p>	<p>“I guess we are making an assumption here that ‘symptoms’ = pain” “I think there is differential evidence for endometriosis associated pain, and for pelvic floor physiotherapy and surgery, so treatments in addition to hormonal treatments, and these are currently not available to all with endometriosis, with differences by superficial versus DIE.”</p>
<p>Diagnostic accuracy of new tests</p>	<p>The new tests have not been assessed in primary care, the identified sensitivity and specificity data are assumed to also apply to primary care.</p>	<p>“I would be uncertain about this assumption.”</p>
<p>Patient choice (for laparoscopy) Current care 50% New Tests 50%</p>	<p>Within the NHS patient choice and active participation in treatment decisions is important. The model builds in patient choice with the choice between whether or not to undergo laparoscopy. Following expert input it is set at 50%, so maximally 50% of diagnosed patients will receive laparoscopy and only these can obtain a definitive diagnosis. With the new tests this patient choice variable is also 50% but can be set independent of patient choice in the current care arm. This was built in to account for expert feedback on the model.</p>	<p>“This is a question for the gynaecologists, but I think the choice from my perspective would be about requesting referral and sometimes to whom. This can include the right to a second opinion. In my experience, patients may request laparoscopy, but I think ultimately the decision about surgery or not would fall to the surgeon?”</p>
<p>Diagnostic findings</p>	<p>The model focuses on endometriosis and so diagnostic accuracy is for endometriosis alone. If a diagnostic, e.g. ultrasound, is negative it means that no endometriosis was identified. As some people have multimorbidity it could be that, in real</p>	<p>“Reasonable. Difficult when an USS [ultrasound scan] finds something other than endometriosis, but there is in fact endometriosis (fibroids on USS for example) but recognise this can’t include every scenario.”</p>

	life, this other pathology is identified instead or as well. The model cannot account for the direct treatment of another condition before the differential diagnosis state has been accessed. This may delay treatment for 'other conditions'.	
Cost of treating other conditions GBP 0.00	The cost of treating other conditions is set to zero as it is unknown which other conditions are present and how they would be treated. As it is possible for a person with endometriosis to be missed and then get a comorbidity diagnosed, this would mean the cost of a missed test is minimised. It is thus a conservative assumption.	"Adenomyosis can co-exist, overlap. The treatments for common comorbidities and also for the symptoms are comparable, which is a complexity worth noting."
Quality of life for other conditions Baseline 0.59	Quality of life in the model is taken from a population with endometriosis. It is assumed that this will apply as an estimate for quality of life for people presenting with symptoms similar to those of endometriosis. This assumption is made as it is not known which other condition the non-endometriosis group has and so data could not be sought for this population.	NA
People achieving reduction in symptoms Relative risk 0.50	It is assumed that people with a misdiagnosis, e.g. non-endometriosis group receiving a presumptive diagnosis of endometriosis, are less likely to achieve symptom reduction when put on treatment. The relative risk for this was set to 0.5 in the base case.	NA

Feedback was provided by only one expert. DIE, deep invasive endometriosis; GnRH, gonadotropin-releasing hormone; GP, general practitioner; MRI, magnetic resonance imaging; NA, not available; OTC, over the counter; USS, ultrasound scan.

6.4 Model validation

Model structure, assumptions, and outcomes were reviewed by clinical experts and patient representatives. The model can be partly validated by comparing the output time to definitive endometriosis diagnosis for the current care arm with published times to diagnosis for the UK.

Three sources for the time to diagnosis were identified. A survey undertaken by Endometriosis UK in October 2025 found that the average time to diagnosis across the UK was 9 years and 4 months ([Endometriosis UK 2026](#)). By country, the range was from 9 years and 4 months in England to 10 years and 2 months in Scotland. Overall times to diagnosis are increasing, as Endometriosis UK reported a time to diagnosis of 8 years and 10 months in 2023 and of 8 years in 2020. A recent systematic literature review performed a global evaluation of time to diagnosis (Corte et al. 2025). They summarised studies reporting on time to diagnosis in primary care, secondary care, and overall diagnosis time (definitive diagnosis). For the UK, one study from 2020 reported 1 year to primary-care diagnosis, 3 years to secondary care diagnosis, and 8 years to definitive diagnosis. This figure is in line with the Endometriosis UK 2020 survey result mentioned above. The National Confidential Enquiry into Patient Outcome and Death 2024 reported that 50% of people surveyed went from their first presentation at the general practice to a diagnosis of endometriosis in approximately 3 years. People in other countries (Australia, Canada, France, Germany, Italy, Ireland, New Zealand, and the USA) took 5 to 12 years to reach a definitive diagnosis of endometriosis.

Time to a presumptive endometriosis diagnosis in the base case was estimated in the model to be 3 years and 6 months. This matches well to the data presented by the National Confidential Enquiry into Patient Outcome and Death 2024. Presumptive diagnoses in the model are potentially impacted by an artefact of the model structure: loops within the model pathway mean that a portion of the cohort will receive a presumptive diagnosis and then move back into differential diagnosis where a second presumptive diagnosis can be made. As individuals are not followed, it is impossible to know which proportions of the cohort received their initial, secondary, or even further presumptive diagnosis of endometriosis. Reducing the time horizon to 10 years (to limit the possibility of receiving a secondary presumptive diagnosis) results in a mean time to a presumptive diagnosis of 3 years (2.97) in current care. Thus, overall, the time to a presumptive diagnosis in the model aligns with published data.

The time to a definitive diagnosis in the model was 9 years and 8 months, which also aligns well with the data reported in [Endometriosis UK 2026](#). Although this time to definitive diagnosis is 4 months longer than the UK average, it falls within the range of values reported for England (9 years and 4 months) and Scotland

(10 years and 2 months). The survey, however, does not specify how diagnoses were defined; they may have captured as either presumptive or definitive diagnoses, whichever came first.

It is important to highlight that no times to presumptive or definitive diagnoses were used as inputs to inform timings in the model relevant to this outcome. As the model has a time to diagnosis that is reflected by previously published times (albeit with some variations) and does not have the time to diagnosis as a model input, the model should roughly be capturing the overall complexity of the current care diagnostic pathway.

6.4.1 Presentation of results

Results are presented in the context of both probabilistic and deterministic sensitivity analyses with scenario analyses providing further insight into clinically relevant situations that were ambiguous or highly uncertain. The model calculated the following outcomes per model arm, current care, EndoTest, DotEndo, and EndoSure:

1. Cost-utility outcomes
 - a. ICER
 - b. Net health benefit
 - c. Net monetary benefit
 - d. Total costs
 - e. Total QALYs
2. Additional outcomes
 - a. Total healthcare professional (HCP) time for non-surgical diagnostic procedures
 - b. Mean time to presumptive diagnosis of endometriosis
 - c. Mean time to definitive diagnosis of endometriosis
 - d. Misdiagnoses (false positives for people without endometriosis) for any diagnostic procedure
 - e. Correct definitive diagnosis of endometriosis (true positive for endometriosis)

Surgery time was not included in the HCP time due to the complexity of having diagnostic and treatment surgery simultaneously or separately. The focus was on the time needed for all diagnostic appointments prior to diagnostic laparoscopy.

6.4.1.1 Sensitivity analyses

Probabilistic sensitivity analysis (PSA) is used to estimate the probability that each strategy is cost-effective at willingness-to-pay thresholds of £0 to £35,000 per QALY gained. For each PSA, 2,000 simulations were performed, with additional simulations run if required to ensure model stability. The PSA

followed a Monte Carlo simulation approach. The cost-effective plane scatter plot is presented with the willingness-to-pay set at £25,000 per QALY gained.

In each simulation, model input parameters were sampled from predefined probability distributions reflecting parameter uncertainty (e.g., normal distributions for continuous parameters and gamma distributions for costs). Random values between 0 and 1 were drawn from uniform distributions and mapped to the corresponding cumulative distribution functions to generate parameter values for each run. A value of 0.5 will return the middle of the cumulative distribution function, which in a normal distribution would reflect the mean value.

Where available, uncertainty of input parameters was taken from the source literature as either the standard deviation (SD) or the 95% confidence interval (CI). If uncertainty data were not available in the literature, they were sourced from expert input. If no data were available, fixed uncertainty ranges that were parameterised by a percentage difference for all clinical ($\pm 20\%$) and cost ($\pm 30\%$) inputs separately, were used.

Results from all simulations were plotted for the cost-effectiveness plane and aggregated to generate cost-effectiveness acceptability curves and 95% credible intervals (CrIs) around total costs and QALYs for each strategy. CrIs represent the range within which 95% of simulated outcomes fall and should not be interpreted as CIs around mean estimates.

A deterministic, one-way sensitivity analysis (OWSA) was performed to identify key model drivers for each new technology separately. The OWSA was performed to assess the impact of each input on both costs (cost difference) and QoL (QALY difference). Key model drivers were then selected for clinically relevant scenario analyses.

6.4.1.2 Scenario analyses

Scenario analyses were explored by modifying input variables to reflect alternative assumptions regarding diagnostic pathways, disease progression, and symptom recurrence, while only focusing on top model drivers. These analyses were used to assess the robustness of results to plausible variations in clinical practice and model structure. Changes to inputs for the scenario analyses were documented alongside a comparison of results to the base case.

6.5 Results from the economic modelling

Model results are presented for each technology separately in the following sections. All sections report cost-effectiveness outcomes only except for Section 6.5.3 where the additional model outcomes are presented for the base case alongside the 95% CrI from the PSA. Additional outcomes were not

reported for scenario analyses but can be gained from running the standalone Excel model submitted alongside this EAR.

6.5.1 Deterministic base-case results

The current care arm estimated the total cost of care for endometriosis to be £20,163 over the 60-year time horizon. In this time, quality-adjusted life expectancy was 14.43 QALYs. The average time to a definitive diagnosis was 9 years and 8 months in the model, which is in line the latest Endometriosis UK survey that identified an average time to diagnosis of 9 years and 4 months ([Endometriosis UK 2026](#)). Full results for all technologies are provided in **Table 16**.

Table 15 Deterministic base case results

Technology	Total costs	Total QALYs	Incremental costs	Incremental QALYs	ICER	NMB	NHB
Current care	£20,163	14.43	-	-	-	-	-
EndoSure	£20,105	14.54	-£58	0.11	Dominant	£2,783	0.11
DotEndo	£20,075	14.54	-£88	0.11	Dominant	£2,763	0.11
EndoTest	£20,746	14.53	£583	0.10	£6,068 per QALY gained	£1,817	0.07

Abbreviations: ICER, Incremental cost-effectiveness ratio; NMB, Net monetary benefit; NHB, Net health benefit; QALY, Quality-adjusted life year

6.5.2 Probabilistic sensitivity analysis results

The model predicted all three technologies to be cost-effective in the majority of simulations (89.80% to 99.25% showed a cost-effective or dominant ICER). QALY gains were roughly similar among technologies, with most simulations showing a positive QALY gain (**Figure 5**, **Figure 9**, and **Figure 13**). In all cases, the 95% CrI did not cross zero, demonstrating consistent QALY gains when the new technologies were in use (**Table 17**). With respect to costs, the 95% CrI ranged from cost-saving (negative cost differential) to cost increasing for all three technologies. The absolute values of the cost differences varied by technology, with EndoSure and DotEndo both being in the range of -£600 to +£400. The 95% CrI for EndoTest was skewed towards increasing costs (-£12 to +£1,190).

Cost and QALY drivers were explored in the OWSA. The sensitivity and specificity of each new test was influential, with sensitivity generally being a cost driver and specificity a QALY driver. The specificity of tests being a major driver of QALYs in the model indicates that diagnostic performance in the non-endometriosis group is important in assessing cost-effectiveness. The performance of TvUS (sensitivity and specificity) was also a common driver of outcomes. The age of the population presenting in primary care with symptoms was a driver for DotEndo and EndoTest but not for EndoSure. This is because DotEndo and EndoTest have age as an eligibility criteria. The larger the population of people under the minimum age or above the maximum age for the tests, the fewer people can potentially benefit from its use.

The PSA and OWSA results are presented and discussed separately for each new technology in the sections below.

Table 16 Probabilistic base case results

Technology	Incremental costs	Incremental QALYs	ICER as % dominant; % cost-effective	NMB	NHB
EndoSure	[-£612 to £426]	[0.011 to 0.274]	54.35%; 99.25%	[£266 to £6,889]	[0.011 to 0.276]
DotEndo	[-£560 to £360]	[0.003 to 0.280]	59.20%; 98.80%	[£66 to £7,075]	[0.003 to 0.283]
EndoTest	[-£12 to £1,190]	[0.000 to 0.250]	2.55%; 89.80%	[-£586 to £5,664]	[-0.023 to 0.227]

Results are presented as the 95% credible interval with 2,000 simulations for the probabilistic sensitivity analysis, which was performed only on the incremental difference between current care and the new technology and not on the total costs and QALYs. As a negative ICER can indicate a dominant or dominated simulation, the range of ICER results is not informative. The ICER is presented as the number of simulations considered dominant and the number of simulations considered cost-effective at a willingness-to-pay threshold of £25,000 per QALY gained. ICER, Incremental cost-effectiveness ratio; NMB, Net monetary benefit; NHB, Net health benefit; QALY, Quality-adjusted life year

6.5.2.1 EndoSure

EndoSure was modelled to be cost-effective in almost all simulations (**Figure 5**) with the majority of simulations being both cost-saving and increasing QALYs (dominant ICER, 54.35%). Overall, at a willingness-to-pay threshold of £25,000 per QALY gained, 99.25% of simulations would be considered cost-effective (**Figure 6**).

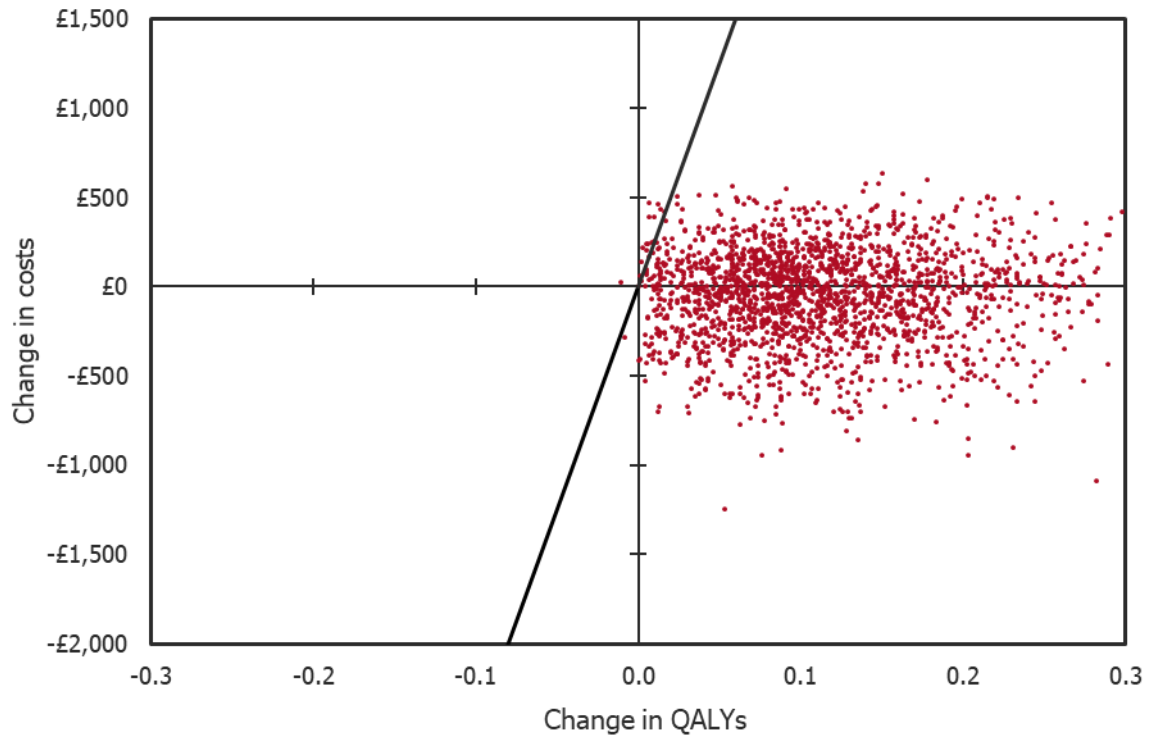


Figure 5. Cost-effectiveness plane for EndoSure in the base case probabilistic sensitivity analysis. QALYs — Quality-adjusted life years. The solid diagonal line is drawn at a willingness-to-pay threshold of £25,000 per QALY gained. Each red point is one simulation and points to the right of the diagonal line are considered to have a cost-effective ICER.

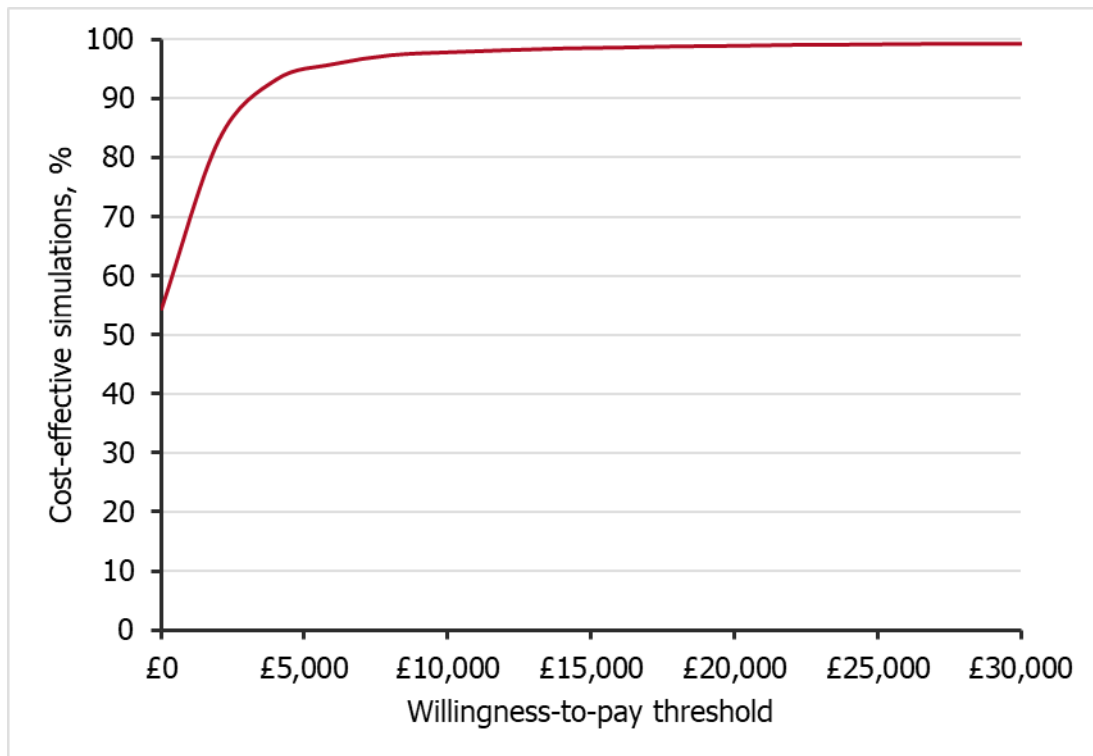


Figure 6. Acceptability curve for EndoSure.

The outcome of the OWSA, the top 15 model drivers, is shown in **Figure 7**. The model for EndoSure was most sensitive to the proportion (prevalence) of people presenting to their GP with endometriosis ('People having endometriosis'). Other key cost drivers were the cost of a secondary care visit and the rate of unplanned physician visits in people with unmanaged symptoms and no diagnosis. The sensitivity of both TvUS and EndoSure, two inputs only used in the endometriosis group (specificity is used for the non-endometriosis group), were cost drivers. The specificity of EndoSure was the main QALY driver. The proportion of people choosing laparoscopy after positive endometriosis findings in secondary care was the next most influential QALY driver.

The percentage change in the differential outcome per 20% change in the base case input was higher for costs than for QALYs. A 20% change in the input for 'People having endometriosis' resulted in a 220% change in differential costs. In absolute terms, though, this was a change of £128 (from -£58 to -£186 or +£70) per person.

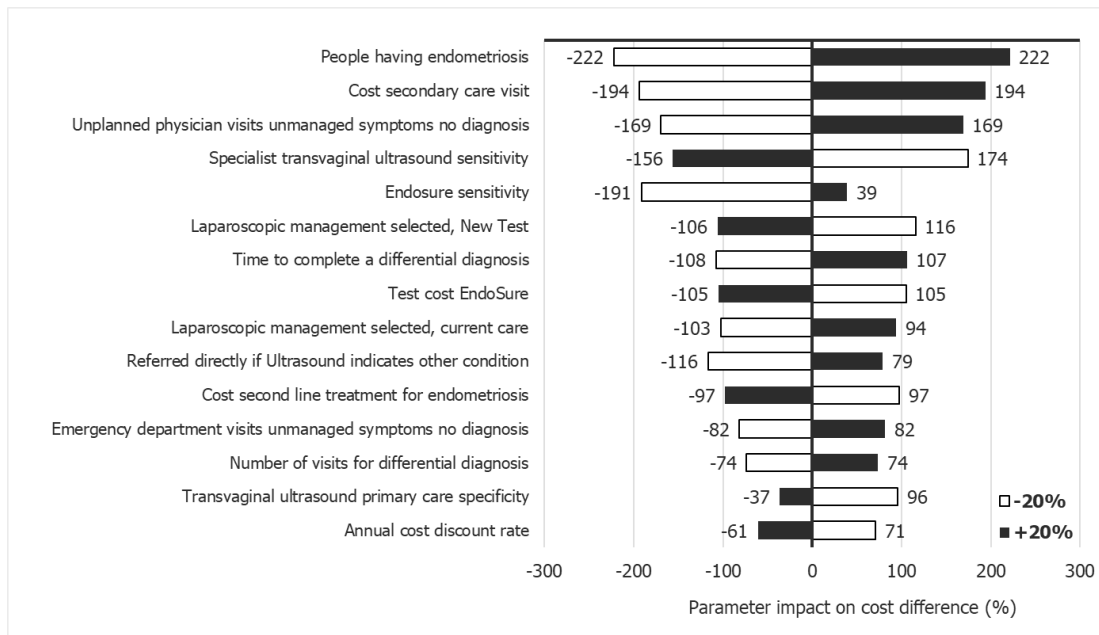


Figure 7. One-way sensitivity analysis to determine cost drivers for EndoSure. Each input parameter is increase by 20% (black bars) or decreased by 20% to assess the overall impact on incremental cost differences. Inputs given in percentages (or rates) are decreased to a minimum of 0% (0.0) or increased to a maximum of 100% (1.0).

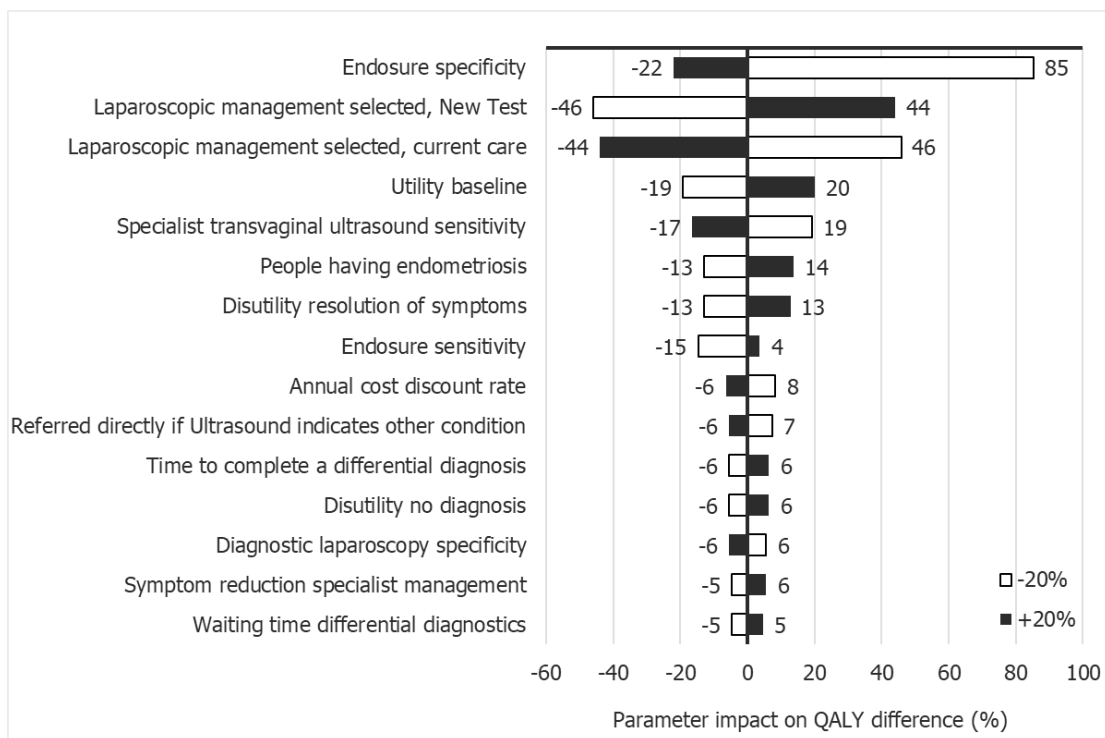


Figure 8. One-way sensitivity analysis to determine QALY drivers for EndoSure. Each input parameter is increase by 20% (black bars) or decreased by 20% to assess the overall impact on incremental cost differences. Inputs given in percentages (or

rates) are decreased to a minimum of 0% (0.0) or increased to a maximum of 100% (1.0).

6.5.2.2 DotEndo

The cost-effectiveness plane for DotEndo (**Figure 8**) showed that the majority of simulations were cost-effective. A minority of simulations resulted in decreased QALYs, both at a cost increase (dominated by current care) and a cost saving. Overall, at a willingness-to-pay threshold of £25,000 per QALY gained over 98.80% of simulations would be considered cost-effective (**Figure 9**). In approximately 60% of cases, DotEndo dominated current care by increasing QALYs and decreasing costs.

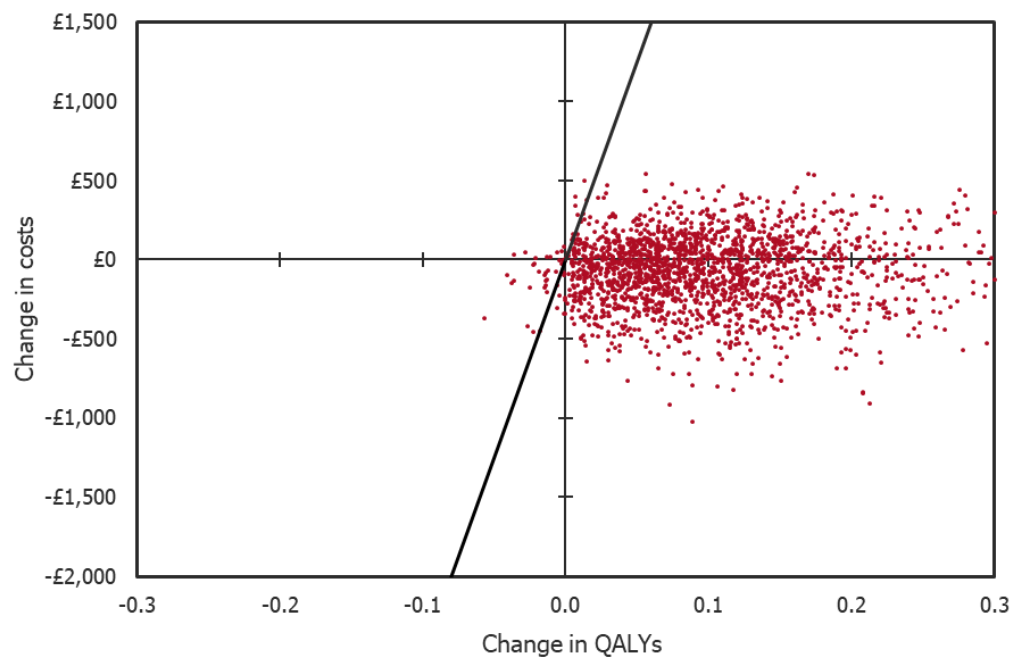


Figure 9 Cost-effectiveness plane for DotEndo in the base case probabilistic sensitivity analysis. QALYs, Quality-adjusted life years. The solid diagonal line is drawn at a willingness-to-pay threshold of £25,000 per QALY gained. Each red point is one simulation and points to the right of the diagonal line are considered to have a cost-effective ICER.

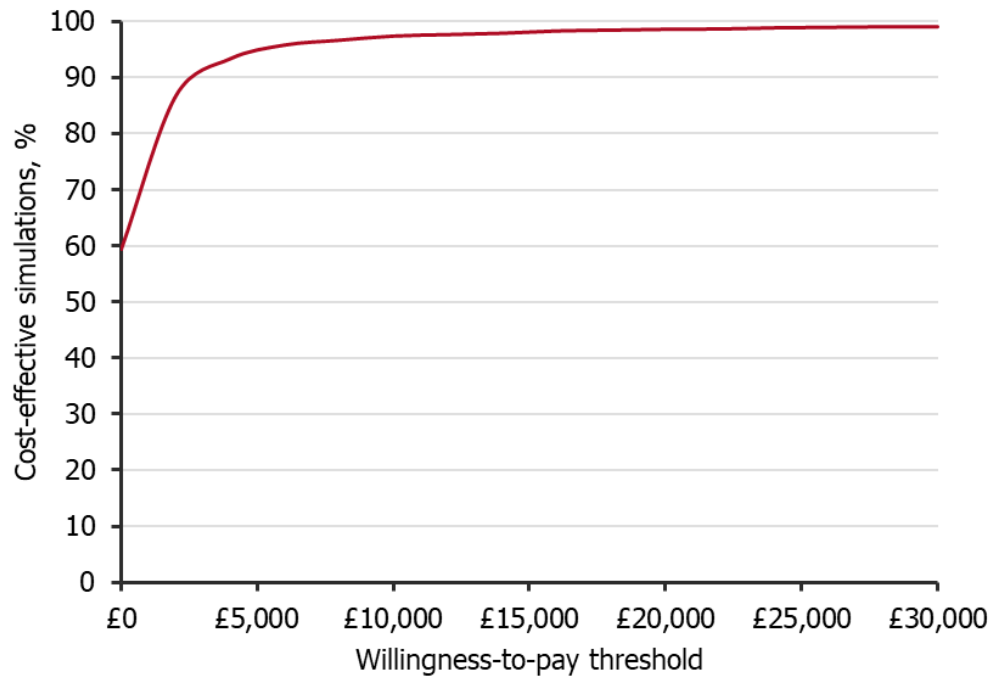


Figure 10 Acceptability curve for DotEndo.

The top four cost drivers for DotEndo matched those identified for EndoSure (**Figure 11**). The key cost driver in the model for DotEndo was the cost of a secondary care visit. Second most impactful was 'People having endometriosis', whereby decreasing this proportion decreased the cost saving accrued through use of DotEndo. The sensitivity and cost of DotEndo were the 5th and 8th most impactful inputs on cost outcomes. The top QALY drivers (**Figure 12**) also aligned closely with those identified for EndoSure. For DotEndo, the age of the population and the minimum age to be eligible to receive DotEndo were also QALY drivers. This is likely because to be eligible for DotEndo people must be at least 18 years old. The population presenting in primary care with symptoms suggestive of endometriosis have a mean age of 22 years; with age normally distributed, a proportion of these people are under 18. If the average age is reduced by 20%, then over 50% of people presenting would not be eligible to receive DotEndo.

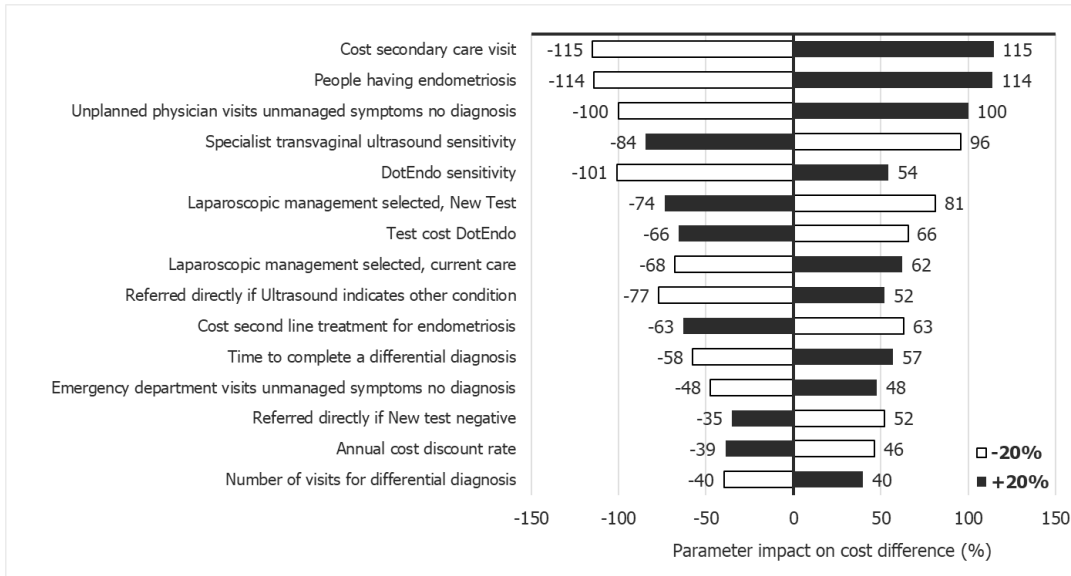


Figure 11. One-way sensitivity analysis to determine cost drivers for DotEndo. Each input parameter is increase by 20% (black bars) or decreased by 20% to assess the overall impact on incremental cost differences. Inputs given in percentages (or rates) are decreased to a minimum of 0% (0.0) or increased to a maximum of 100% (1.0).

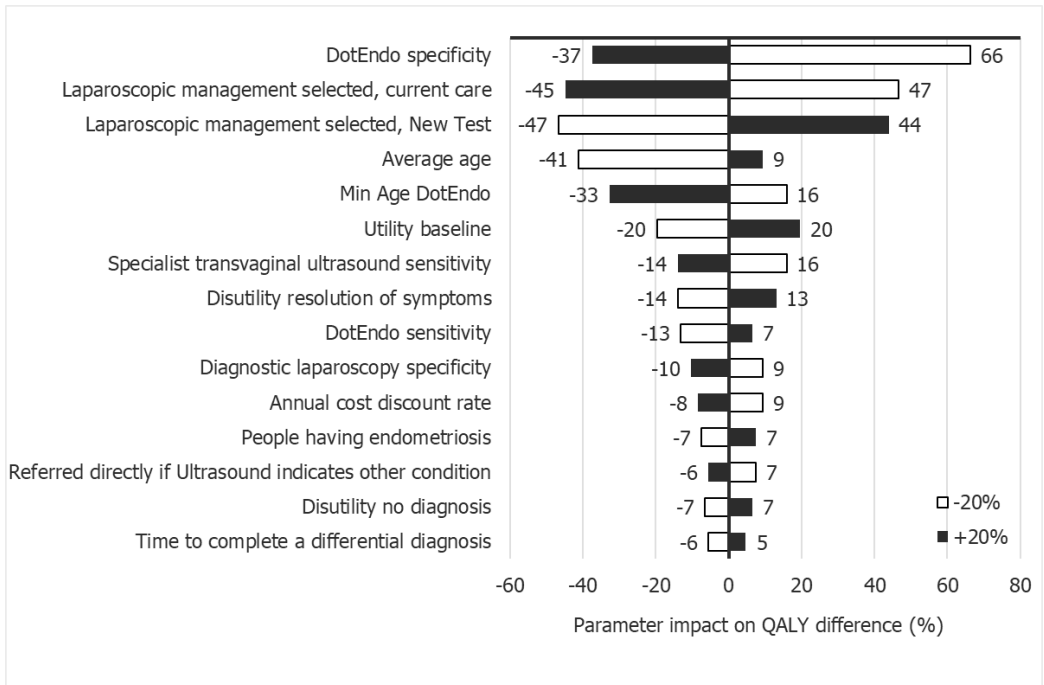


Figure 12. One-way sensitivity analysis to determine QALY drivers for DotEndo. Each input parameter is increase by 20% (black bars) or decreased by 20% to assess the overall impact on incremental cost differences. Inputs given in percentages (or

rates) are decreased to a minimum of 0% (0.0) or increased to a maximum of 100% (1.0).

6.5.2.3 EndoTest

The cost-effectiveness plane for EndoTest (**Figure 13**) showed that the majority of simulations were cost-effective. In a few simulations EndoTest dominated current care and in a few simulations EndoTest was dominated by current care. Overall, at a willingness-to-pay threshold of £25,000 per QALY gained 89.80% of simulations would be considered cost-effective (**Figure 14**). Of the simulations, EndoTest dominated current care in 2.55% of cases.

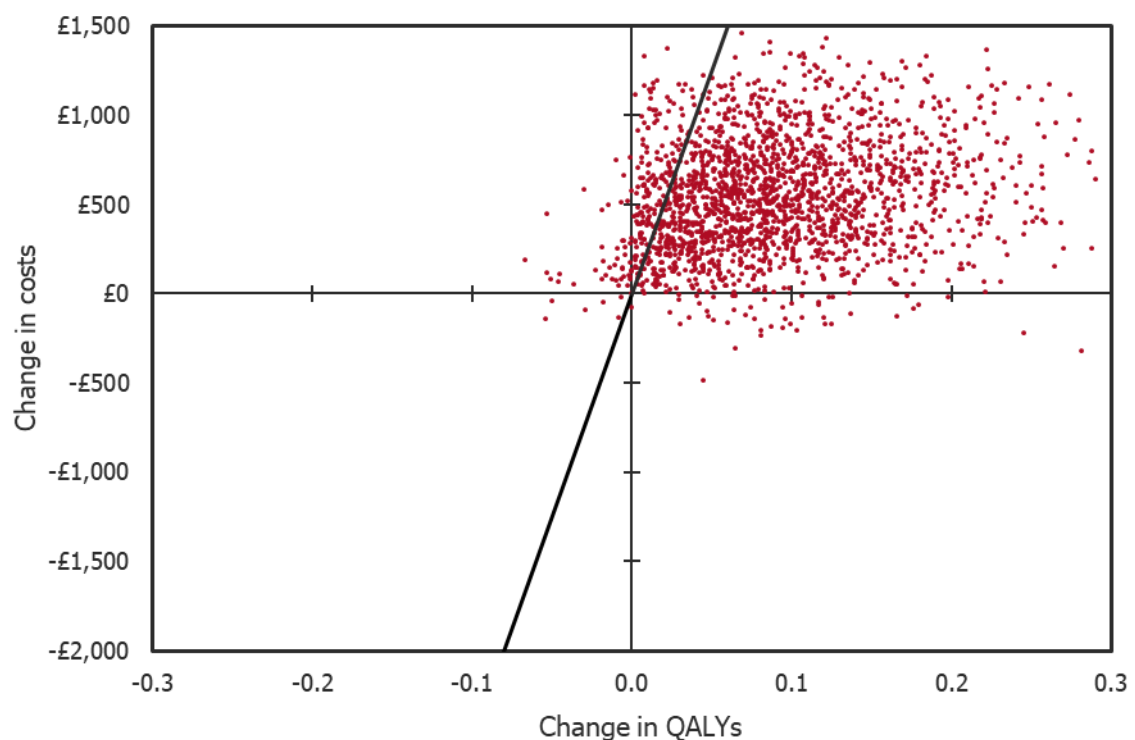


Figure 13. Cost-effectiveness plane for EndoTest in the base case probabilistic sensitivity analysis. QALYs, Quality-adjusted life years. The solid diagonal line is drawn at a willingness-to-pay threshold of £25,000 per QALY gained. Each red point is one simulation and points to the right of the diagonal line are considered to have a cost-effective ICER.

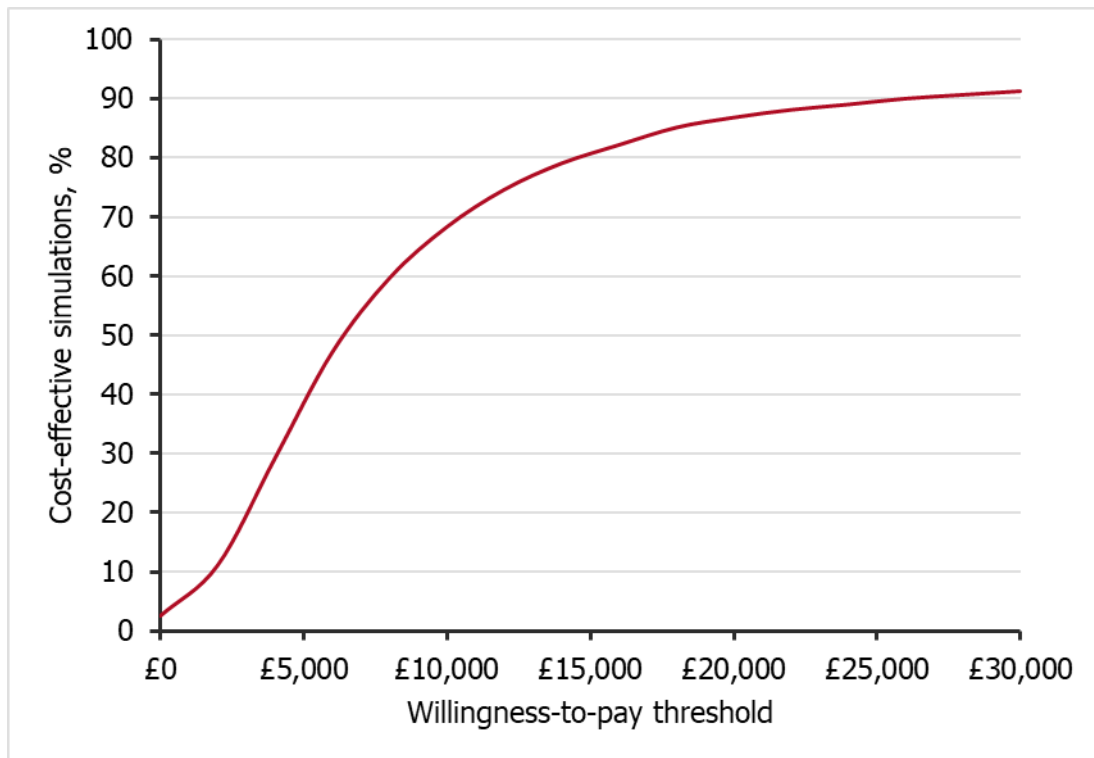


Figure 14 Acceptability curve for EndoTest.

The most impactful drivers of cost in the EndoTest model were the same as those seen for EndoSure and DotEndo, though their order differed (**Figure 15**). The average age of the population is the biggest driver of costs, likely for reasons similar to those presented for DotEndo as EndoTest also has a minimum age for eligibility of 18 years old. Proportionally, a 20% change in input parameters in the model for EndoTest had a smaller impact than the equivalent change in the models for EndoSure and DotEndo. The largest change in costs was 46% for a 20% change in an input parameter in the EndoTest model; for comparison, changes of >100% and >200% were seen in the models for DotEndo and EndoSure, respectively. QALY drivers in the EndoTest model (**Figure 16**) aligned with those identified for EndoSure and DotEndo.

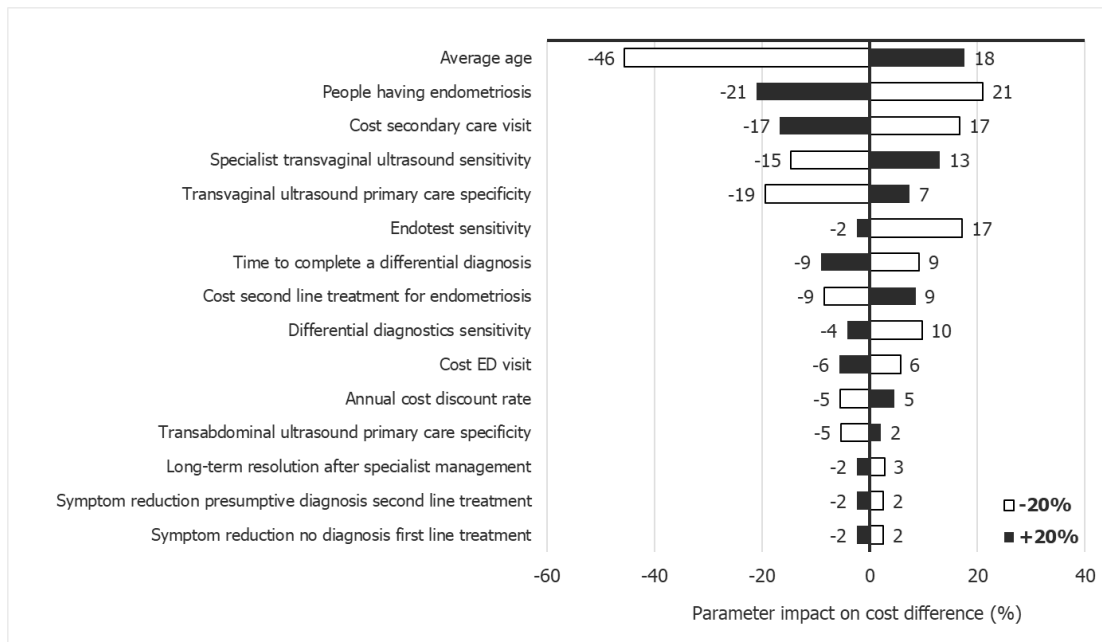


Figure 15. One-way sensitivity analysis to determine cost drivers for EndoTest. Each input parameter is increase by 20% (black bars) or decreased by 20% to assess the overall impact on incremental cost differences. Inputs given in percentages (or rates) are decreased to a minimum of 0% (0.0) or increased to a maximum of 100% (1.0).

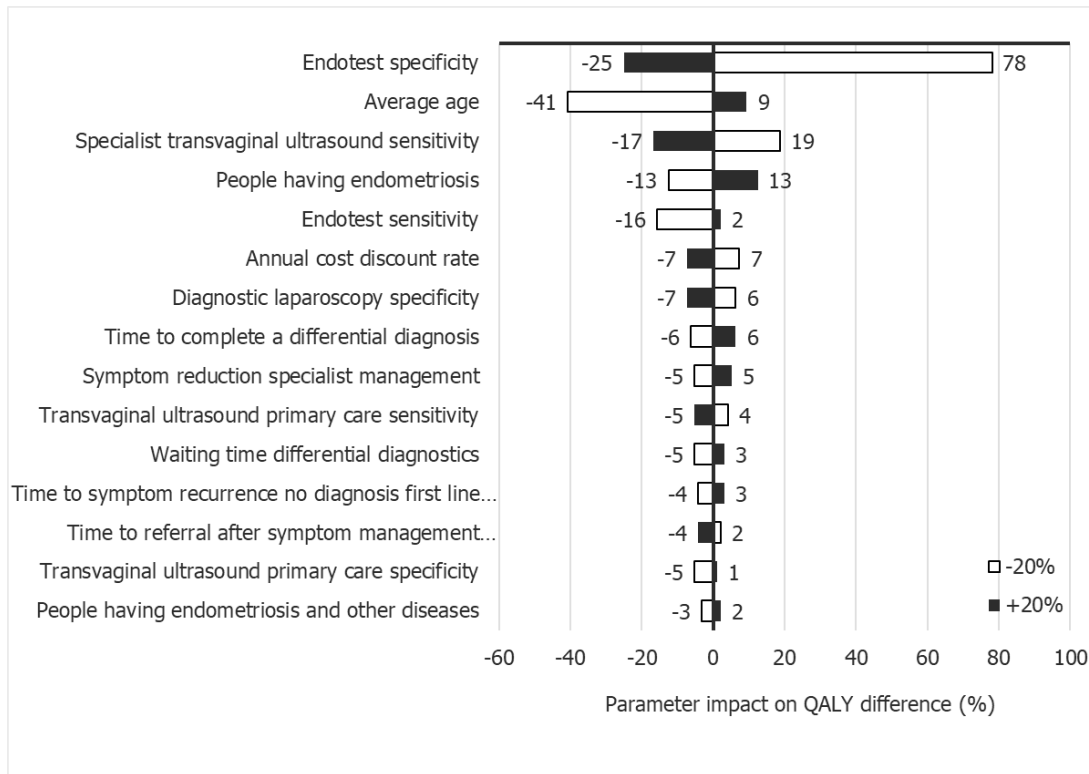


Figure 16. One-way sensitivity analysis to determine QALY drivers for EndoTest. Each input parameter is increase by 20% (black bars) or decreased by 20% to assess the overall impact on incremental cost differences. Inputs given in percentages (or rates) are decreased to a minimum of 0% (0.0) or increased to a maximum of 100% (1.0).

6.5.3 Additional model outcomes

Costs, QoL, and cost-effectiveness are not the only considerations within this early use assessment. When implementing a new technology, consideration for resource use and pathway changes is needed. Deterministic results found that DotEndo and EndoTest reduced HCP time for endometriosis diagnostic tests. The time saving was not substantial in the base case or sensitivity analyses, with the 95% CrI showing a maximal time saving of -0.16 hours (9 minutes and 36 seconds). EndoSure was found to increase HCP time spent on tests for endometriosis, adding 0.59 hours (95% CrI 0.39 to 0.79 hours).

All the new technologies reduced the average time to a presumptive diagnosis and to a definitive diagnosis. The average time to obtaining a presumptive diagnosis was reduced by at least a year by all new technologies. EndoSure and EndoTest both reduced the average time to a definitive diagnosis by at least a year. DotEndo reduced the average time to a definitive diagnosis by just under 1 year. All the new technologies increased the number of false-positive

endometriosis diagnoses. The absolute percentage-point change in these values was small, but on a population level could represent a substantial number of people. For every 100,000 people presenting with symptoms suggestive of endometriosis (whereby 57.5% do not have endometriosis) a 0.5%-point increase in false-positive results represents 288 additional people getting a false-positive diagnosis of endometriosis.

All technologies reduced the percentage of people with a correct definitive diagnosis of endometriosis. This is likely an artefact of the model structure, as more people received a correct presumptive diagnosis of endometriosis when the new technologies were used. In the model structure, getting an initial false-negative diagnosis of endometriosis moves the person towards a differential diagnosis. People with endometriosis identified via a differential diagnosis had more direct access to laparoscopy than patients who received a diagnosis via the initial primary care tests. This might not be true outside of the model environment and is a result of linking testing states within the model to provide a simpler model flow.

Results are provided separately for EndoSure (**Table 18**), DotEndo (**Table 19**), and EndoTest (**Table 20**).

Table 17. Additional outcomes for EndoSure per person

Additional outcome	EndoSure	Current care	Incremental [95% CrI]
HCP time for non-surgical diagnostic procedures	2.56 hours	1.98 hours	0.59 hours [0.39 to 0.79]
Mean time to presumptive diagnosis	1.71 years	3.52 years	-1.82 years [-2.39 to -1.43]
Mean time to definitive endometriosis diagnosis	8.46 years	9.68 years	-1.22 years [-2.56 to 0.01]
Misdiagnoses (false positives; any diagnostic)	2.62%	2.11%	0.50 percentage points [0.20 to 0.90]
Correct definitive diagnosis of endometriosis (true positives; laparoscopy)	54.06%	54.25%	-0.10 percentage points [-8.90 to 8.20]

Incremental results are given in the base case alongside the 95% credible interval from the probabilistic sensitivity analysis using 2,000 simulations. HCP — healthcare provider. Rounding inaccuracies explain discrepancies between the absolute and incremental values. Abbreviations: HCP, health care professional.

Table 18. Additional outcomes for DotEndo per person

Additional outcome	DotEndo	Current care	Incremental [95% CrI]
HCP time for non-surgical diagnostic procedures	1.93 hours	1.98 hours	-0.04 hours [-0.16 to 0.07]
Mean time to presumptive diagnosis	2.08 years	3.52 years	-1.44 years [-2.08 to -0.44]
Mean time to definitive endometriosis diagnosis	8.72 years	9.68 years	-0.97 years [-2.29 to 0.46]
Misdiagnoses (false positives; any diagnostic)	2.94%	2.11%	0.80 percentage points [0.10 to 1.60]
Correct definitive diagnosis of endometriosis (true positives; laparoscopy)	54.10%	54.25%	-0.10 percentage points [-8.90 to 8.20]

Incremental results are given in the base case alongside the 95% credible interval from the probabilistic sensitivity analysis using 2,000 simulations. Rounding inaccuracies explain discrepancies between the absolute and incremental values. HCP — healthcare provider. Abbreviations: HCP, health care professional.

Table 19. Additional outcomes for EndoTest per person

Additional outcome	EndoTest	Current care	Incremental [95% CrI]
HCP time for non-surgical diagnostic procedures	1.92 hours	1.98 hours	-0.05 hours [-0.16 to 0.05]
Mean time to presumptive diagnosis	1.97 years	3.52 years	-1.55 years [-2.17 to -0.43]
Mean time to definitive endometriosis diagnosis	8.64 years	9.68 years	-1.04 years [-2.33 to 0.42]
Misdiagnoses (false positives; any diagnostic)	2.60%	2.11%	0.50 percentage points [0.00 to 0.90]
Correct definitive diagnosis of endometriosis (true positives; laparoscopy)	54.09%	54.25%	-0.10 percentage points [-8.80 to 8.20]

Incremental results are given in the base case alongside the 95% credible interval from the probabilistic sensitivity analysis using 2,000 simulations. Rounding inaccuracies explain discrepancies between the absolute and incremental values. HCP — healthcare provider. Abbreviations: HCP, health care professional.

6.5.4 Scenario analysis results

In this early use assessment, subgroups were not explored due to the limited evidence for the general population presenting with symptoms suggestive of endometriosis. There were even less data for specific subgroups. Instead, the EAG explored the impact on ICERs, costs, and QALYs of input parameters for which the available data were limited or missing or any input parameters that were key drivers across the three technologies. Per technology, 26 standard scenario analyses were performed, plus an additional three for DotEndo to explore the different sensitivity and specificity values provided for threshold and specificity optimised use. An overview of results is provided for DotEndo in **Table 19**, for EndoTest in **Table 20**, and for EndoSure in **Table 21**.

Of the 29 scenarios tested, DotEndo remained dominant (lower cost and more QALYs) compared to current care in 27 cases. The sensitivity and specificity used for DotEndo did not change the interpretation of results. In the two scenarios in which DotEndo resulted in increased costs and increased QALY, the technology remained cost-effective. The first scenario where the ICER changed from dominant to an ICER of 164 was when the sensitivity of TvUS in primary care was increased from 25% to 50%. This means that the lower the sensitivity of TvUS in primary care, the greater the value of DotEndo. Conversely, a decrease in the sensitivities of TvUS in primary and secondary care increased the cost-saving potential of DotEndo. The second major driver of cost-effectiveness for DotEndo was the proportion of people entering the model with symptoms suggestive of endometriosis who were disease-positive. When decreasing this input from 42.5% to 20%, the ICER changed from dominant to £2,091 per QALY gained. Conversely, when increasing the proportion of people with endometriosis to 52.5%, the cost-saving potential of DotEndo increased from £88 to £206 per person with the ICER remaining dominant.

For EndoTest, dominance was observed only in the scenario in which all symptomatic individuals entering the model were assumed to have endometriosis, providing insight into the QALY gains among this population (+0.17 versus +0.10 in the base case) and a decrease in costs. However, due to the higher cost of EndoTest in comparison to the other technologies, providing it to all individuals who do not have endometriosis is predicted to increase overall costs. In all other scenarios, EndoTest was associated with higher costs and higher QALYs but remained cost-effective under a £25,000 per QALY threshold.

For EndoSure, the technology remained dominant in 21 of the 26 scenarios tested. In the remaining five scenarios, EndoSure was associated with higher

costs and higher QALYs but remained cost-effective under the £25,000 per QALY threshold, with the highest ICER below £4,000 per QALY gained. Increases in costs were observed when increasing the sensitivity of TvUS in primary and secondary care, decreasing the sensitivity of EndoSure to 80%, decreasing the proportion of people having endometriosis that enter the model, and decreasing the number of people achieving symptom reduction in primary care from 36.56% to 5%.

One assumed benefit of having an early presumptive diagnosis in primary care is that having the diagnosis increases QoL without being directly linked to the success of a treatment. This is supported by the Endometriosis UK survey where 76% of respondents said their QoL improved after their received a diagnosis, although it was unclear whether this was due to treatment or other factors ([Endometriosis UK 2026](#)). Changing the disutility from 0.0625 to 0 for all three technologies decreased the QALY increment by 0.03; however, it still remained positive for all three technologies.

In conclusion, the value of the new technologies mostly depends on test sensitivities, with the sensitivity of TvUS in primary care being one of the most important parameters. The better the new technologies are at detecting endometriosis in the primary care setting in comparison to ultrasound, the greater the potential for being cost-effective. Another important factor is the proportion of people presenting to primary care with symptoms of endometriosis who have endometriosis. The greater the proportion of disease-positive people who receive the test, the more cost-effective the test is. This is likely because disease-negative people do not benefit directly from the test but incur costs. The final parameter of interest is symptom reduction in primary care: cost-effectiveness is decreased with decreased symptom reduction and increased with increased symptom reduction. This means that if the quality of primary care treatment improves, then the new technology has a greater potential for being cost-effective.

Table 20. Incremental costs and QALYs for scenarios exploring important model parameters for DotEndo

Input parameter	Base case value	Scenario analysis value	Comments	Cost difference, £	QALY difference	ICER, cost (£) per QALY gained
Base case	All inputs as base case	-	The base case is presented here for comparative purposes	-88	+0.11	Dominant
Increasing TvUS sensitivity in primary care	25%	50%	Limited data exist for any of the diagnostics used in primary care, relative performance of current diagnostics and new technologies are a driver of outcomes.	+10	+0.09	111
Decreasing TvUS sensitivity in primary care	25%	20%	Limited data exist for any of the diagnostics used in primary care, relative performance of current diagnostics and new technologies are a driver of outcomes.	-109	+0.11	Dominant
Increasing TvUS sensitivity in secondary care	83.3%	95.3%	Data in specialist care are available but have a wide range of sensitivity values presented, dependent on the type of endometriosis studied (e.g. superficial versus deep), used in the scenario analysis is the upper estimate for deep endometriosis.	-34	+0.10	Dominant
Decreasing TvUS sensitivity in secondary care	83.3%	51.5%	Data in specialist care are available but have a wide range of sensitivity values presented, dependent on the type of endometriosis studied	-260	+0.14	Dominant

			(e.g. superficial versus deep), used in the scenario analysis is the data for superficial endometriosis.			
Decreasing sensitivities of new technology to 80%	90%	80%	None of the new technologies tested accuracies in the real-world, primary care setting where sensitivities may be decreased.	-39	+0.10	Dominant
Increasing the number of visits required for new technology	2	3	Experts reported uncertainty on the number of visits needed to perform the test, to communicate results to the patient, and to plan follow-up treatment.	-61	+0.11	Dominant
People with symptoms having endometriosis entering the model	42.5%	52.5%	A multicentre study with data from 19 hospitals and 13 countries identified 46.7% (group 1) and 58.2% (group 2) of people presenting with symptoms of endometriosis were identified as having endometriosis via diagnostic laparoscopy (Nnoaham et al. 2012). Used the middle value here.	-206	+0.12	Dominant
People with symptoms having endometriosis entering the model	42.5%	20%	Testing a smaller proportion of the cohort presenting at primary care having endometriosis.	+178	+0.08	2,091
People with symptoms having endometriosis entering the model	42.5%	100%	Results in the base case are driven by changes in people with endometriosis, but only a subset of the cohort have endometriosis. This scenario analysis will give insight into QALY benefits seen in people with endometriosis.	-768	+0.16	Dominant

Time to first presentation	8.9 months	6 months	This changes the time to initial presentation at the GP and will impact all subsequent timings in the model.	-86	+0.10	Dominant
Waiting time until laparoscopy	13.57 months	6 months	This will directly impact the time to a definitive diagnosis (defined as confirmed by laparoscopy).	-63	+0.11	Dominant
Waiting time until laparoscopy	13.57 months	24 months	This will directly impact the time to a definitive diagnosis (defined as confirmed by laparoscopy).	-110	+0.11	Dominant
Number of people with comorbid conditions with overlapping symptoms	25%	50%	Increasing this value would potentially result in more people initially being treated for only one condition and not receiving a timely endometriosis diagnosis.	-138	+0.12	Dominant
Number of people achieving symptom reduction in primary care	36.56%	5%	Decreasing this value will impact on quality of life as fewer people would not achieve “managed symptoms”.	-24	+0.11	Dominant
Number of people achieving symptom reduction in primary care	36.56%	50%	Increasing this value will impact on quality of life as more people would not achieve “managed symptoms”.	-114	+0.10	Dominant
Number of people achieving symptom reduction in secondary care	45.70%	20%	Decreasing this value will impact on quality of life as fewer people would not achieve “managed symptoms”.	-146	+0.09	Dominant

Number of people achieving symptom reduction in secondary care	45.70%	60%	Increasing this value will impact on quality of life as more people would not achieve “managed symptoms”.	-70	+0.11	Dominant
Number of people reaching symptom resolution in symptom management in primary care	5.68%	2.5%	These people achieve resolution of symptoms and will stay longer in primary care before their presumptive diagnosis.	-51	+0.11	Dominant
Number of people reaching symptom resolution in symptom management in secondary care	7.1%	15%	These people achieve resolution of symptoms, do not undergo laparoscopy, and cannot get a definitive diagnosis.	-181	+0.12	Dominant
Relative risk for symptom reduction if misdiagnosed	0.5	0.9	Expert feedback indicates that similar treatments are prescribed for conditions that have symptoms overlapping with those of endometriosis. People may therefore respond to treatment.	-139	+0.12	Dominant
Cost of treating other conditions	0	13.36	People diagnosed with another condition will receive treatment. Expert feedback indicates that similar treatments are prescribed for conditions that have symptoms overlapping with those of endometriosis. Here the cost of Line 1 treatment for endometriosis is applied.	-149	+0.11	Dominant

Cost of treating other conditions	0	38.44	People diagnosed with another condition will receive treatment. Expert feedback indicates that similar treatments are prescribed for conditions that have symptoms overlapping with those of endometriosis. Here the cost of Line 2 treatment for endometriosis is applied.	-264	+0.11	Dominant
Baseline quality of life utility	0.59	0.56	(Aubry et al. 2017) report utilities using EQ-5D-3L and EQ-VAS measures. Because the baseline utility of the EQ-VAS is more in line with utilities for the UK reported in Khan et al, we use the EQ-VAS outcomes in this scenario analysis (Khan et al. 2018).	-88	+0.10	Dominant
Disutility for managed symptoms	-0.075	-0.06	(Aubry et al. 2017) report utilities using EQ-5D-3L and EQ-VAS measures. In this scenario analysis the disutility for managed symptoms is switched to the EQ-VAS measure.	-88	+0.11	Dominant
Disutility for no diagnosis	0.0625	0	(Aubry et al. 2017) report utilities using EQ-5D-3L in a population with endometriosis (i.e. all with at least a presumptive diagnosis). We assumed that the presence of symptoms corresponded to an undiagnosed state. Removing the disutility for no diagnosis is explored in this scenario analysis.	-88	+0.07	Dominant
DotEndo sensitivity	90%	83%	In (Moustafa et al. 2020) two viable options for DotEndo sensitivity are provided, one balanced threshold optimised (used in the base case) and one specificity optimised (tested here).	-54	+0.10	Dominant

DotEndo specificity	90%	96%	In (Moustafa et al. 2020) two viable options for DotEndo specificity are provided, one balanced threshold optimised (used in the base case) and one specificity optimised (tested here).	-90	+0.08	Dominant
DotEndo sensitivity and specificity	90% and 90%	83% and 96%	In (Moustafa et al. 2020) two viable options for DotEndo sensitivity and specificity are provided, one balanced threshold optimised (used in the base case) and one specificity optimised (tested here).	-56	+0.08	Dominant

Abbreviations: QALY, Quality-adjusted life year; TvUS, Transvaginal ultrasound

Table 21. Incremental costs and QALYs for scenarios exploring important model parameters for EndoTest

Input parameter	Base case value	Scenario analysis value	Comments	Cost difference	QALY difference	ICER
Base case	All inputs as base case	-	The base case is presented here for comparative purposes	+583	+0.10	6,068
Increasing TvUS sensitivity in primary care	25%	50%	Limited data exist for any of the diagnostics used in primary care, relative performance of current diagnostics and new technologies are a driver of outcomes.	+623	+0.07	8,413

Decreasing TvUS sensitivity in primary care	25%	20%	Limited data exist for any of the diagnostics used in primary care, relative performance of current diagnostics and new technologies are a driver of outcomes.	+573	+0.10	5,733
Increasing TvUS sensitivity in secondary care	83.3%	95.3%	Data in specialist care are available but have a wide range of sensitivity values presented, dependent on the type of endometriosis studied (e.g. superficial versus deep), used in the scenario analysis is the upper estimate for deep endometriosis.	+638	+0.08	7,594
Decreasing TvUS sensitivity in secondary care	83.3%	51.5%	Data in specialist care are available but have a wide range of sensitivity values presented, dependent on the type of endometriosis studied (e.g. superficial versus deep), used in the scenario analysis is the data for superficial endometriosis.	+410	+0.13	3,126
Decreasing sensitivities of new technology to 80%	97.3%	80%	None of the new technologies tested accuracies in the real-world, primary care setting where sensitivities may be decreased.	+671	+0.08	8,087
Increasing the number of visits required for new technology	2	3	Experts reported uncertainty on the number of visits needed to perform the test, to communicate results to the patient, and to plan follow-up treatment.	+609	+0.10	6,346
People with symptoms having endometriosis	42.5%	52.5%	A multicentre study with data from 19 hospitals and 13 countries identified 46.7% (group 1) and 58.2% (group 2) of people presenting with symptoms of endometriosis were identified as	+439	+0.11	4,025

entering the model			having endometriosis via diagnostic laparoscopy (Nnoaham et al. 2012). Used the middle value here.			
People with symptoms having endometriosis entering the model	42.5%	20%	Testing a smaller proportion of the cohort presenting at primary care having endometriosis.	+906	+0.06	13,942
People with symptoms having endometriosis entering the model	42.5%	100%	Results in the base case are driven by changes in people with endometriosis, but only a subset of the cohort have endometriosis. This scenario analysis will give insight into QALY benefits seen in people with endometriosis.	-245	+0.17	Dominant
Time to first presentation	8.9 months	6 months	This changes the time to initial presentation at the GP and will impact all subsequent timings in the model.	+595	+0.09	6,328
Waiting time until laparoscopy	13.57 months	6 months	This will directly impact the time to a definitive diagnosis (defined as confirmed by laparoscopy).	+599	+0.10	6,111
Waiting time until laparoscopy	13.57 months	24 months	This will directly impact the time to a definitive diagnosis (defined as confirmed by laparoscopy).	+568	+0.09	6,046
Number of people with comorbid conditions with overlapping symptoms	25%	50%	Increasing this value would potentially result in more people initially being treated for only one condition and not receiving a timely endometriosis diagnosis.	+531	+0.11	4,826

Number of people achieving symptom reduction in primary care	36.56%	5%	Decreasing this value will impact on quality of life as fewer people would not achieve “managed symptoms”.	+646	+0.10	6,336
Number of people achieving symptom reduction in primary care	36.56%	50%	Increasing this value will impact on quality of life as more people would not achieve “managed symptoms”.	+557	+0.09	5,985
Number of people achieving symptom reduction in secondary care	45.70%	20%	Decreasing this value will impact on quality of life as fewer people would not achieve “managed symptoms”.	+529	+0.08	6,618
Number of people achieving symptom reduction in secondary care	45.70%	60%	Increasing this value will impact on quality of life as more people would not achieve “managed symptoms”.	+601	+0.10	5,836
Number of people reaching symptom resolution in symptom management in primary care	5.68%	2.5%	These people achieve resolution of symptoms and will stay longer in primary care before their presumptive diagnosis.	+620	+0.09	6,592

Number of people reaching symptom resolution in symptom management in secondary care	7.1%	15%	These people achieve resolution of symptoms, do not undergo laparoscopy, and cannot get a definitive diagnosis.	+518	+0.10	5,132
Relative risk for symptom reduction if misdiagnosed	0.5	0.9	Expert feedback indicates that similar treatments are prescribed for conditions that have symptoms overlapping with those of endometriosis. People may therefore respond to treatment.	+554	+0.10	5,428
Cost of treating other conditions	0	13.36	People diagnosed with another condition will receive treatment. Expert feedback indicates that similar treatments are prescribed for conditions that have symptoms overlapping with those of endometriosis. Here the cost of Line 1 treatment for endometriosis is applied.	+539	+0.10	5,619
Cost of treating other conditions	0	38.44	People diagnosed with another condition will receive treatment. Expert feedback indicates that similar treatments are prescribed for conditions that have symptoms overlapping with those of endometriosis. Here the cost of Line 2 treatment for endometriosis is applied.	+458	+0.10	4,776
Baseline quality of life utility	0.59	0.56	(Aubry et al. 2017) report utilities using EQ-5D-3L and EQ-VAS measures. Because the baseline utility of the EQ-VAS is more in line with utilities for the UK reported in Khan et al, we use the EQ-VAS outcomes in this scenario analysis (Khan et al. 2018).	+583	+0.09	6,473

Disutility for managed symptoms	-0.075	-0.06	(Aubry et al. 2017) report utilities using EQ-5D-3L and EQ-VAS measures. In this scenario analysis the disutility for managed symptoms is switched to the EQ-VAS measure.	+583	+0.10	6,006
Disutility for no diagnosis	0.0625	0	(Aubry et al. 2017) report utilities using EQ-5D-3L in a population with endometriosis (i.e. all with at least a presumptive diagnosis). We assumed that the presence of symptoms corresponded to an undiagnosed state. Removing the disutility for no diagnosis is explored in this scenario analysis.	+583	+0.07	8,826

Abbreviations: QALY, Quality-adjusted life year; TvUS, Transvaginal ultrasound

Table 22. Incremental costs and QALYs for scenarios exploring important model parameters for EndoSure

Input parameter	Base case value	Scenario analysis value	Comments	Cost difference	QALY difference	ICER
Base case	All inputs as base case	-	The base case is presented here for comparative purposes	-58	+0.11	Dominant
Increasing TvUS sensitivity in primary care	25%	50%	Limited data exist for any of the diagnostics used in primary care, relative performance of current diagnostics and new technologies are a driver of outcomes.	+59	+0.08	697

Decreasing TvUS sensitivity in primary care	25%	20%	Limited data exist for any of the diagnostics used in primary care, relative performance of current diagnostics and new technologies are a driver of outcomes.	-83	+0.11	Dominant
Increasing TvUS sensitivity in secondary care	83.3%	95.3%	Data in specialist care are available but have a wide range of sensitivity values presented, dependent on the type of endometriosis studied (e.g. superficial versus deep), used in the scenario analysis is the upper estimate for deep endometriosis.	+8	+0.10	85
Decreasing TvUS sensitivity in secondary care	83.3%	51.5%	Data in specialist care are available but have a wide range of sensitivity values presented, dependent on the type of endometriosis studied (e.g. superficial versus deep), used in the scenario analysis is the data for superficial endometriosis.	-265	+0.15	Dominant
Decreasing sensitivities of new technology to 80%	96%	80%	None of the new technologies tested accuracies in the real-world, primary care setting where sensitivities may be decreased.	+34	+0.10	362
Increasing the number of visits required for new technology	2	3	Experts reported uncertainty on the number of visits needed to perform the test, to communicate results to the patient, and to plan follow-up treatment.	-26	+0.11	Dominant
People with symptoms having endometriosis	42.5%	52.5%	A multicentre study with data from 19 hospitals and 13 countries identified 46.7% (group 1) and 58.2% (group 2) of people presenting with symptoms of endometriosis were identified as	-211	+0.13	Dominant

entering the model			having endometriosis via diagnostic laparoscopy (Nnoaham et al. 2012). Used the middle value here.			
People with symptoms having endometriosis entering the model	42.5%	20%	Testing a smaller proportion of the cohort presenting at primary care having endometriosis.	285	+0.07	3,952
People with symptoms having endometriosis entering the model	42.5%	100%	Results in the base case are driven by changes in people with endometriosis, but only a subset of the cohort have endometriosis. This scenario analysis will give insight into QALY benefits seen in people with endometriosis.	-934	+0.21	Dominant
Time to first presentation	8.9 months	6 months	This changes the time to initial presentation at the GP and will impact all subsequent timings in the model.	-54	+0.11	Dominant
Waiting time until laparoscopy	13.57 months	6months	This will directly impact the time to a definitive diagnosis (defined as confirmed by laparoscopy).	-42	+0.11	Dominant
Waiting time until laparoscopy	13.57 months	24 months	This will directly impact the time to a definitive diagnosis (defined as confirmed by laparoscopy).	-73	+0.11	Dominant
Number of people with comorbid conditions with overlapping symptoms	25%	50%	Increasing this value would potentially result in more people initially being treated for only one condition and not receiving a timely endometriosis diagnosis.	-119	+0.13	Dominant

Number of people achieving symptom reduction in primary care	36.56%	5%	Decreasing this value will impact on quality of life as fewer people would not achieve “managed symptoms”.	+16	+0.12	141
Number of people achieving symptom reduction in primary care	36.56%	50%	Increasing this value will impact on quality of life as more people would not achieve “managed symptoms”.	-89	+0.11	Dominant
Number of people achieving symptom reduction in secondary care	45.70%	20%	Decreasing this value will impact on quality of life as fewer people would not achieve “managed symptoms”.	-121	+0.09	Dominant
Number of people achieving symptom reduction in secondary care	45.70%	60%	Increasing this value will impact on quality of life as more people would not achieve “managed symptoms”.	-36	+0.12	Dominant
Number of people reaching symptom resolution in symptom management in primary care	5.68%	2.5%	These people achieve resolution of symptoms and will stay longer in primary care before their presumptive diagnosis.	-15	+0.11	Dominant

Number of people reaching symptom resolution in symptom management in secondary care	7.1%	15%	These people achieve resolution of symptoms, do not undergo laparoscopy, and cannot get a definitive diagnosis.	-127	+0.12	Dominant
Relative risk for symptom reduction if misdiagnosed	0.5	0.9	Expert feedback indicates that similar treatments are prescribed for conditions that have symptoms overlapping with those of endometriosis. People may therefore respond to treatment.	-87	+0.12	Dominant
Cost of treating other conditions	0	13.36	People diagnosed with another condition will receive treatment. Expert feedback indicates that similar treatments are prescribed for conditions that have symptoms overlapping with those of endometriosis. Here the cost of Line 1 treatment for endometriosis is applied.	-105	+0.11	Dominant
Cost of treating other conditions	0	38.44	People diagnosed with another condition will receive treatment. Expert feedback indicates that similar treatments are prescribed for conditions that have symptoms overlapping with those of endometriosis. Here the cost of Line 2 treatment for endometriosis is applied.	-194	+0.11	Dominant
Baseline quality of life utility	0.59	0.56	(Aubry et al. 2017) report utilities using EQ-5D-3L and EQ-VAS measures. Because the baseline utility of the EQ-VAS is more in line with utilities for the UK reported in Khan et al, we use the EQ-VAS outcomes in this scenario analysis (Khan et al. 2018).	-58	+0.10	Dominant

Disutility for managed symptoms	-0.075	-0.06	(Aubry et al. 2017) report utilities using EQ-5D-3L and EQ-VAS measures. In this scenario analysis the disutility for managed symptoms is switched to the EQ-VAS measure.	-58	+0.11	Dominant
Disutility for no diagnosis	0.0625	0	(Aubry et al. 2017) report utilities using EQ-5D-3L in a population with endometriosis (i.e. all with at least a presumptive diagnosis). We assumed that the presence of symptoms corresponded to an undiagnosed state. Removing the disutility for no diagnosis is explored in this scenario analysis.	-58	+0.08	Dominant

Abbreviations: QALY, Quality-adjusted life year; TvUS, Transvaginal ultrasound

6.6 Summary and interpretation of the economic evidence

There was limited published economic evidence available for the new technologies and none directly for the NHS or primary care setting. Studies in the UK and other countries have demonstrated long delays in diagnosis (Ghai et al. 2020; Corte et al. 2025) and increased healthcare resource use in the pre-diagnosis of endometriosis (Surrey et al. 2020). Cost-effectiveness has not been considered to date for the UK and an early model to determine the cost-utility of the new technologies in the NHS primary care setting was developed. This early use assessment of three new technologies found that all three technologies are expected to be considered cost-effective in the NHS at a willingness-to-pay threshold £25,000 per QALY gained. Being cost-effective does not translate into affordability and consideration should be given to how many tests may be expected to be performed per year. The Office for National Statistics reported that 262,065 women in England were diagnosed with endometriosis in the period 27 March 2011 to 31 December 2021. This equates to approximately 24,500 endometriosis diagnoses per year and the number of tests performed per year could be more than double this. If new diagnostic tests become widely used, consideration of the potential budget impact may be important.

There are still outstanding evidence needs and thus uncertainty in input parameters, most notably how the diagnostic accuracy of the new technologies performs in the primary care population—and especially in direct comparison to ultrasound scans in the primary care setting. Scenario analyses tested what might be expected if diagnostic accuracy is reduced in the primary care population. Over the range of scenario analyses tested, increases in QoL were ubiquitous (all QALY increments were positive). One can conclude that the tests are unlikely to do harm on average in any scenario (individuals were not modelled). Many scenarios were cost-saving, however, cost increases did occur but never exceeded +£1,000 per person. If the proportion of people with endometriosis in the presenting population was reduced to 20% for EndoTest the cost increase would be +£906. The lack or limited upfront costs for the new technologies may make uncertainty in outcomes less impactful for decision-making. Only one technology (EndoSure) comes with a capital cost and training for use that is expected to be a few hours per user. The cost of reversing a wrong decision is therefore likely not substantial unless new processes or rooms need to be provided to complete the testing. This level of specification was out of [scope](#) of the current cost-utility analysis.

The model has limitations that should be considered when interpreting the results presented. Sensitivity and specificity data on all diagnostics, current and new technologies, for endometriosis were lacking for the primary care setting. The OWSA indicated that sensitivity of the tests was a key driver and scenario

analyses tested. It is uncertain how changes in sensitivity would impact model results. Changes in input parameters tested did change absolute results but not their interpretation: that, overall, the new technologies would be considered cost-effective or cost-saving. There is also uncertainty in the population, with respect to how many people present with endometriosis plus other comorbidities that are associated with symptoms similar to those of endometriosis. As per the [scope](#), the tests are planned to be used in primary care after an initial ultrasound scan finds no signs of endometriosis: this population represents a group not tested by the new technologies at this stage. The potential for false positives and false negatives may increase compared to testing undertaken in a secondary care cohort that has already had a presumptive diagnosis of endometriosis.

Although the model care pathway was approved by clinical experts, it cannot capture all the complexity of the endometriosis care pathway. This is particularly true for people with multimorbidity. A negative ultrasound in the model, though negative for endometriosis, might be positive for other pathology and prompt a change in care that is not captured in our model. The costs and potential symptom impact of this change in care is missing in cost and QALY estimates of the model. In the base case, it is assumed that once fully diagnosed for another (general not specific) condition, people do receive treatment and can have symptom reduction. No cost for this is included in the base case. The group of people without endometriosis, reflects the real-life use case expected for the new technologies in the NHS. In the model, though, it limits the QALY benefit available as this subgroup (57.5% in the base case) obtains no benefit from the new tests. Scenario analyses suggest that people with endometriosis obtain a QALY benefit greater than that indicated in the base case. Costs of prescribed treatments were also impacted by uncertainty as a multitude of treatments exist and the ones prescribed are dependent on the person's medical history and life situation (e.g., desire to have children) among other factors.

7 Integration into the NHS

7.1 Patient attitudes towards the adoption of the new diagnostic tests within the NHS

The EAG feel that it is important to acknowledge the contributions of patient representatives towards this early use assessment. During the assessment period, the EAG received submissions from the patient organisations “Fair Treatment for the Women of Wales” and “Hull and East Yorkshire Endometriosis Support”, as well as individual patient representatives. Collectively, they expressed strong support for the introduction of new, non-

invasive diagnostic tests such as EndoSure, DotEndo, and EndoTest into the NHS pathway. Their views emphasised the urgent need to reduce the lengthy diagnostic delays (often 8 to 10 years) that patients currently face. An earlier and more accessible diagnosis would be empowering and validating for patients, enabling timely access to treatment, support, and reasonable adjustments in education and employment. However, the patient representatives also stressed that while these technologies may offer significant benefits, such as reducing reliance on invasive procedures, improving patient experience, and potentially alleviating pressure on surgical services, they are not a complete solution. There remain concerns about false negatives, the need for sensitive communication of results, and the risk of new technologies compounding existing inequalities (e.g., for older people, adolescents, those with comorbidities, or those facing socioeconomic or geographic barriers). Patient groups call for these tests to be universally accessible, accompanied by improved awareness, education, and clear care pathways. They also stress that the tests should not replace access to specialist surgical care or ongoing research into better treatments and cures for endometriosis.

7.2 Current use of the new diagnostic technologies in the NHS

7.2.1 EndoSure

Existing technology use within the NHS

The RFI document submitted by the company states that the technology is already available to the NHS. It is currently in use as part of the ADDEND study 2024 in the NHS hospital in Worcester, as well as at 19 clinics across the UK.

System changes required/potential barriers to implementation

The company RFI states that the only barriers to EndoSure implementation in the NHS are space (a room is required for the procedure) and personnel (staff trained in EVG).

Training

The company RFI states that there is an already well-developed training programme for staff and that it takes an average of 1 to 2 cases to become proficient.

7.2.2 DotEndo

Existing technology use within the NHS

The company RFI states that the technology is not currently available to the NHS but that the company is interested in launching the technology within the

NHS, with timelines and pilot opportunities currently under exploration (see Section 8).

System changes required/potential barriers to implementation

The company RFI states that the system changes required are digital integration with existing clinical workflows (e.g., referral pathways, electronic patient record systems) and the establishment of procurement and reimbursement pathways for diagnostic testing using DotEndo. Potential barriers listed in the company RFE include “the requirement for education around non-invasive diagnosis in a historically surgery-based paradigm, evidence expectations for clinical utility and health-economic impact, and digital governance and data protection requirements”.

Training

The company RFI states that the training requirements for DotEndo are expected to be modest, consisting of short (e.g., 1 to 2 hours) onboarding modules for healthcare professionals, covering intended use, interpretation of outputs, and clinical integration, with the provision of optional deeper training for specialist users.

7.2.3 EndoTest

Existing technology use within the NHS

The company RFI submission states that the product is not yet in use in the NHS; however, it is currently being trialled at an NHS hospital in Bristol, UK (see Section 8).

System changes required/potential barriers to implementation

The company RFI states that no major system changes are expected for NHS adoption of EndoTest, as the test requires only a saliva sample and does not rely on specialist equipment or additional clinical training. Collection kits can be used in primary care, community services, or specialist clinics without modification to existing infrastructure. Potential barriers to adoption may include the need for awareness among clinicians regarding the role of molecular diagnostics in endometriosis assessment, and the integration of a new test within established referral and diagnostic pathways.

Training

The company RFI states that experience in the French healthcare setting has shown adoption to be swift and relatively simple to implement. In France, EndoTest has been integrated into routine clinical practice in 100 hospitals with full reimbursement for 25,000 people.

A number of UK NHS studies are planned or ongoing for all three technologies. Please see Section 8 for more information.

8 Evidence gap analysis

8.1 Ongoing or planned studies

Ongoing studies are listed in **Table 19**. The EAG considers these studies may partially address some of the clinical uncertainties.

Table 23 Ongoing studies and their relevance to the decision problem

Technology	Ongoing or planned study	Alignment with scope	Indicated study end date	Source	EAG comments
EndoSure (3PCM/Endosure)	<p>ADDEND study 2024 Prospective, single-centre, pilot diagnostic accuracy study (protocol/registration only) Trial registration: http://isrctn.com, ISRCTN83220665 Registered 17/12/2024; status: recruiting England/UK</p>	<p>Participants: N=78 (26 per cohort) pre-menopausal women (aged 18 to 50 years): Cohort 1: Scheduled laparoscopy for pelvic pain/suspected endometriosis Cohort 2: Scheduled laparoscopy for other benign conditions Cohort 3: Healthy female volunteers without pelvic pain (Partial match to scope)</p> <p>Setting: NHS secondary care, UK (Partial match to scope)</p> <p>Intervention: EndoSure test (Full match to scope)</p>	Results expected in the third or fourth quarter (calendar year) of 2026	Literature search and company submission	<ul style="list-style-type: none"> • No results available to date • UK NHS setting • Moderate* sample size

Technology	Ongoing or planned study	Alignment with scope	Indicated study end date	Source	EAG comments
		<p>Comparator: Laparoscopy with standardised surgical imaging and histological biopsy (Full match to scope)</p> <p>Outcomes: Diagnostic accuracy (sensitivity, specificity) vs. laparoscopy 8-week follow-up visit post-surgery (Full match to scope)</p>			
EndoSure (3PCM/Endosure)	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	Company submission	<ul style="list-style-type: none"> • No results available to date • UK NHS setting • Moderate* sample size

Technology	Ongoing or planned study	Alignment with scope	Indicated study end date	Source	EAG comments
		<p>██████████</p> <p>██████████</p> <p>██████████</p> <p>██████████</p>			
DotEndo (DotLab)	<p>EMPOWER study 2020</p> <p>Prospective observational multicentre diagnostic accuracy study (trial registration only)</p> <p>USA (multi-site)</p> <p>Trial registration: NCT04598698</p> <p>Status: Active, not recruiting.</p> <p>Last updated August 2024</p>	<p>Participants:</p> <p>Estimated N=740 women aged 18 to 49 years with unexplained pelvic pain and/or suspected endometriosis. (Partial match to scope)</p> <p>Setting: Tertiary care centres in the US (No match to scope)</p> <p>Intervention: ██████████ ██████████ (Full match to scope)</p> <p>Comparator: Current care; ██████████ ██████████ ██████████ ██████████</p>	<p>██████████</p> <p>██████</p>	<p>Literature review (study protocol) and company submission (preliminary abstract)</p>	<ul style="list-style-type: none"> • Preliminary data, not peer-reviewed • Non-UK setting • Large* planned study sample, although final sample size unknown • Study population diverse in terms of ethnicity, disease stage, and hormonal therapy use. • Remaining outcomes unknown • ██████████

Technology	Ongoing or planned study	Alignment with scope	Indicated study end date	Source	EAG comments
		(Partial match to scope) Outcomes: DotEndo 2 specificity of 96%, with robust performance is across rASRM disease stages, demographic subgroups, and in patients using hormonal therapies. (Partial match to scope)			
DotEndo (DotLab)	EMPOWER study 2020, continued follow-up Prospective multicentre observational study	As above	██████████ ██████	Company submission	<ul style="list-style-type: none"> • No results available to date • Non-UK setting • Sample size unknown
DotEndo (DotLab)	Prospective observational pilot study (planned) UK	Participants: Women with recurrent symptoms, normal clinical examination, and negative or unavailable imaging. (Full match to scope)	██████████ ██████████ ██████ ██████████ ██████████	Company submission	<ul style="list-style-type: none"> • No results available to date • UK NHS setting • Sample size unknown

Technology	Ongoing or planned study	Alignment with scope	Indicated study end date	Source	EAG comments
		<p>Setting: UK NHS secondary care (gynaecology or fertility clinics) (Partial match to scope)</p> <p>Intervention: DotEndo 2 (Full match to scope)</p> <p>Comparator: Current diagnostic pathway (Full match to scope)</p> <p>Outcomes:</p>			
EndoTest (Ziwig)	Prospective single-centre study by Bristol and Weston NHS Trust, UK	<p>Participants: N=100 women with signs and symptoms suggestive of endometriosis, enrolled from the current referral waiting list. (Partial match to scope)</p> <p>Setting: One UK NHS tertiary centre</p>	Results anticipated in the second or third quarter (calendar year) of 2026	Company submission	<ul style="list-style-type: none"> • No results available to date • UK NHS setting • Moderate* sample size

Technology	Ongoing or planned study	Alignment with scope	Indicated study end date	Source	EAG comments
		(Partial match to scope) Intervention: EndoTest (Full match to scope) Comparator: No comparator (Partial match to scope) Outcomes: Unknown (N/A)			
EndoTest (Ziwig)	ENDOBEST study 2025 Prospective, multicentre, interventional management impact study (trial registration only) France (planned) Trial registration: ClinicalTrials.gov NCT06794424	Participants: Estimated N=2,500 patients with chronic disabling pelvic pain strongly suggestive of endometriosis and negative/uncertain baseline imaging (Full match to scope) Setting: 100 hospitals across France, including at least 20 secondary hospitals and at least 60 tertiary hospitals (No match to scope)	Results anticipated in the first or second quarter (calendar year) of 2027	Literature review (trial registration) and company submission (preliminary data)	<ul style="list-style-type: none"> • Trial registration only; not yet recruiting. • Management impact study, not a diagnostic accuracy study. • Aims to show whether EndoTest reduces diagnostic laparoscopy in women with uncertain imaging. • Non-UK setting but results will be directly relevant to NHS

Technology	Ongoing or planned study	Alignment with scope	Indicated study end date	Source	EAG comments
		<p>Intervention: EndoTest (Full match to scope)</p> <p>Comparator: Unknown (N/A)</p> <p>Outcomes: Primary: Change in proportion of patients for whom laparoscopy is indicated before vs. after EndoTest result. Secondary: Change in management decisions, QoL, pain; 6-month follow-up (Full match to scope)</p>			<p>pathway impact assessment.</p> <ul style="list-style-type: none"> • Large* sample size planned
EndoTest (Ziwig)	ENDOLIFE study 2026 Prospective, multicentre, longitudinal, real-life study France and Switzerland (No published trial registration)	<p>Participants: Estimated N=20,000 women with signs and symptoms suggestive of endometriosis (Partial match to scope)</p> <p>Setting: France and Switzerland, centre type unknown</p>	Results anticipated in January 2030	Company submission	<ul style="list-style-type: none"> • Large* sample size • First study to evaluate impact of diagnosis on patient QoL • Non-UK setting

Technology	Ongoing or planned study	Alignment with scope	Indicated study end date	Source	EAG comments
		<p>(Partial match to scope)</p> <p>Intervention: EndoTest (Full match to scope)</p> <p>Comparator: Unknown (N/A)</p> <p>Outcomes: QoL of people with endometriosis at different time points and impact of diagnosis on QoL (SF-12 and Breif COPE questionnaires) at inclusion and at 6 months and at 12 months post-test. (Full match to scope)</p>			
EndoTest (Ziwig)	ADOMiRNA study 2023 Prospective, multicentre, longitudinal, observational study (trial registration only) France/Belgium (planned) Trial registration:	Participants: Estimated N=80 female adolescents with signs and symptoms suggestive of endometriosis	Trial registration that the results are anticipated in 2024; the date of result availability is unknown.	Literature review	<ul style="list-style-type: none"> • Subgroup analysis in adolescents • Unclear why availability of results delayed • Moderate* sample size

Technology	Ongoing or planned study	Alignment with scope	Indicated study end date	Source	EAG comments
	ClinicalTrials.gov NCT05928442	(Partial match to scope) Setting: France and Belgium, secondary and tertiary care (Partial match to scope) Intervention: EndoTest (Full match to scope) Comparator: Unknown (N/A) Outcomes: Diagnostic accuracy (Full match to scope)			<ul style="list-style-type: none"> • Non-UK setting

*Common working definitions of samples sizes: small = <50, moderate = 50 to 200, large= >200

8.2 Evidence gap analysis

The evidence gap analysis identified key outcomes that are absent or insufficiently characterised in the current evidence base for each technology. For all three technologies, the primary gap is the absence of primary care or UK NHS data on diagnostic accuracy and, critically, the absence of evidence on downstream clinical and patient-reported outcomes. Health-economic data is so far only available for EndoTest. The evidence landscape by outcome domain is summarised in **Table 20**; a traffic light system, whereby green=considerable evidence, amber=limited evidence, and red=minimal/no evidence, was used to help with data gap visualisation. The same traffic light system was used to highlight which ongoing studies may address these gaps (**Table 21**).

Table 24 Evidence gap analysis by outcome domain

Outcome	EndoSure (3PCM Endosure)	DotEndo (DotLab)	EndoTest (Ziwig)	All technologies/pathway
Company-sponsored diagnostic test accuracy (index test performance: sensitivity, specificity, PPV, NPV, AUC) for high endometriosis prevalence populations	Data available from two company-sponsored published studies (N=50 to 165) reporting sensitivity 91% to 96%, specificity 95% to 96%.	Data available from one company-sponsored published study (Moustafa et al. 2020) reporting sensitivity 83%, specificity 96% (90% balanced threshold for both),.	Data available from three company-sponsored published studies, two of which were independently validated (final results published in Bendifallah et al. 2025, N=971) reporting sensitivity 97%, specificity 94%.	All technologies have evidence from at least one published diagnostic accuracy study.
Independently validated diagnostic test studies	Not available	Not available.	Results reported in (Bendifallah et al. 2023) and (Bendifallah et al. 2025) were company-sponsored but independently validated. Note: These publications relate to the same study with interim analysis results reported in the first publication.	Gap: Limited number of independently validated studies for all three technologies.
Diagnostic test accuracy data from UK/NHS studies	Pilot UK data available (N=10) but unpublished.	Not available.	Not available.	Gap: No full-scale, published UK NHS diagnostic accuracy studies for any technology.
Diagnostic test accuracy data for populations representative of NHS primary care	Not available	Not available.	Not available.	Gap: No published primary care NHS diagnostic accuracy data for any technology.

Outcome	EndoSure (3PCM Endosure)	DotEndo (DotLab)	EndoTest (Ziwig)	All technologies/pathway
Diagnostic accuracy vs current care (comparative DTA study)	Not available.	Not available.	Not available.	Gap: None of the technologies has been evaluated head-to-head against standard NHS imaging in the same patient cohort.
Reduction in diagnostic laparoscopy rate and impact on the diagnostic pathway	Not available.	Not available.	Not available (prospective data modelled only in Ferrier et al. 2023).	Gap: Critical evidence gap for all technologies.
Time from symptom onset to confirmed diagnosis	Not available.	Not available.	Not available.	Gap: No study has evaluated whether use of any technology reduces the average diagnostic delay of 9 years 4 months in the UK.
Detection of endometriosis by subtype, anatomical location (e.g., superficial peritoneal, deep infiltrating, ovarian) or subgroup (e.g., adolescents, peri-/menopausal women, women with infertility, different ethnicities)	Not available	Not available	Partial. (Bendifallah et al. 2025) and Moawad 2026 subgroup data available for ovarian and deep infiltrating endometriosis, SPE, and infertility. Stage I/II accuracy reported.	Gap: Subtype- and subgroup-specific performance data are limited for EndoTest and absent for EndoSure and DotEndo.
Quality of life (e.g., EHP-30, EQ-5D)	Not available.	Not available.	Not available.	Gap: No study has evaluated the impact of receiving a positive/negative test result on patient quality of life.

Outcome	EndoSure (3PCM Endosure)	DotEndo (DotLab)	EndoTest (Ziwig)	All technologies/pathway
Patient satisfaction and anxiety related to diagnostic process	Minimal. Tanos et al. reported patient preference for EndoSure vs TvUS (conference abstract only).	Not available.	Partial. Nigdelis et al. 2025 (German clinician survey, N=141) assessed clinician acceptability.	Gap: Qualitative data on patient experience with the new tests in UK settings are absent.
NHS cost-effectiveness (incremental cost per QALY or per correct diagnosis)	Not available.	Not available.	Partial. Ferrier et al. 2023 (French cost-effectiveness analysis). Not UK NHS setting. No QALY-based analysis.	Gap: No NHS-specific cost-effectiveness analysis available for any technology. Early economic modelling in this assessment is subject to uncertainty.
Healthcare resource use (GP consultations, specialist referrals, secondary care attendances)	Not available.	Not available.	Not available.	Gap: None of the included studies reported healthcare resource use as an outcome.
Safety/adverse events	No AEs reported. Non-invasive (surface electrodes, water ingestion). Low risk.	No AEs reported. Minimally invasive (standard venipuncture). Low risk.	No AEs reported. Non-invasive (saliva sample). Low risk.	No safety signals identified in regulatory databases (MHRA, FDA MAUDE). Post-market surveillance data limited for all three technologies.

Abbreviations: AE, adverse event; AUC, area under the receiver operating characteristic curve; DTA, diagnostic test accuracy; FDA, US Food and Drug Administration; MAUDE, Manufacturer and User Facility Device Experience; MHRA, Medicines and Health products Regulatory Agency; NPV, negative predictive value; PPV, positive predictive value; QALY, quality-adjusted life year; SPE, superficial peritoneal endometriosis; TvUS, transvaginal ultrasound

Table 25 Evidence gaps that could be addressed by the ongoing or planned studies

Key evidence gap	EndoSure (3PCM Endosure)	DotEndo (DotLab)	EndoTest (Ziwig)
Diagnostic test accuracy data from UK/NHS	Study: ADDEND study 2024 Design: Prospective cohort, secondary care N=78 Trial registration: ISRCTN83220665 Results expected in the third or fourth quarter (calendar year) of 2026.	Study: UK NHS pilot study (planned) Design: Prospective cohort, secondary care N=TBC Trial registration: Pending ████████████████████ ████████████████████ ████████████████████ Note: Amber rating as study planned, not ongoing	Study: UK NHS pilot study (planned) Design: Prospective cohort, secondary care N=100 Results expected in the second or third quarter (calendar year) of 2026.
Independent diagnostic accuracy validation (free from manufacturer conflict of interest)	Study: ADDEND study 2024 Note: Independent NHS study underway (primary gap for EndoSure)	Study: UK NHS pilot (planned) Note: Independence from DotLab to be confirmed in study governance	Study: Bendifallah et al. 2025 used independent monitoring (Monitoring Force) and is Ziwig-funded but investigator-led; further independent replication desirable Note: Independent NHS pilot study underway
Reduction in diagnostic laparoscopy rate and pathway impact (time to diagnosis, referral rates)	Study: ADDEND study 2024 Note: Primary endpoint is diagnostic accuracy, not pathway impact; partial laparoscopy data may be captured	Study: None identified Note: No ongoing study with pathway impact primary endpoint for DotEndo	Study: ENDOBEST study 2025 Design: Prospective interventional study, multicentre, secondary care (France) N=2,500 Trial registration: NCT06794424 Results expected in the first or second quarter (calendar year) of 2027. Note: Primary endpoint is impact of EndoTest on diagnostic laparoscopy rate

<p>Detection of endometriosis by subtype and in subgroups</p>	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	<p>Study: EMPOWER study 2020 Design: Prospective observational multicentre diagnostic accuracy study in secondary care N= approximately 750 Trial registration: NCT04598698 Results expected in [REDACTED] Note: Study population diverse in terms of ethnicity, disease stage, and hormonal therapy use.</p>	<p>Study: ADOmiRNA study 2023 Design: Prospective observational multicentre diagnostic accuracy study in secondary care N= approximately 80 Trial registration: NCT05928442 Results expected: Unknown Note: Study aims to explore the performance of the test in adolescents with suspected endometriosis.</p>
<p>Patient-reported outcomes and quality of life (EHP-30, EQ-5D, anxiety)</p>	<p>Study: None identified Note: PROMs not specified as primary endpoint in any ongoing studies on public record</p>	<p>Study: None identified Note: PROMs not specified as primary endpoint in any ongoing studies on public record</p>	<p>Study: ENDOBEST study 2025 and ENDOLIFE Note: ENDOBEST study outcomes include impact of EndoTest on patient management decisions, QoL, and pain. ENDOLIFE study outcomes include QoL, with follow-up</p>

Abbreviations: NPV, negative predictive value; PPV, positive predictive value; PROM, patient-reported outcome measure; TBC, to be confirmed; UKCA, UK Conformity Assessed

8.3 Key areas for evidence generation

Based on the evidence gap analysis presented in Section 8.2 and the clinical context described in the protocol, the EAG has identified the following key priorities for evidence generation to support a future adoption decision by NICE. For any technology to be recommended for routine NHS adoption, evidence will be needed on diagnostic accuracy in UK NHS populations, downstream pathway impact, patient-reported outcomes, and cost-effectiveness from an NHS perspective.

Priority 1: Diagnostic accuracy in primary care NHS populations

All three technologies require prospective diagnostic accuracy studies in NHS settings, ideally in populations representative of the target population described in the [scope](#) (people with enduring symptoms suggestive of endometriosis with normal or unavailable imaging). These studies should report sensitivity, specificity, PPV, and NPV using an agreed upon gold standard as the reference. The reliance on laparoscopy as the gold standard for such a study might be limiting, as the time to laparoscopic treatment can be years after presentation in primary care and, from expert input, the uptake of laparoscopy is reducing. One potential approach is to have an expert group providing a consensus diagnosis informed by multiple evidence streams: clinical notes, TvUS, TaUS, MRI, and the new technology. At endometriosis prevalence rates representative of NHS primary and secondary, which are estimated to be 43% (see Table 6 of Khan et al. 2018), such a study should be feasible in primary care. Such a study could also give insight into the diagnostic performance of TaUS, TvUS, and MRI in a primary care population. At present, none of the ongoing or planned studies address the use of the new technologies in primary care, where these technologies are intended to be used according to the [scope](#) of this early use assessment.

Priority 2: Impact on the diagnostic pathway

Another important evidence gap is the absence of data on how these tests, when used in routine clinical practice, affect the downstream diagnostic and treatment pathway. Key outcomes include: (1) reduction in diagnostic laparoscopy rates; (2) time from symptom onset to diagnosis; (3) time from first presentation to specialist referral; (4) number of GP and secondary care consultations; and (5) treatments prescribed. Prospective cohort studies or interventional studies comparing care pathways with and without the test are needed. The planned ENDOBEST study 2025 (EndoTest, N=2,500, France) is designed to assess change in laparoscopy rate and is the most directly relevant ongoing study for this outcome, though it is not UK-based or set in primary care.

Priority 3: Patient-reported outcomes and QoL

None of the included studies evaluated validated PROMs. Studies assessing the impact of test results on patient wellbeing (e.g., pain, symptom burden), QoL, and test acceptability are needed. This is a particularly important gap given the known psychological burden of diagnostic delays on people with suspected endometriosis. There is an expectation, but no clinical evidence, to support the assumption that a diagnosis of endometriosis improves a person's QoL. This data gap needs addressing.

Priority 4: NHS-specific cost-effectiveness evidence

There is currently no UK NHS health-economic evidence available for any of the included technologies. The early model presented in Section 6 was based as much as possible on inputs that were derived from published UK data or obtained from consultations with clinicians working in the NHS. To ensure that the health-economic assessment accurately reflected NHS costs and practice, the EAG used company-supplied NHS-specific test costs, NHS unit costs for the diagnostic pathway components that would be additional or avoided with a positive or negative test result, and longitudinal NHS data on healthcare resource use in people with confirmed versus undetected endometriosis. Despite the availability of many key NHS-specific model parameters, many model inputs had to be sourced from unpublished or non-UK sources. A well-designed UK NHS pilot study generating these data would substantially strengthen any future economic case for EndoSure, Dot Endo, or EndoTest adoption.

How evidence could be generated via real-world use

The EAG considers that evidence generation via real-world use in the NHS offers a practical pathway to address these gaps for all three technologies. The EAG notes that any early use of these technologies in the NHS should be accompanied by systematic data collection on prioritised outcomes, using standardised protocols and validated outcome measures. This approach will help ensure that the evidence generated is of sufficient quality to support a future adoption decision. Collaboration with initiatives such as [NHS Digital](#) and [Getting It Right First Time](#) would strengthen the infrastructure for collecting and analysing such data.

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10 Appendices

Appendix A Clinical search strategies

Source	Date searched	Total number of records retrieved
Databases	-	-
MEDLINE (PubMed)	03.03.2026	446
EMBASE (Elsevier)	03.03.2026	997
Cochrane Database of Systematic Reviews (CDSR)	03.03.2026	7
Cochrane Central Register of Controlled Trials (CENTRAL)	03.03.2026	58
Epistemonikos	03.03.2026	189
International HTA database (INAHTA)	03.03.2026	1
ClinicalTrials.gov	03.03.2026	314
EU Clinical Trials Register	03.03.2026	47
International Clinical Trials Registry Platform (ICTRP)	03.03.2026	41
Other	-	-
Company websites	04.03.2026	18
Reference list checking	24.03.2026	0
New evidence submitted by companies	11.03.2026	23

MEDLINE (PubMed)

#	Search string	Results
1	Endometriosis*[tiab] OR Endometrioma[tiab] OR Endometrioses[tiab] OR Endometriomas[tiab] OR Endometriosis[majr]	37,606
2	EndoSure[tw] OR EndoSure*[tw] OR "Endo Sure"[tw] OR "Endo Sure**"[tw] OR DotEndo*[tw] OR "Dot Endo"[tw] OR DotEndo[tw] OR "Dot Endo**"[tw] OR "Dot Lab"[tw] OR DotLab[tw] OR DotLab*[tw] OR "Dot Lab**"[tw] OR "EndoTest"[tw] OR "Endo Test**"[tw] OR "EndoTest**"[tw] OR "Endo Test"[tw] OR Ziwig[tw] OR Ziwig*[tw]	10,301
3	Diagnosis[tiab] OR Test[tiab] OR Diagnose*[tiab] OR Testing[tiab] OR Diagnostic[tiab] OR Tests[tiab] OR Signature[tiab] OR Screening[tiab] OR Diagnose[tiab]	6,834,986
4	Non-invasive[tiab] OR non-invasively[tiab] OR "non invasive"[tiab] OR "non invasively"[tiab] OR "Gastrointestinal myoelectrical activity"[tiab] OR noninvasive[tiab] OR noninvasively[tiab] OR electroviscerography[tiab] OR GIMA[tiab] OR electroviscerogram[tiab] OR miRNA*[tiab] OR Salivary[tiab] OR microRNA*[tiab] OR miRNome[tiab] OR microRNome[tiab] OR "micro RNome" OR miRNA[tiab] OR microRNA[tiab] OR "micro RNA"[tiab] OR Saliva[tiab] OR "blood test"[tiab:~3] OR "blood testing"[tiab:~3]	633,881

#	Search string	Results
5	#3 AND #4	248,528
6	#1 AND (#2 OR #5)	947
7	English[la]	35,293,876
8	2015/01/01:2026/03/03[edat] AND 2015/01/01:2026/03/03[dp]	15,211,473
9	#6 AND #7 AND #8	725
10	"ex vivo"[tw] OR ex-vivo[tw] OR cadaver[tw] OR cadaveric[tw] OR "deceased donor"[tw]	344,546
11	Address[pt] OR Autobiography[pt] OR Biography[pt] OR Bibliography[pt] OR "Clinical Trial, Veterinary"[pt] OR "Collected Work"[pt] OR Comment[pt] OR Dictionary[pt] OR Directory[pt] OR "Duplicate Publication"[pt] OR Editorial[pt] OR "Expression of Concern"[pt] OR Festschrift[pt] OR "Historical article"[pt] OR "Interactive tutorial"[pt] OR Interview[pt] OR "Introductory Journal Article"[pt] OR Lecture[pt] OR "Legal Case"[pt] OR Legislation[pt] OR Letter[pt] OR News[pt] OR "Newspaper Article"[pt] OR "Observational Study, Veterinary"[pt] OR "Patient Education Handout"[pt] OR "Periodical Index"[pt] OR Portrait[pt] OR "Published Erratum"[pt] OR "Randomized Controlled Trial, Veterinary"[pt] OR "Retracted Publication"[pt] OR "Retraction of Publication"[pt] OR "Twin Study"[pt] OR "Video-Audio Media"[pt] OR Webcast[pt] OR Review[pt]	7,243,779
12	"animal experimentation"[mh] OR "models, animal"[mh] OR invertebrates[mh] OR Animals[mh:NoExp] OR "animal population groups"[mh] OR chordata[mh:NoExp] OR "chordata, nonvertebrate"[mh] OR vertebrates[mh:NoExp] OR amphibians[mh] OR birds[mh] OR fishes[mh] OR reptiles[mh] OR mammals[mh:NoExp] OR primates[mh:NoExp] OR artiodactyla[mh] OR carnivora[mh] OR cetacea[mh] OR chiroptera[mh] OR elephants[mh] OR hyraxes[mh] OR Eulipotyphla[mh] OR lagomorpha[mh] OR marsupialia[mh] OR monotremata[mh] OR perissodactyla[mh] OR rodentia[mh] OR scandentia[mh] OR sirenia[mh] OR xenarthra[mh] OR haplorhini[mh:NoExp] OR strepsirhini[mh] OR platyrrhini[mh] OR tarsii[mh] OR catarrhini[mh:NoExp] OR cercopithecidae[mh] OR hylobatidae[mh] OR hominidae[mh:NoExp] OR "gorilla gorilla"[mh] OR "pan paniscus"[mh] OR "pan troglodytes"[mh] OR "pongo pygmaeus"[mh] OR ((animals[tiab] OR animal[tiab] OR mice[tiab] OR mus[tiab] OR mouse[tiab] OR murine[tiab] OR woodmouse[tiab] OR rats[tiab] OR rat[tiab] OR murinae[tiab] OR muridae[tiab] OR cottonrat[tiab] OR cottonrats[tiab] OR hamster[tiab] OR hamsters[tiab] OR cricetinae[tiab] OR rodentia[tiab] OR rodent[tiab] OR rodents[tiab] OR pigs[tiab] OR pig[tiab] OR swine[tiab] OR swines[tiab] OR piglets[tiab] OR piglet[tiab] OR boar[tiab] OR boars[tiab] OR "sus scrofa"[tiab] OR ferrets[tiab] OR ferret[tiab] OR polecat[tiab] OR polecats[tiab] OR "mustela putorius"[tiab] OR "guinea pigs"[tiab] OR "guinea pig"[tiab] OR cavia[tiab] OR callithrix[tiab] OR marmoset[tiab] OR marmosets[tiab] OR cebuella[tiab] OR hapale[tiab] OR octodon[tiab] OR chinchilla[tiab] OR chinchillas[tiab] OR gerbillinae[tiab] OR gerbil[tiab] OR gerbils[tiab] OR jird[tiab] OR jirds[tiab] OR merione[tiab] OR meriones[tiab] OR rabbits[tiab] OR rabbit[tiab] OR hares[tiab] OR hare[tiab] OR diptera[tiab] OR flies[tiab] OR fly[tiab] OR dipteral[tiab] OR drosophila[tiab] OR drosophilidae[tiab] OR cats[tiab] OR cat[tiab] OR carus[tiab] OR felis[tiab] OR nematoda[tiab] OR	8,517,233

#	Search string	Results
	nematode[tiab] OR nematodes[tiab] OR sipunculida[tiab] OR dogs[tiab] OR dog[tiab] OR canine[tiab] OR canines[tiab] OR canis[tiab] OR sheep[tiab] OR sheeps[tiab] OR mouflon[tiab] OR mouflons[tiab] OR ovis[tiab] OR goats[tiab] OR goat[tiab] OR capra[tiab] OR capras[tiab] OR rupicapra[tiab] OR chamois[tiab] OR haplorhini[tiab] OR monkey[tiab] OR monkeys[tiab] OR anthropoidea[tiab] OR anthropoids[tiab] OR saguinus[tiab] OR tamarin[tiab] OR tamarins[tiab] OR leontopithecus[tiab] OR hominidae[tiab] OR ape[tiab] OR apes[tiab] OR pan[tiab] OR paniscus[tiab] OR "pan paniscus"[tiab] OR bonobo[tiab] OR bonobos[tiab] OR troglodytes[tiab] OR "pan troglodytes"[tiab] OR gibbon[tiab] OR gibbons[tiab] OR siamang[tiab] OR siamangs[tiab] OR nomascus[tiab] OR symphalangus[tiab] OR chimpanzee[tiab] OR chimpanzees[tiab] OR prosimians[tiab] OR "bush baby"[tiab] OR prosimian[tiab] OR "bush babies"[tiab] OR galagos[tiab] OR galago[tiab] OR pongidae[tiab] OR gorilla[tiab] OR gorillas[tiab] OR pongo[tiab] OR "pongo pygmaeus"[tiab] OR orangutans[tiab] OR pygmaeus[tiab] OR lemur[tiab] OR lemurs[tiab] OR lemuridae[tiab] OR horse[tiab] OR horses[tiab] OR equus[tiab] OR cow[tiab] OR calf[tiab] OR bull[tiab] OR chicken[tiab] OR chickens[tiab] OR gallus[tiab] OR quail[tiab] OR bird[tiab] OR birds[tiab] OR quails[tiab] OR poultry[tiab] OR poultries[tiab] OR fowl[tiab] OR fowls[tiab] OR reptile[tiab] OR reptilia[tiab] OR reptiles[tiab] OR snakes[tiab] OR snake[tiab] OR lizard[tiab] OR lizards[tiab] OR alligator[tiab] OR alligators[tiab] OR crocodile[tiab] OR crocodiles[tiab] OR turtle[tiab] OR turtles[tiab] OR amphibian[tiab] OR amphibians[tiab] OR amphibia[tiab] OR frog[tiab] OR frogs[tiab] OR bombina[tiab] OR salientia[tiab] OR toad[tiab] OR toads[tiab] OR "epidalea calamita"[tiab] OR salamander[tiab] OR salamanders[tiab] OR eel[tiab] OR eels[tiab] OR fish[tiab] OR fishes[tiab] OR pisces[tiab] OR catfish[tiab] OR catfishes[tiab] OR siluriformes[tiab] OR arius[tiab] OR heteropneustes[tiab] OR sheatfish[tiab] OR perch[tiab] OR perches[tiab] OR percidae[tiab] OR perca[tiab] OR trout[tiab] OR trouts[tiab] OR char[tiab] OR chars[tiab] OR salvelinus[tiab] OR "fathead minnow"[tiab] OR minnow[tiab] OR cyprinidae[tiab] OR carps[tiab] OR carp[tiab] OR zebrafish[tiab] OR zebrafishes[tiab] OR goldfish[tiab] OR goldfishes[tiab] OR guppy[tiab] OR guppies[tiab] OR chub[tiab] OR chubs[tiab] OR tinca[tiab] OR barbels[tiab] OR barbuis[tiab] OR pimephales[tiab] OR promelas[tiab] OR "poecilia reticulata"[tiab] OR mullet[tiab] OR mullets[tiab] OR seahorse[tiab] OR seahorses[tiab] OR "mugil curema"[tiab] OR "atlantic cod"[tiab] OR shark[tiab] OR sharks[tiab] OR catshark[tiab] OR anguilla[tiab] OR salmonid[tiab] OR salmonids[tiab] OR whitefish[tiab] OR whitefishes[tiab] OR salmon[tiab] OR salmons[tiab] OR sole[tiab] OR solea[tiab] OR "sea lamprey"[tiab] OR lamprey[tiab] OR lampreys[tiab] OR pumpkinseed[tiab] OR sunfish[tiab] OR sunfishes[tiab] OR tilapia[tiab] OR tilapias[tiab] OR turbot[tiab] OR turbot[tiab] OR flatfish[tiab] OR flatfishes[tiab] OR sciuridae[tiab] OR squirrel[tiab] OR squirrels[tiab] OR chipmunk[tiab] OR chipmunks[tiab] OR suslik[tiab] OR susliks[tiab] OR vole[tiab] OR voles[tiab] OR lemming[tiab] OR lemmings[tiab] OR muskrat[tiab] OR muskrats[tiab] OR lemmus[tiab] OR otter[tiab] OR otters[tiab] OR marten[tiab] OR martens[tiab] OR martes[tiab] OR weasel[tiab] OR badger[tiab] OR badgers[tiab] OR ermine[tiab] OR mink[tiab] OR minks[tiab] OR sable[tiab] OR sables[tiab]	

#	Search string	Results
	OR gulo[tiab] OR gulos[tiab] OR wolverine[tiab] OR wolverines[tiab] OR mustela[tiab] OR llama[tiab] OR llamas[tiab] OR alpaca[tiab] OR alpacas[tiab] OR camelid[tiab] OR camelids[tiab] OR guanaco[tiab] OR guanacos[tiab] OR chiroptera[tiab] OR chiropteras[tiab] OR bat[tiab] OR bats[tiab] OR fox[tiab] OR foxes[tiab] OR iguana[tiab] OR iguanas[tiab] OR "xenopus laevis"[tiab] OR parakeet[tiab] OR parakeets[tiab] OR parrot[tiab] OR parrots[tiab] OR donkey[tiab] OR donkeys[tiab] OR mule[tiab] OR mules[tiab] OR zebra[tiab] OR zebras[tiab] OR shrew[tiab] OR shrews[tiab] OR bison[tiab] OR bisons[tiab] OR buffalo[tiab] OR buffaloes[tiab] OR deer[tiab] OR deers[tiab] OR bear[tiab] OR bears[tiab] OR panda[tiab] OR pandas[tiab] OR "wild hog"[tiab] OR "wild boar"[tiab] OR fitchew[tiab] OR fitch[tiab] OR beaver[tiab] OR beavers[tiab] OR jerboa[tiab] OR jerboas[tiab] OR capybara[tiab] OR capybaras[tiab]) NOT medline[SB])	
13	#9 NOT (#10 OR #11 OR #12)	446

EMBASE (Elsevier)

#	Search string	Results
1	endometriosis*:ti,ab OR endometrioma:ti,ab OR endometrioses:ti,ab OR endometriomas:ti,ab OR endometriosis/exp/mj	55,787
2	EndoSure OR 'Dot Endo' OR 'Endo Test' OR DotLab OR DotEndo OR Ziwig OR EndoTest* OR Ziwig* OR 'Endo Test*' OR EndoTest OR DotLab* OR 'Dot Lab' OR 'Dot Lab*' OR EndoSure* OR 'Endo Sure*' OR 'Endo Sure' OR DotEndo* OR 'Dot Endo*' OR EndoSure/de OR EndoTest/de OR DotEndo/de OR DotLab/df OR Ziwig/df OR EndoSure/df	489
3	Diagnosis:ti,ab OR Test:ti,ab OR Diagnose*:ti,ab OR Testing:ti,ab OR Diagnostic:ti,ab OR Tests:ti,ab OR Signature:ti,ab OR Screening:ti,ab OR Diagnose:ti,ab	9,868,953
4	('Gastrointestinal myoelectrical activity':ti,ab OR GIMA:ti,ab OR electroviscerography:ti,ab OR electroviscerogram:ti,ab) OR (non-invasive:ti,ab OR noninvasive:ti,ab OR microRNA*:ti,ab OR miRNA*:ti,ab OR non-invasively:ti,ab OR noninvasively:ti,ab OR miRNome:ti,ab OR miRNA:ti,ab OR microRNA:ti,ab OR 'micro RNA':ti,ab OR 'non invasive':ti,ab OR 'non invasively':ti,ab OR MicroRNome:ti,ab) OR (blood NEAR/4 (test OR testing)) OR (Saliva:ti,ab OR Salivary:ti,ab OR Saliva-based:ti,ab)	927,465
5	#3 AND #4	416,833
6	#1 AND (#2 OR #5)	1,465
7	English:la	42,823,117
8	[01-01-2015]/sd OR [2015-2026]/py	21,348,621
9	#6 AND #7 AND #8	1,117
10	'ex vivo' OR ex-vivo OR cadaver OR cadaveric OR 'deceased donor' OR 'tissue culture' OR 'in silico'	522,965
11	'comment':it OR 'editorial':it OR 'letter':it OR 'note':it OR 'short survey':it OR 'retracted publication':it OR 'duplicate publication':it OR 'conference review':it OR 'human tissue':it OR 'human cell':it OR 'nonhuman':it OR	3,707,607

#	Search string	Results
	'animal experiment':it OR 'animal tissue':it OR 'animal cell':it OR 'animal model':it OR 'mouse':it OR 'rat':it	
12	'animal experiment'/exp OR 'animal model'/exp OR 'invertebrate'/exp OR 'animal'/de OR 'chordata'/de OR 'vertebrate'/de OR 'amphibia'/exp OR 'bird'/exp OR 'fish'/exp OR 'reptile'/exp OR 'mammal'/de OR 'primate'/de OR 'artiodactyla'/exp OR 'carnivora'/exp OR 'cetacea'/exp OR 'bat'/exp OR 'elephant'/exp OR 'hyrax'/exp OR 'afrotheria'/exp OR 'insectivora'/exp OR 'lagomorph'/exp OR 'marsupial'/exp OR 'monotreme'/exp OR 'perissodactyla'/exp OR 'rodent'/exp OR 'scandentia'/exp OR 'sirenia'/exp OR 'xenarthra'/exp OR 'haplorhini'/de OR 'platyrrhini'/exp OR 'tarsiiform'/exp OR 'catarrhini'/de OR 'prosimian'/exp OR 'chimpanzee'/exp OR 'gorilla'/exp OR 'orangutan'/exp OR 'cercopithecidae'/exp OR 'hylobatidae'/exp OR 'hominidae'/de OR ((animals:ab,ti,kw,de OR animal:ab,ti,kw,de OR mice:ab,ti,kw,de OR mus:ab,ti,kw,de OR mouse:ab,ti,kw,de OR murine:ab,ti,kw,de OR woodmouse:ab,ti,kw,de OR rats:ab,ti,kw,de OR rat:ab,ti,kw,de OR murinae:ab,ti,kw,de OR muridae:ab,ti,kw,de OR cottonrat:ab,ti,kw,de OR cottonrats:ab,ti,kw,de OR hamster:ab,ti,kw,de OR hamsters:ab,ti,kw,de OR cricetinae:ab,ti,kw,de OR rodentia:ab,ti,kw,de OR rodent:ab,ti,kw,de OR rodents:ab,ti,kw,de OR pigs:ab,ti,kw,de OR pig:ab,ti,kw,de OR swine:ab,ti,kw,de OR swines:ab,ti,kw,de OR piglets:ab,ti,kw,de OR piglet:ab,ti,kw,de OR boar:ab,ti,kw,de OR boars:ab,ti,kw,de OR 'sus scrofa':ab,ti,kw,de OR ferrets:ab,ti,kw,de OR ferret:ab,ti,kw,de OR polecat:ab,ti,kw,de OR polecats:ab,ti,kw,de OR 'mustela putorius':ab,ti,kw,de OR 'guinea pigs':ab,ti,kw,de OR 'guinea pig':ab,ti,kw,de OR cavia:ab,ti,kw,de OR callithrix:ab,ti,kw,de OR marmoset:ab,ti,kw,de OR marmosets:ab,ti,kw,de OR cebuella:ab,ti,kw,de OR hapale:ab,ti,kw,de OR octodon:ab,ti,kw,de OR chinchilla:ab,ti,kw,de OR chinchillas:ab,ti,kw,de OR gerbillinae:ab,ti,kw,de OR gerbil:ab,ti,kw,de OR gerbils:ab,ti,kw,de OR jird:ab,ti,kw,de OR jirds:ab,ti,kw,de OR merione:ab,ti,kw,de OR meriones:ab,ti,kw,de OR rabbits:ab,ti,kw,de OR rabbit:ab,ti,kw,de OR hares:ab,ti,kw,de OR hare:ab,ti,kw,de OR diptera:ab,ti,kw,de OR flies:ab,ti,kw,de OR fly:ab,ti,kw,de OR dipteral:ab,ti,kw,de OR drosophila:ab,ti,kw,de OR drosophilidae:ab,ti,kw,de OR cats:ab,ti,kw,de OR cat:ab,ti,kw,de OR carus:ab,ti,kw,de OR felis:ab,ti,kw,de OR nematoda:ab,ti,kw,de OR nematode:ab,ti,kw,de OR nematodes:ab,ti,kw,de OR sipunculida:ab,ti,kw,de OR dogs:ab,ti,kw,de OR dog:ab,ti,kw,de OR canine:ab,ti,kw,de OR canines:ab,ti,kw,de OR canis:ab,ti,kw,de OR sheep:ab,ti,kw,de OR sheeps:ab,ti,kw,de OR mouflon:ab,ti,kw,de OR mouflons:ab,ti,kw,de OR ovis:ab,ti,kw,de OR goats:ab,ti,kw,de OR goat:ab,ti,kw,de OR capra:ab,ti,kw,de OR capras:ab,ti,kw,de OR rupicapra:ab,ti,kw,de OR chamois:ab,ti,kw,de OR haplorhini:ab,ti,kw,de OR monkey:ab,ti,kw,de OR monkeys:ab,ti,kw,de OR anthropoidea:ab,ti,kw,de OR anthropoids:ab,ti,kw,de OR saguinus:ab,ti,kw,de OR tamarin:ab,ti,kw,de OR tamarins:ab,ti,kw,de OR leontopithecus:ab,ti,kw,de OR hominidae:ab,ti,kw,de OR ape:ab,ti,kw,de OR apes:ab,ti,kw,de OR paniscus:ab,ti,kw,de OR 'pan paniscus':ab,ti,kw,de OR bonobo:ab,ti,kw,de OR bonobos:ab,ti,kw,de OR troglodytes:ab,ti,kw,de OR 'pan troglodytes':ab,ti,kw,de OR	10,112,555

#	Search string	Results
	<p>gibbon:ab,ti,kw,de OR gibbons:ab,ti,kw,de OR siamang:ab,ti,kw,de OR siamangs:ab,ti,kw,de OR nomascus:ab,ti,kw,de OR symphalangus:ab,ti,kw,de OR chimpanzee:ab,ti,kw,de OR chimpanzees:ab,ti,kw,de OR prosimians:ab,ti,kw,de OR 'bush baby':ab,ti,kw,de OR prosimian:ab,ti,kw,de OR 'bush babies':ab,ti,kw,de OR galagos:ab,ti,kw,de OR galago:ab,ti,kw,de OR pongidae:ab,ti,kw,de OR gorilla:ab,ti,kw,de OR gorillas:ab,ti,kw,de OR 'pongo pygmaeus':ab,ti,kw,de OR orangutans:ab,ti,kw,de OR pygmaeus:ab,ti,kw,de OR lemur:ab,ti,kw,de OR lemurs:ab,ti,kw,de OR lemoridae:ab,ti,kw,de OR horse:ab,ti,kw,de OR horses:ab,ti,kw,de OR pongo:ab,ti,kw,de OR equus:ab,ti,kw,de OR cow:ab,ti,kw,de OR calf:ab,ti,kw,de OR bull:ab,ti,kw,de OR chicken:ab,ti,kw,de OR chickens:ab,ti,kw,de OR gallus:ab,ti,kw,de OR quail:ab,ti,kw,de OR bird:ab,ti,kw,de OR birds:ab,ti,kw,de OR quails:ab,ti,kw,de OR poultry:ab,ti,kw,de OR poultries:ab,ti,kw,de OR fowl:ab,ti,kw,de OR fowls:ab,ti,kw,de OR reptile:ab,ti,kw,de OR reptilia:ab,ti,kw,de OR reptiles:ab,ti,kw,de OR snakes:ab,ti,kw,de OR snake:ab,ti,kw,de OR lizard:ab,ti,kw,de OR lizards:ab,ti,kw,de OR alligator:ab,ti,kw,de OR alligators:ab,ti,kw,de OR crocodile:ab,ti,kw,de OR crocodiles:ab,ti,kw,de OR turtle:ab,ti,kw,de OR turtles:ab,ti,kw,de OR amphibian:ab,ti,kw,de OR amphibians:ab,ti,kw,de OR amphibia:ab,ti,kw,de OR frog:ab,ti,kw,de OR frogs:ab,ti,kw,de OR bombina:ab,ti,kw,de OR salientia:ab,ti,kw,de OR toad:ab,ti,kw,de OR toads:ab,ti,kw,de OR 'epidalea calamita':ab,ti,kw,de OR salamander:ab,ti,kw,de OR salamanders:ab,ti,kw,de OR eel:ab,ti,kw,de OR eels:ab,ti,kw,de OR fish:ab,ti,kw,de OR fishes:ab,ti,kw,de OR pisces:ab,ti,kw,de OR catfish:ab,ti,kw,de OR catfishes:ab,ti,kw,de OR siluriformes:ab,ti,kw,de OR arius:ab,ti,kw,de OR heteropneustes:ab,ti,kw,de OR sheatfish:ab,ti,kw,de OR perch:ab,ti,kw,de OR perches:ab,ti,kw,de OR percidae:ab,ti,kw,de OR perca:ab,ti,kw,de OR trout:ab,ti,kw,de OR trouts:ab,ti,kw,de OR salvelinus:ab,ti,kw,de OR 'fathead minnow':ab,ti,kw,de OR minnow:ab,ti,kw,de OR cyprinidae:ab,ti,kw,de OR carps:ab,ti,kw,de OR carp:ab,ti,kw,de OR zebrafish:ab,ti,kw,de OR zebrafishes:ab,ti,kw,de OR goldfish:ab,ti,kw,de OR goldfishes:ab,ti,kw,de OR guppy:ab,ti,kw,de OR guppies:ab,ti,kw,de OR chub:ab,ti,kw,de OR chubs:ab,ti,kw,de OR tinca:ab,ti,kw,de OR barbels:ab,ti,kw,de OR barbuis:ab,ti,kw,de OR pimephales:ab,ti,kw,de OR promelas:ab,ti,kw,de OR 'poecilia reticulata':ab,ti,kw,de OR mullet:ab,ti,kw,de OR mullets:ab,ti,kw,de OR seahorse:ab,ti,kw,de OR seahorses:ab,ti,kw,de OR 'mugil curema':ab,ti,kw,de OR 'atlantic cod':ab,ti,kw,de OR shark:ab,ti,kw,de OR sharks:ab,ti,kw,de OR catshark:ab,ti,kw,de OR anguilla:ab,ti,kw,de OR salmonid:ab,ti,kw,de OR salmonids:ab,ti,kw,de OR whitefish:ab,ti,kw,de OR whitefishes:ab,ti,kw,de OR salmon:ab,ti,kw,de OR salmons:ab,ti,kw,de OR solea:ab,ti,kw,de OR 'sea lamprey':ab,ti,kw,de OR lamprey:ab,ti,kw,de OR lampreys:ab,ti,kw,de OR pumpkinseed:ab,ti,kw,de OR sunfish:ab,ti,kw,de OR sunfishes:ab,ti,kw,de OR tilapia:ab,ti,kw,de OR tilapias:ab,ti,kw,de OR turbot:ab,ti,kw,de OR turbots:ab,ti,kw,de OR flatfish:ab,ti,kw,de OR flatfishes:ab,ti,kw,de OR sciuridae:ab,ti,kw,de OR squirrel:ab,ti,kw,de OR squirrels:ab,ti,kw,de OR chipmunk:ab,ti,kw,de OR</p>	

#	Search string	Results
	chipmunks:ab,ti,kw,de OR suslik:ab,ti,kw,de OR susliks:ab,ti,kw,de OR vole:ab,ti,kw,de OR voles:ab,ti,kw,de OR lemming:ab,ti,kw,de OR lemmings:ab,ti,kw,de OR muskrat:ab,ti,kw,de OR muskrats:ab,ti,kw,de OR lemmus:ab,ti,kw,de OR otter:ab,ti,kw,de OR otters:ab,ti,kw,de OR marten:ab,ti,kw,de OR martens:ab,ti,kw,de OR martes:ab,ti,kw,de OR weasel:ab,ti,kw,de OR badger:ab,ti,kw,de OR badgers:ab,ti,kw,de OR ermine:ab,ti,kw,de OR mink:ab,ti,kw,de OR sable:ab,ti,kw,de OR sables:ab,ti,kw,de OR gulo:ab,ti,kw,de OR gulos:ab,ti,kw,de OR wolverine:ab,ti,kw,de OR wolverines:ab,ti,kw,de OR minks:ab,ti,kw,de OR mustela:ab,ti,kw,de OR llama:ab,ti,kw,de OR llamas:ab,ti,kw,de OR alpaca:ab,ti,kw,de OR alpacas:ab,ti,kw,de OR camelid:ab,ti,kw,de OR camelids:ab,ti,kw,de OR guanaco:ab,ti,kw,de OR guanacos:ab,ti,kw,de OR chiroptera:ab,ti,kw,de OR chiropteras:ab,ti,kw,de OR bat:ab,ti,kw,de OR bats:ab,ti,kw,de OR fox:ab,ti,kw,de OR foxes:ab,ti,kw,de OR iguana:ab,ti,kw,de OR iguanas:ab,ti,kw,de OR xenopus:ab,ti,kw,de OR parakeet:ab,ti,kw,de OR parakeets:ab,ti,kw,de OR parrot:ab,ti,kw,de OR parrots:ab,ti,kw,de OR donkey:ab,ti,kw,de OR donkeys:ab,ti,kw,de OR mule:ab,ti,kw,de OR mules:ab,ti,kw,de OR zebra:ab,ti,kw,de OR zebras:ab,ti,kw,de OR shrew:ab,ti,kw,de OR shrews:ab,ti,kw,de OR bison:ab,ti,kw,de OR bisons:ab,ti,kw,de OR buffalo:ab,ti,kw,de OR buffaloes:ab,ti,kw,de OR deer:ab,ti,kw,de OR deers:ab,ti,kw,de OR panda:ab,ti,kw,de OR pandas:ab,ti,kw,de OR 'wild hog':ab,ti,kw,de OR 'wild boar':ab,ti,kw,de OR fitchew:ab,ti,kw,de OR fitch:ab,ti,kw,de OR beaver:ab,ti,kw,de OR beavers:ab,ti,kw,de OR jerboa:ab,ti,kw,de OR jerboas:ab,ti,kw,de OR capybara:ab,ti,kw,de OR capybaras:ab,ti,kw,de OR porcupine:ab,ti,kw,de OR porcupines:ab,ti,kw,de) NOT 'medline'/exp)	
13	#9 NOT (#10 OR #11 OR #12)	997

Cochrane library

The Cochrane library searches both the Cochrane Database of Systematic Reviews (CDSR) and the Cochrane Central Register of Controlled Trials (CENTRAL).

#	Search string	Results
1	endometriosis*:ti,ab,kw OR endometrioma:ti,ab OR endometrioses:ti,ab OR endometriomas:ti,ab OR endometriosis:kw	3669
2	EndoSure:ti,ab,kw OR "Dot Endo":ti,ab,kw OR "Endo Test":ti,ab,kw OR DotLab:ti,ab,kw OR DotEndo:ti,ab,kw OR Ziwig:ti,ab,kw OR EndoTest*:ti,ab,kw OR Ziwig*:ti,ab,kw OR ("Endo" NEXT Test*):ti,ab,kw OR EndoTest:ti,ab,kw OR DotLab*:ti,ab,kw OR "Dot Lab":ti,ab,kw OR ("Dot" NEXT Lab*):ti,ab,kw OR EndoSure*:ti,ab,kw OR ("Endo" NEXT Sure*):ti,ab,kw OR "Endo Sure":ti,ab,kw OR DotEndo*:ti,ab,kw OR ("Dot" NEXT Endo*):ti,ab,kw	7
3	Diagnosis:ti,ab OR Test:ti,ab OR Diagnose*:ti,ab OR Testing:ti,ab OR Diagnostic:ti,ab OR Tests:ti,ab OR Signature:ti,ab OR Screening:ti,ab OR Diagnose:ti,ab	652,463
4	("Gastrointestinal myoelectrical activity":ti,ab OR GIMA:ti,ab OR electroviscerography:ti,ab OR electroviscerogram:ti,ab) OR (non-	60,302

#	Search string	Results
	invasive:ti,ab OR noninvasive:ti,ab OR microRNA*:ti,ab OR miRNA*:ti,ab OR non-invasively:ti,ab OR noninvasively:ti,ab OR miRNome:ti,ab OR miRNA:ti,ab OR microRNA:ti,ab OR "micro RNA":ti,ab OR "non invasive":ti,ab OR "non invasively":ti,ab OR microRNome:ti,ab OR "micro RNome":ti,ab OR (blood NEAR/4 (test OR testing)) OR (Saliva:ti,ab OR Salivary:ti,ab OR Saliva-based:ti,ab)	
5	#3 AND #4	32,417
6	#1 AND (#2 OR #5)	65
7	"ex vivo" OR "ex-vivo" OR cadaver OR cadaveric OR "deceased donor" OR "tissue culture" OR "in silico"	8,581
8	#6 NOT #7	65
9	#8 in Cochrane Reviews	7
10	#8 in Trials	58

Epistemonikos

#	Search string	Results
1	(title:(endometriosis OR endometrioma OR endometrioses OR endometriomas OR endometriosis*) OR abstract:(endometriosis OR endometrioma OR endometrioses OR endometriomas OR endometriosis*)) AND ((title:(EndoSure OR "Dot Endo" OR "Endo Test" OR DotLab OR DotEndo OR Ziwig OR EndoTest* OR Ziwig* OR "Endo Test" OR EndoTest OR DotLab* OR "Dot Lab" OR "Dot Lab" OR EndoSure* OR "Endo Sure" OR DotEndo* OR "Dot Endo") OR abstract:(EndoSure OR "Dot Endo" OR "Endo Test" OR DotLab OR DotEndo OR Ziwig OR EndoTest* OR Ziwig* OR "Endo Test" OR EndoTest OR DotLab* OR "Dot Lab" OR EndoSure* OR "Endo Sure" OR DotEndo* OR "Dot Endo")) OR ((title:(Diagnosis OR Test OR Diagnose OR Testing OR Diagnostic OR Tests OR Signature OR Screening OR Diagnose) OR abstract:(Diagnosis OR Test OR Diagnose OR Testing OR Diagnostic OR Tests OR Signature OR Screening OR Diagnose)) AND (title:("Gastrointestinal myoelectrical activity" OR GIMA OR electroviscerography OR electroviscerogram OR "non-invasive" OR noninvasive OR microRNA* OR miRNA* OR "non-invasively" OR noninvasively OR miRNome OR miRNA OR microRNA OR "micro RNA" OR "non invasive" OR "non invasively" OR MicroRNome OR "blood test" OR "blood testing" OR Saliva OR Salivary OR "Saliva-based") OR abstract:("Gastrointestinal myoelectrical activity" OR GIMA OR electroviscerography OR electroviscerogram OR "non-invasive" OR noninvasive OR microRNA* OR miRNA* OR "non-invasively" OR noninvasively OR miRNome OR miRNA OR microRNA OR "non invasive" OR "non invasively" OR microRNome OR "micro RNome" OR "blood test" OR "blood testing" OR Saliva OR Salivary OR "Saliva-based"))))	189

International HTA database (INAHTA)

#	Search string	Results
1	(endometriosis OR endometrioma OR endometrioses OR endometriomas OR endometriosis*) AND ((EndoSure OR "Dot Endo" OR "Endo Test" OR DotLab OR DotEndo OR Ziwig OR EndoTest* OR Ziwig* OR "Endo Test"	1

#	Search string	Results
	OR EndoTest OR DotLab* OR "Dot Lab" OR EndoSure* OR "Endo Sure" OR DotEndo* OR "Dot Endo") OR ((Diagnosis OR Test OR Diagnose OR Testing OR Diagnostic OR Tests OR Signature OR Screening OR Diagnose) AND ("Gastrointestinal myoelectrical activity" OR GIMA OR electroviscerography OR electroviscerogram OR "non-invasive" OR noninvasive OR microRNA* OR miRNA* OR "non-invasively" OR noninvasively OR miRNome OR miRNA OR microRNA OR "microRNA" OR "non invasive" OR "non invasively" OR MicroRNome OR "blood test" OR "blood testing" OR Saliva OR Salivary OR "Saliva-based"))))	

ClinicalTrials.gov

#	Search string	Results
1	(endometriosis OR endometrioma OR endometrioses OR endometriomas) AND ((EndoSure OR EndoSure* OR "Endo Sure" OR DotEndo* OR "Dot Endo" OR DotEndo OR "Dot Lab" OR DotLab OR DotLab* OR EndoTest OR "Endo Test" OR EndoTest* OR Ziwig OR Ziwig*) OR ((Diagnosis OR Test OR Diagnose* OR Testing OR Diagnostic OR Tests OR Signature OR Screening OR Diagnose) AND (electroviscerography OR GIMA OR electroviscerogram OR "Gastrointestinal myoelectrical activity" OR miRNA* OR microRNA* OR miRNome OR miRNA OR microRNA OR "micro RNA" OR microRNome OR "micro RNome" OR "non-invasive" OR "non invasive" OR noninvasive OR "non-invasively" OR "non invasively" OR noninvasively OR "blood testing" OR "blood test" OR "saliva-based" OR saliva OR salivary)))	314

EU Clinical Trials Register

#	Search string (AL)	Results
1	(endometriosis OR endometrioma OR endometrioses OR endometriomas) AND ((EndoSure OR "Endo Sure" OR DotEndo OR "Dot Endo" OR DotLab OR "Dot Lab" OR EndoTest OR "Endo Test" OR Ziwig) OR ((Diagnosis OR Test OR Diagnose OR Testing OR Diagnostic OR Tests OR Signature OR Screening) AND ("Gastrointestinal myoelectrical activity" OR GIMA OR electroviscerography OR electroviscerogram OR "micro RNA" OR microRNA OR miRNA OR microRNome OR miRNome OR "micro RNome" OR "non invasively" OR noninvasively OR "non-invasively" OR "non invasive" OR noninvasive OR "non-invasive" OR blood OR saliva)))	89
2	Date range: 01.01.2025-03.03.2026	47

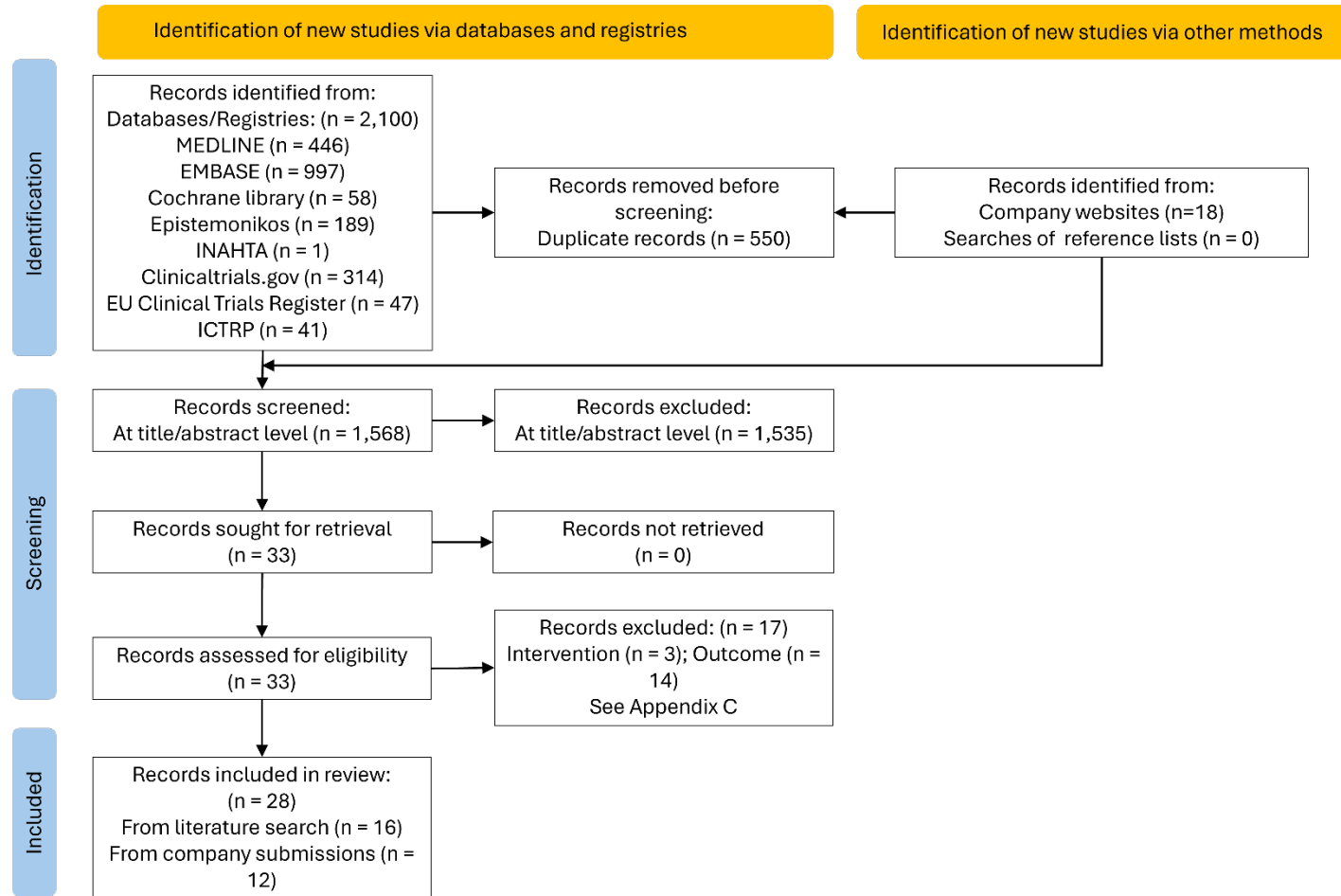
International Clinical Trials Registry Platform (ICTRP)

#	Search string	Results
1	(endometriosis OR endometrioma OR endometrioses OR endometriomas) AND ((EndoSure OR "Endo Sure" OR DotEndo OR "Dot Endo" OR DotLab OR "Dot Lab" OR EndoTest OR "Endo Test" OR Ziwig) OR ((Diagnosis OR Test OR Diagnose OR Testing OR Diagnostic OR Tests OR Signature OR Screening) AND ("Gastrointestinal myoelectrical activity" OR GIMA OR electroviscerography OR electroviscerogram OR "micro RNA" OR microRNA	41

#	Search string	Results
	OR miRNA OR microRNome OR miRNome OR "micro RNome" OR "non invasively" OR noninvasively OR "non-invasively" OR "non invasive" OR noninvasive OR "non-invasive" OR blood OR saliva)))	

PRISMA diagram/s, if appropriate.


Appendix B PRISMA flow diagram



Appendix C Excluded studies

The following studies were excluded from the evidence base.

Technology	Study	Publication type	Source	Reasons for exclusion
EndoSure (3PCM/Endosure)	Testimonial from a Consultant Gynaecologist, UK	Testimonial obtained by Lawmed, EndoSure distributor in the UK	Company submission	Study type: Testimonials are subjective opinion rather than empirical data, and because they lack methodological rigour, quantifiable outcomes, and protection against bias, they cannot be considered part of the formal evidence base for decision-making.
EndoSure (3PCM/Endosure)	Testimonial from a Consultant Gynaecologist, UK	Testimonial obtained by Lawmed, EndoSure distributor in the UK	Company submission	As above
EndoSure (3PCM/Endosure)	Testimonial from a Consultant Gynaecologist, UK	Testimonial obtained by Lawmed, EndoSure distributor in the UK	Company submission	As above
EndoSure (3PCM/Endosure)	Testimonial from a Consultant Gynaecologist, UK	Testimonial obtained by Lawmed, EndoSure distributor in the UK	Company submission	As above
EndoSure (3PCM/Endosure)	Testimonial from a Consultant Gynaecologist, UK	Testimonial obtained by Lawmed, EndoSure	Company submission	As above

Technology	Study	Publication type	Source	Reasons for exclusion
		distributor in the UK		
DotEndo (DotLab)	Moustafa et al. 2017	Conference abstract	Literature review	Outcome: This study describes the development of the DotEndo test, not its use as a diagnostic tool; no relevant outcomes are reported.
DotEndo (DotLab)	Monnaka et al. 2021	Full-text publication	Literature review	Outcome: This study describes the development of the DotEndo test, not its use as a diagnostic tool; no relevant outcomes are reported.
DotEndo (DotLab)	Cosar et al. 2016	Full-text publication	Company submission	Outcome: This study documents the development of a miRNA signature rather than the use of the DotEndo test as a diagnostic tool; no relevant outcomes are reported.
DotEndo (DotLab)	Cosar et al. 2019	Full-text publication	Company submission	Study type: This is an animal study.
DotEndo (DotLab)	Poster presentation at HHS National Conference on Women's Health United States March 2026	Poster abstract	Company submission	Outcome: This study reports correlation between specific miRNA levels and response to fertility treatment; no relevant outcomes are reported.
DotEndo (DotLab)		Study outline	Company submission	Outcome: This is a treatment monitoring study;

Technology	Study	Publication type	Source	Reasons for exclusion
				no relevant outcomes are reported.
DotEndo (DotLab)	Zafari et al. 2022	Full-text publication	Literature review	Outcome: Although the meta-analysis includes some miRNA signature development studies published on the DotLab website, it does not present sufficient outcome data on DotEndo or the other included tests.
EndoTest (Ziwig)/DotEndo (DotLab)	Bischoff et al. 2025b	Conference abstract	Literature review	Intervention: Although the blood test manufacturer is not disclosed in this abstract for an oral presentation, the listed authors belong to HerAnova Lifesciences, a company engaged in the commercial development of diagnostic tests for endometriosis.
EndoTest (Ziwig)/DotEndo (DotLab)	Bischoff et al. 2025a	Conference abstract	Literature review	Intervention: The study authors belong to HerAnova Lifesciences.
EndoTest (Ziwig)/DotEndo (DotLab)	Nisenblat et al. 2016	Full-text publication	Literature review	Intervention: No relevant intervention included.
EndoTest (Ziwig)	Dabi et al. 2023	Full-text publication	Literature review	Outcome: This study documents

Technology	Study	Publication type	Source	Reasons for exclusion
				the development of a saliva-based miRNA signature rather than the use of the EndoTest as a diagnostic tool; no relevant outcomes reported.
EndoTest (Ziwig)	Bendifallah et al. 2022a	Full-text publication	Literature review	Outcome: This study describes the development of EndoTest rather than its use as a diagnostic tool; no relevant outcomes are reported.
EndoTest (Ziwig)	Bendifallah et al. 2024	Full-text publication	Literature review	Outcome: This study describes the identification of a new miRNA signature for the diagnosis of superficial peritoneal endometriosis (SPE); it does not describe the diagnostic use of the test or report outcomes relevant to the scope.
EndoTest (Ziwig)	ENDOREpro study 2023 Trial registration: ClinicalTrials.gov NCT06072820	Trial registration	Literature review	Outcome: Analytical validation study only; no relevant outcomes reported.
EndoTest (Ziwig)	Bendifallah et al. 2022c	Full-text publication	Literature review	Outcome: This study documents the development of the EndoTest rather than the use of the

Technology	Study	Publication type	Source	Reasons for exclusion
				EndoTest as a diagnostic tool; no relevant outcomes reported.
EndoTest (Ziwig)	Bendifallah et al. 2022b	Full-text publication	Literature review	Outcome: This is a methodological paper that documents the development of the EndoTest; no relevant outcomes reported.
EndoTest (Ziwig)	Battiloro and Dominici 2025 Editorial	Full-text publication	Company submission	Outcomes: This study focuses on random-forest-based feature extraction and classification; no relevant outcomes reported.
EndoTest (Ziwig)	Spiers et al. 2025 Rapid review	Full-text publication	Literature review and company submission	Outcomes: The study summarises data reported in (Bendifallah et al. 2022c; Bendifallah et al. 2022d; Bendifallah et al. 2023), which have already been assessed as part of the literature review; no new outcomes reported.
EndoTest (Ziwig)	Liu 2023 Editorial	Full-text publication	Company submission	Outcome: The study focus is the importance of interim analyses; no relevant outcomes reported that have not been

Technology	Study	Publication type	Source	Reasons for exclusion
				captured in the cited studies.
EndoTest (Ziwig)	GynRNA study 2024 International Trial registration: ClinicalTrials.gov NCT06392997	Trial registration	Literature review	Outcome: This study reported the identification of salivary RNA diagnostic signatures for gynaecological pathologies; no relevant outcomes reported.
EndoTest (Ziwig)	ENDOmRNA study 2021 Trial registration: ClinicalTrials.gov NCT04728152	Trial registration	Literature review	Outcome: The trial data are included in the evidence base as (Bendifallah et al. 2022d); no new outcomes reported.
EndoTest (Ziwig)	ENDOmRNA Saliva Test study 2022 Trial registration: ClinicalTrials.gov NCT05244668	Trial registration	Literature review	Outcome: The trial data are included in the evidence base as (Bendifallah et al. 2023; Bendifallah et al. 2025); no new outcomes reported.
EndoTest (Ziwig)	Scheck et al. 2024 Short communication / critical commentary	Full-text publication	Literature review	Outcome: Commentary reviewing (Bendifallah et al. 2023; Bendifallah et al. 2022d); no new outcomes reported.

Appendix D Summary of critical appraisal results for key diagnostic accuracy studies included in the clinical evidence review

The table summarises the risk of bias (RoB) and applicability assessments for all key diagnostic accuracy studies included in the review. RoB and applicability concerns were rated as LOW (green), UNCLEAR (yellow), or HIGH (red) for each domain.

Technology	Study	N	Study Design	D1: Patient Selection (RoB)	D2: Index Test (RoB)	D3: Reference Standard (RoB)	D4: Flow & Timing (RoB)	Overall RoB	D1: Patient Selection (Applicability)	D2: Index Test (Applicability)	D3: Reference Standard (Applicability)	Overall Applicability
EndoSure (3PCM/Endosure)	Noar et al. 2024a	165	Prospective multicentre (USA)	UNCLEAR	HIGH	LOW	UNCLEAR	HIGH	HIGH	HIGH	LOW	HIGH
EndoSure (3PCM/Endosure)	Noar et al. 2024b	50 (interim)	Prospective blinded multicentre, interim (USA)	UNCLEAR	HIGH	LOW	UNCLEAR	HIGH	HIGH	HIGH	LOW	HIGH
DotEndo (DotLab)	Moustafa et al. 2020	100	Prospective case-control, single-centre (USA)	UNCLEAR	HIGH	LOW	LOW	HIGH	UNCLEAR	HIGH	LOW	HIGH
EndoTest (Ziwig)	Bendifallah et al. 2022d	200	Prospective, single-centre, development cohort (France)	UNCLEAR	HIGH	UNCLEAR	UNCLEAR	HIGH	HIGH	HIGH	UNCLEAR	HIGH
EndoTest (Ziwig)	Bendifallah et al. 2023	200 (interim)	Prospective multicentre, interim validation (France)	LOW	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	HIGH	LOW	UNCLEAR	HIGH

Technology	Study	N	Study Design	D1: Patient Selection (RoB)	D2: Index Test (RoB)	D3: Reference Standard (RoB)	D4: Flow & Timing (RoB)	Overall RoB	D1: Patient Selection (Applicability)	D2: Index Test (Applicability)	D3: Reference Standard (Applicability)	Overall Applicability
EndoTest (Ziwig)	Bendifallah et al. 2025	971	Prospective multicentre, full validation (France/Canada)	LOW	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	HIGH	LOW	UNCLEAR	HIGH

Appendix E Previous economic evidence - literature search details

PubMed search string to capture previously published economic models:

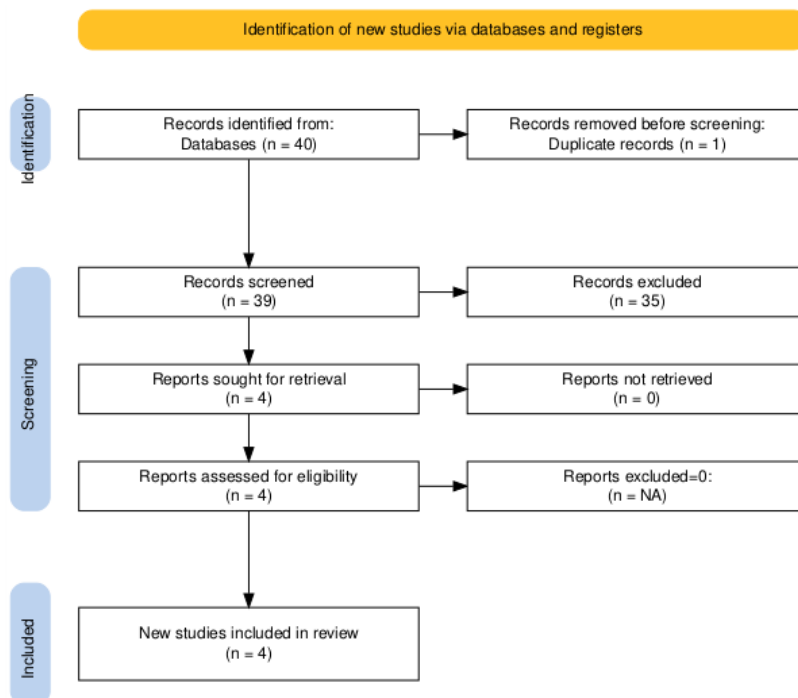
“endometriosis[tiab] AND (economics[tiab] OR health-economics[tiab] OR economic[tiab] OR health-economic[tiab] OR budget-impact[tiab] OR cost-effectiveness[tiab] OR cost-utility[tiab] OR cost-benefit[tiab]) AND (model[tiab] OR analysis[tiab]) AND (diagnosis[tiab] OR diagnostic[tiab] OR diagnose[tiab])”

Economic evaluations were included when satisfying the following informal criteria below. No formal PICOS criteria was established since the type of articles required were easily identified and described.

Inclusion: Health-economic models that evaluate any aspect of the diagnosis (including any non-definitive diagnostics) of endometriosis.

Exclusion: Any article that did not publish the methods and results of a de novo health-economic model, or any model that did not evaluate an element of the diagnostic pathway of endometriosis, for example models that compared treatment modalities.

PRISMA diagram:



Health Tech Programme

HTE10082 Technologies for the rapid diagnosis of endometriosis

External Assessment Report (EAR) and economic model – Collated Comments

Section A: External Assessment Report – Comments

Any confidential sections of the information provided should be underlined and highlighted. Please underline all confidential information, and separately highlight information that is **commercial in confidence** in blue and all that is **academic in confidence** in yellow

Comment no.	Company name	Page no.	Section no.	Comment	EAG Response
1 - critical	Ziwig	<i>Section 6.3.3</i> <i>Section 6.3.4.1 health states "Patient choice" assumption, Table 15</i>	<i>(p. 69)</i> <i>(p. 75-78)</i> <i>(p. 93)</i>	Absence of modelling of diagnostic laparoscopy replacement The model does not allow new tests to replace diagnostic laparoscopy, despite the fact that current recommendations from organizations such as European Society of Human Reproduction and Embryology (ESHRE) and the French Health Authority (Haute Autorité de Santé, HAS) no longer recommend diagnostic laparoscopy as a routine diagnostic approach. In the Model, a positive test result generates only a “presumptive diagnosis” and never a definitive diagnosis.	This is out of scope.

			<p>Diagnostic laparoscopy remains the sole pathway to a “definitive diagnosis” across all 21 health states of the Markov model. In addition, the “patient choice for laparoscopy” parameter is identical (50%) in both the standard care and the new technologies arms. Consequently, the tests have no modelled effect on laparoscopy rates.</p> <p>It is recognised in scientific literature that laparoscopy combined with histology also has inherent limitations: it relies on a macroscopic visual assessment of potentially microscopic lesions, is highly operator-dependent, and carries the risks associated with any surgical procedure. Consequently, laparoscopy cannot be considered a fully reliable diagnostic standard (McKee D, Wasson M. <i>Diagnosis of Endometriosis: The Surgeon's Eye Compared to Histopathology. Journal of Minimally Invasive Gynecology</i>, 29S4).</p> <p>The presentation of results from the ongoing analysis at University Hospitals Bristol and Weston shows patient pathway costs in an NHS hospital setting. This analysis is independent, with Ziwig only providing the tests. Slide 9 highlights the cost difference, between £3,435 with the current traditional pathway and £1,050 with a positive Endotest result. This</p>	
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			<p>presentation has been shared with NICE by email as new data.</p> <p>The current NHS pathway concentrates diagnostic confirmation in secondary care at a time when this capacity is structurally overwhelmed: over 752,000 women in the UK are waiting for hospital gynaecology services, with lists growing faster since 2020 than any other elective specialty. The impact of non-invasive molecular tests should be considered for the NHS as a positive organisational and budget impact.</p> <ul style="list-style-type: none"> - Maria Pencheri, Karina Ejgaard Hansen, Liv Juul Nielsen, Sharon Dixon, Lisa Hinton, Anders Prior, Axel Forman, Henrik Marschall, Mikkel Seyer-Hansen & Ulrik Bak Kirk. (2026) Understanding the diagnostic process of endometriosis in primary care: An interview study with general practitioners in Denmark using clinical vignettes. <i>European Journal of General Practice</i> 32:1. - Karavadra B et al. (2025). Building Bridges. <i>Women's Reprod Health</i>. DOI: 10.1080/23293691.2025.2540344 - NHS England (2025). RTT Waiting Times. <p>Impact on the modelling</p> <p>Maximal impact: the central value proposition of non-invasive tests, namely</p>	
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			<p>to avoid diagnostic laparoscopy through a reliable biomarker, is entirely absent from the model. The use of tests to avoid diagnostic laparoscopy is the primary endpoint of the ENDOBEST study (NCT06794424). Given the diagnostic performances of the Endotest, the threshold authorising the replacement of a procedure according to the Cochrane review criteria is robustly met. (Nisenblat et al. 2016)</p> <p>The savings generated by avoiding diagnostic laparoscopy are not accounted for.</p> <p>Moreover, the systemic effect of freeing up surgical capacity (a 13.57-month reduction in the waiting list) benefiting other pathologies is not modelled.</p> <p>The model structurally underestimates the value of non-invasive tests for the healthcare system as a whole</p> <p>Proposed adjustments</p> <ul style="list-style-type: none"> - Add a "test as replacement" scenario: a positive result on the new test allows initiation of medical treatment without prior diagnostic laparoscopy for a defined percentage of patients (parameter may be calibrated on available ENDOBEST data). 	
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				<ul style="list-style-type: none"> - Distinguish diagnostic laparoscopy (to be avoided) from therapeutic laparoscopy (treatment of lesions) in the model structure. - Develop a complementary system-level budget impact model, quantifying the freeing up of surgical capacity. - Integrate the cost of the avoided diagnostic laparoscopy as an incremental saving, which has an impact on the total cost for Endotest 	
2 - critical	Ziwig	<p><i>Table 10, "Specialist transvaginal ultrasound sensitivity"</i></p> <p><i>Note from Bailey et al. 2024: "The value used is the sensitivity for deep endometriosis"</i></p>	<p><i>(p. 84)</i></p> <p><i>(Tables 21-23, p. 117, 122, 129)</i></p> <p><i>(Table 4, p. 49-50)</i></p>	<p>Non-differentiation of endometriosis subtypes</p> <p>The model applies a single sensitivity and specificity value to the whole "with endometriosis" population, without distinguishing the three clinical subtypes: Isolated superficial peritoneal endometriosis (SPE), ovarian endometriosis (OE), and deep infiltrating endometriosis (DIE).</p> <ul style="list-style-type: none"> - Chapron C, Marcellin L, Borghese B, Santulli P. Rethinking mechanisms, diagnosis and management of endometriosis. Nat Rev Endocrinol 2019 ; 15 : 666–82. - Chapron C, Parpex G, Bosch T ...Changing the paradigm of endometriosis – from diagnosis to 	<p>Differentiation of sensitivity and specificity is out of scope, as no patient subgroups were considered.</p> <p>The new tests are only used in primary care. The performance of secondary care ultrasound is not replaced by the new tests. Differences seen when changing the secondary care ultrasound are due to changing the number of patients receiving additional imaging and laparoscopy. Worse sensitivity in specialist ultrasound means that more people go through the diagnostic pathway multiple times to get to a correct diagnosis.</p>

		<p><i>"Decreasing TvUS sensitivity in secondary care" scenarios 83.3 % → 51.5 %</i></p>		<p>integrated long-term management: a joint society opinion paper. Reproductive BioMedicine Online, 2026;</p> <p>For specialist ultrasound in secondary care, the value used in the base case (83.3%) is explicitly that for deep forms (Bailey et al. 2024, cited on p. 84 of the EAG report); the corresponding value for SPE from the same publication (51.5%) is only used in scenario analysis (p. 117). The EAG itself acknowledges that performance varies substantially depending on the type of endometriosis studied. Yet the epidemiological literature indicates that SPE represents a majority of cases (up to 80% according to Saunders & Horne 2021 and Koninckx et al. 1994, cited in Spiers et al. 2025): the model therefore uses the performance of the reference comparator on a minority form (DIE) as its central value, which tends to overestimate the sensitivity of "standard" TvUS and, consequently, to underestimate the incremental benefit of the new technologies.</p> <p>Table 4 of the 2025 Bendifallah study demonstrates the superiority of Endotest over ultrasound. The economic model relies solely on pooled average sensitivity and specificity values for each technology. It incorporates neither direct head-to-head comparative data against transvaginal ultrasound (where available), nor subtype-</p>	
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			<p>specific performance (SPE, DIE, OE). Since diagnostic performance varies substantially by endometriosis subtype - and since the subtypes are unequally prevalent in the target population - using pooled averages introduces a structural bias in the ICER estimates.</p> <p>Impact on the model</p> <p>By using the DIE sensitivity (83.3 %) as the base case instead of the SPE/DIE weighted value ($\approx 57\%$), the model overestimates the performance of conventional ultrasound on the most frequent form. It compresses the differential benefit of the new technologies relative to standard imaging.</p> <p>Quantifiable impact: the shift from 83.3 % to 51.5 % sensitivity for secondary care ultrasound (scenario Tables 21-23) improves the results of all technologies — DotEndo moves from $-\pounds 88$ to $-\pounds 260$ (dominant) and Endotest's ICER is reduced. If this SPE scenario were the base case, the comparative conclusions would be substantially modified.</p> <p>Endotest's major differential advantage on SPE is not valued: Moawad 2026a shows stable performance between SPE and DIE (sensitivity 96 %, specificity 95 % on confirmed SPE), while specialist ultrasound sensitivity falls from 83.3 % to 51.5 % on the same forms. This comparative advantage - relevant to 80 % of cases - is entirely absent from the model.</p>	
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				<p>DotEndo and EndoSure have no published data by subtype: the uniformity of their performance between SPE and DIE is an unverified implicit assumption that grants them an unsupported benefit on SPE.</p> <p>Laparoscopy itself has a specificity of 77 % in the model (Walter et al. 2001), reflecting the difficulty of visualising superficial lesions. This weakens the position of laparoscopy as the absolute gold standard for superficial forms and reinforces the value of a non-invasive test with 95 % specificity on SPE.</p> <p>Proposed adjustments</p> <ul style="list-style-type: none"> - Use as the base case a specialist ultrasound sensitivity weighted by subtype prevalence: 80 % SPE × 51.5 % + 20 % DIE/ovarian × 83.3 % ≈ 57 %, instead of the DIE-only value of 83.3 %. - Add a "form-representative population" scenario as the main scenario (80 % SPE / 20 % DIE), calculating the ICER of each technology in this clinically realistic context. - Incorporate the Endotest data by subtype (Moawad 2026a: SPE sensitivity 96 % / specificity 95 %) as differentiated inputs in an "SPE-dominant population" scenario, to capture Endotest's specific 	
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				<p>comparative advantage on the majority form.</p> <p>Account accordingly for the absence of subtype-specific performance data for DotLab and 3PCM/EndoSure: without these data, the assumption of uniformity between SPE and DIE is unsupported and potentially favourable to these technologies to the detriment of Endotest.</p>	
3 - critical	Ziwig	<p><i>Section 6.3.4</i></p> <p><i>Table 9, "People with symptoms that have endometriosis" parameter</i></p> <p><i>Section 6.6</i></p>	<p><i>(p. 70-71)</i></p> <p><i>(p. 80)</i></p> <p><i>(p. 133)</i></p>	<p>Disease-based approach and uncertainty regarding prevalence in primary care</p> <p>The model adopts a disease-based approach: the two cohorts (with and without endometriosis) are known a priori and the prevalence of 42.5 % is used to define their relative size. This prevalence is derived from Khan et al. 2018 (secondary care population) and has not been measured in the actual target population: symptomatic women with negative or inconclusive imaging in NHS primary care.</p> <p>Impact on the modelling</p> <p>If the true prevalence in NHS primary care is lower (15-20 %), the model overestimates the benefit of all tests by over-populating the "confirmed endometriosis" arm.</p>	<p>Marked as scientific disagreement rather than factual inaccuracy.</p> <p>The EAG will run additional scenario analyses to explore more variations in the prevalence of people with endometriosis.</p> <p>With respect to "post-negative imaging" prevalence (potentially 40-60%): This is likely to be lower than the all-comer prevalence, as some people with endometriosis have already been 'removed' from the cohort as they had already been 'found' to have endometriosis.</p>

				<p>The OWSA shows that varying the prevalence from 42.5 % to 20 % changes the ICER from dominant to £2 091/QALY for DotEndo (p118) and from £6 068 to £13 942/QALY for Endotest (p124), and £3 952 for EndoSure.</p> <p>Prevalence is the leading cost driver for EndoSure (a 220 % variation in differential costs for a 20 % change in the input).</p> <p>The disease-based choice conceals the prevalence problem rather than solving it: uncertainty on this central parameter is not sufficiently quantified</p> <p>Proposed adjustments</p> <ul style="list-style-type: none"> - Test a range of prevalences from 15 % to 55 % in scenario analyses (instead of only the current 20 % and 52.5 % scenarios) to quantify the full uncertainty. - Consider a complementary test-based analysis using PPV/NPV calibrated on a realistic primary care prevalence, allowing a direct comparison with the disease-based approach. - Distinguish "all-comers" prevalence (15-20 %) from "post-negative imaging" prevalence (potentially 40-60 %) corresponding to the actual target population of the tests. 	
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4 - major	Ziwig	<p><i>Section 6.3.6 cost inputs</i></p> <p><i>Table 13 unit cost of tests</i></p>	<p><i>(p. 86-87)</i></p> <p><i>(p. 87)</i></p>	<p>Differential price treated without regard to technological content and level of clinical evidence</p> <p>The model incorporates the unit price of the three technologies as a direct input without accounting for the underlying technological complexity or the level of clinical evidence underpinning each test. Endotest’s higher price reflects a precision-medicine approach combining next-generation sequencing (NGS) with an algorithm based on 109 microRNAs, validated in prospective studies (Bendifallah et al. 2025, 2023; Moawad 2026) on independent surgical cohorts. EndoSure (3PCM, single-protein ELISA) and DotEndo (small-panel saliva assay) are based on substantially simpler technological architectures, with a narrower evidence base, partly limited to founder-led studies (see comment no. 8). The model treats the three tests as interchangeable diagnostic black boxes characterised solely by their reported sensitivity and specificity, ignoring the technological hierarchy and the differential robustness of clinical evidence.</p> <p>Impact on the model</p> <p>The unit cost of the tests is a leading cost driver in the OWSA for all three technologies. Because the model attributes performance values uniformly across study populations (see comment</p>	<p>Marked as scientific disagreement rather than factual inaccuracy.</p> <p>The suggested approach is not standard. The costs provided by the companies are used in the model as these are the cost the NHS would pay.</p>
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				<p>no. 8) and does not penalise technologies with weaker evidence by widening their uncertainty ranges, Endotest's ICER is mechanically penalised by its higher price while EndoSure and DotEndo benefit from price advantages that are not offset by any structural adjustment for evidentiary fragility. The resulting comparison favours lower-cost tests irrespective of the strength of evidence supporting their reported accuracy.</p> <p>The reported added value of a precision-medicine diagnostic - reproducibility, robustness across subtypes (Moawad 2026: sensitivity 96 % / specificity 95 % on confirmed SPE), reliability as a definitive diagnostic anchor enabling replacement of laparoscopy (see comment no. 1) - is not captured by sensitivity and specificity values alone. Endotest's diagnostic reliability is what supports its use as a reference test allowing laparoscopy avoidance (ENDOBEST primary endpoint); this clinical positioning is not reflected in the model and therefore does not contribute to its modelled value.</p> <p>The ICER of Endotest is structurally inflated by the combination of (i) a higher unit price, (ii) structural penalties already identified (age restriction - comment no. 5); false-negative artefact - comment no. 6; specificity-as-QALY-driver - comment no. 7), and (iii) the absence of</p>	
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				<p>any model element reflecting the comparative robustness of its evidence base or its capacity to replace diagnostic laparoscopy.</p> <p>Proposed adjustments</p> <ul style="list-style-type: none"> - Conduct a sensitivity analysis varying the unit prices of EndoSure and DotEndo upward to reflect the evidentiary uncertainty surrounding their reported performance (e.g. apply a +20-30 % price equivalent or, equivalently, widen their performance uncertainty ranges asymmetrically), to test whether the dominance of these technologies persists once differential evidence robustness is accounted for. - Add a value-based scenario in which the test capable of replacing diagnostic laparoscopy (credited with the avoided cost of diagnostic laparoscopy - £1 522 per case, Ferrier et al. 2023, see comment no. 1); - Present a structured qualitative summary alongside the ICER comparing the three technologies on (i) underlying technology (NGS + 109-miRNA algorithm vs single-protein ELISA vs small-panel saliva assay), (ii) number and independence of validating studies, and (iii) availability of subtype-specific performance data, so that 	
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				decision-makers can interpret the cost-effectiveness results.	
5 - moderate	Ziwig	<p><i>Section 6.5.2.3 Endotest</i></p> <p><i>Figures 15-16 OWSA Endotest</i></p>	<p><i>(p. 108)</i></p> <p><i>(p. 110)</i></p>	<p>Endotest 18-43 age restriction: asymmetric impact on QALYs</p> <p>Endotest is indicated for ages 18-43, DotEndo for ages 18-49, EndoSure with no age restriction. Over a 60-year horizon with an entry age of 22 (normal distribution, p80), patients exceed 43 years during the modelling and can no longer benefit from Endotest. These lost years of eligibility mechanically reduce the accumulated incremental QALYs. This is the leading cost and QALY driver identified for Endotest in the OWSA.</p> <p>Impact on the model</p> <p>A 0.01 QALY gap between Endotest (0.10) and EndoSure/DotEndo (0.11) is mainly attributable to this restriction. Endotest's ICER (£6 068/QALY) is penalised relative to the two dominant technologies, whose apparent superiority is not clinical but structural to the model.</p> <p>The 18-43 age restriction reflects the inclusion criteria of the validation studies, not an intrinsic biological limit of the test.</p> <p>Proposed adjustments</p> <ul style="list-style-type: none"> - Add a scenario with an age upper bound extended to 49 (aligned with 	<p>Marked as scientific disagreement rather than factual inaccuracy.</p> <p>The population cohort is the same between technologies, only the age restrictions differ. This is based on expected CE mark limitations of the technologies, for which only the age restrictions differ.</p> <p>For clarity, the bigger impact here is that at baseline a proportion of the cohort (mean age 22) is under 18 and cannot use two of the new technologies.</p>

				DotEndo) in order to isolate the impact of this restriction on the ICER and QALYs.	
6 - major	Ziwig	<p><i>Section 6.5.3 additional results</i></p> <p><i>Tables 18-20</i></p> <p><i>Section 6.3.4.1 "Differential diagnostic state"</i></p>	<p><i>(p. 111-112)</i></p> <p><i>(p. 112-114)</i></p> <p><i>(p. 76)</i></p>	<p>Structural artefact: false negatives paradoxically gain faster access to laparoscopy</p> <p>In the model, a patient with endometriosis who receives a false negative on the new test is redirected to the differential diagnosis pathway in secondary care, which gives them more direct access to laparoscopy than the standard presumptive pathway. In clinical reality, a false negative delays diagnosis. The model itself acknowledges this structural artefact.</p> <p>Impact on the model</p> <p>The artefact artificially neutralises Endotest's sensitivity advantage (97.3 % vs 83 -90 % for DotEndo): fewer false negatives means fewer patients taking the paradoxical shortcut.</p> <p>The three technologies produce nearly identical reductions in diagnostic delay (0.97-1.22 years) despite very different sensitivities.</p> <p>The 95 % CIs for the rate of correct definitive diagnoses are enormous ([-8.9 %; +8.2 %]): the model does not reliably estimate this outcome.</p> <p>The most clinically relevant outcome (rate of correct definitive diagnoses) is the only</p>	<p>Marked as scientific disagreement rather than factual inaccuracy.</p> <p>The EAG can run additional scenario analyses to explore.</p>

				<p>scenario for which the new technologies produce a slightly negative result: an artefact acknowledged but not corrected.</p> <p>Proposed adjustments</p> <ul style="list-style-type: none"> - Modify the false-negative flow in the model: patients with a false negative should follow the same pathway as in the standard care arm (return to the start of the pathway, without artificial acceleration via differential diagnosis). - Test a scenario analysis in which the probability of direct access to laparoscopy via the differential pathway is set back to the level of the standard pathway, to isolate the impact of the artefact. - The preliminary results of the ENDOBEST study conducted with French Health Authority (HAS) showing the transformation of practices and the use of diagnostic surgery may provide an additional element for NICE 	
7 - major	Ziwig	<p><i>Section 6.5.2</i></p> <p><i>Section 6.6</i></p>	<p><i>(p. 100)</i></p> <p><i>(p. 133-134)</i></p>	<p>Specificity as the principal QALY driver: a logic that reverses the comparative advantage</p> <p>The OWSA establishes specificity as the principal QALY driver for all three technologies, and sensitivity as the cost</p>	<p>Marked as scientific disagreement rather than factual inaccuracy.</p> <p>It is expected that after initial tests a proportion of the endometriosis-positive population are removed (already have a presumptive diagnosis), leaving a population for the new tests that has a</p>

		<p><i>Figures 8, 12, 16 OWSA QALY drivers</i></p>	<p>driver. This hierarchy is a direct consequence of the 42.5 % prevalence. Thus, 57.5 % of the cohort (without endometriosis) obtains no QALY benefit from the new technologies.</p> <p>Impact on the model</p> <p>Endotest's superior sensitivity (97.3 % vs 83-96 %) - its main clinical strength - is penalised in QALY terms because it only acts on 42.5 % of the cohort. This choice may be considered conservative for the modelling but may not be realistic. If the true prevalence in the target population is higher (e.g. 55-60 % after filtering by negative imaging), sensitivity would become the dominant driver, reversing the comparative advantage in favour of Endotest.</p> <p>The 100 % prevalence scenario (Table 22) shows QALYs of +0.17 for Endotest vs +0.10 in the base case, confirming this dynamic.</p> <p>Proposed adjustments</p> <p>Test a scenario with enriched prevalence (55-65 %) corresponding to the actual post-negative-imaging population: in this context, sensitivity becomes the principal driver and Endotest's advantage would be fully captured.</p> <p>Present a scenario in which the 57.5 % without endometriosis benefit from the true-negative result of the test</p>	<p>lower proportion of people with endometriosis in it.</p>
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				<p>(reassurance, reduction in unnecessary consultations) with a modest but non-zero QALY gain.</p> <p>Provide data on the prevalence in the ENDOBEST target population (symptomatic women with inconclusive imaging) to calibrate this parameter.</p>	
8 - major	Ziwig	<p><i>Table 15, "Diagnostic accuracy of new tests" assumption</i></p> <p><i>Table 10</i></p> <p><i>Section 5.4</i></p>	<p><i>(p. 91)</i></p> <p><i>(p. 83-85)</i></p> <p><i>(p. 57-58)</i></p>	<p>Transfer of diagnostic performance from secondary care populations to primary care</p> <p>The sensitivities and specificities used for the three technologies come from studies conducted in high-prevalence surgical populations (77-80 % for Endotest, ~80 % for EndoSure). The model applies them directly to a primary care population with 42.5 % prevalence, without spectrum correction. The EAG itself describes this assumption as "uncertain" in the expert feedback (Table 15, p. 91).</p> <p>Impact on the model</p> <p>Sensitivity is the principal cost driver: a real degradation of performance in primary care (milder, less symptomatic forms) substantially modifying results. EndoSure and DotEndo are particularly vulnerable: a 20 % variation in their sensitivity produces changes of >100 % and >200 % in differential costs.</p>	<p>Marked as scientific disagreement rather than factual inaccuracy.</p> <p>The variation in sensitivity and specificity has been explored already in scenario analyses. It is impossible to know how test performance will vary in the primary care population. It is commonly perceived that the 'spectrum effect' results in lower sensitivity and higher specificity when moving from a clinical study population to a more general population. A scenario analysis with decreased sensitivity and increased specificity can be performed.</p>

				<p>EndoSure studies report specificities ranging from 0 % to 96 % across independent studies, with the 95 % value used in the base case sourced exclusively from studies led by the technology's founder (Noar et al. 2024a, 2024b)</p> <p>Proposed adjustments</p> <ul style="list-style-type: none"> - Test a "primary care performance degradation" scenario with a 10-15 % reduction in the sensitivity of each technology, in addition to the current ± 20 %. - Apply a spectrum correction to the published sensitivities based on the prevalence difference between the study populations and the NHS target population. 	
9 - major	Ziwig	<p>Section 6.4 validation</p> <p>Tables 18-20</p> <p>Table 9, "Waiting time for laparoscopy"</p>	<p>(p. 95-96)</p> <p>(p. 112-114)</p> <p>(p. 81)</p>	<p>Small reduction in diagnostic delay (0.97-1.22 years) and ceiling effect from the laparoscopy waiting list</p> <p>The model predicts a reduction in time to definitive diagnosis of only 0.97 to 1.22 years, while the mean diagnostic delay is 9 years 4 months and the wait for a laparoscopy is 13.57 months. The benefit of the tests is capped by this bottleneck, which does not vary between arms. Furthermore, delay differences between technologies (-1.22 years EndoSure vs -1.04 years Endotest) appear despite</p>	<p>Marked as scientific disagreement rather than factual inaccuracy.</p> <p>The EAG can run additional scenario analyses to explore removing wait time for laparoscopy and increasing the patient preference for avoiding laparoscopy.</p>

			<p>identical positioning in the pathway, due to the false-negative artefact and the age restriction.</p> <p>Impact on the model</p> <p>The laparoscopy wait (13.57 months) is a fixed parameter, identical across all arms: the tests accelerate access to laparoscopy but does not reduce the delay once on the waiting list.</p> <p>If Endotest avoids diagnostic laparoscopies (ENDOBEST), the waiting list should shorten for all patients - a systemic effect that is not modelled.</p> <p>The difference in delay reduction between EndoSure (-1.22 years) and Endotest (-1.04 years) results from the false-negative artefact and the age restriction, not from a difference in clinical performance.</p> <p>Proposed adjustments</p> <ul style="list-style-type: none"> - Model a scenario in which the reduction in the rate of diagnostic laparoscopies translates into a proportional reduction in waiting time for all patients on the list. - Clearly distinguish "time to initial presentation" (modifiable by awareness-raising) from "post-negative-imaging delay" (where the tests actually intervene) in the analysis. 	
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				<ul style="list-style-type: none"> - Correct the delay difference between technologies by addressing the false-negative artefact () and the age restriction. 	
10 - moderate	Ziwig	<p><i>Section 6.3.7</i></p> <p><i>Table 14</i></p> <p><i>Scenarios Tables 21-23</i></p>	<p><i>(p. 88-89)</i></p> <p><i>(p. 88-89)</i></p>	<p>Single source of utility data (Aubry et al. 2017): limitations and consequences</p> <p>All utility and disutility values come from a French study (Aubry et al. 2017, N=253), conducted in a population with confirmed endometriosis. No quality-of-life data specific to the new technologies are available. The gain linked to the speed of diagnosis is not valued over time (fixed disutility regardless of the duration of the diagnostic journey).</p> <p>Impact on the model</p> <p>The laparoscopy wait (13.57 months) is a fixed parameter, identical across all arms: the tests accelerate access to laparoscopy but do not reduce the delay once on the waiting list.</p> <p>The difference in delay reduction between EndoSure (-1.22 years) and Endotest (-1.04 years) results from the false-negative artefact and the age restriction, not from a difference in clinical performance.</p> <p>In practice, the QALY is a poorly relevant outcome for this type of evaluation. Avoided surgeries, FPs and FNs, the</p>	<p>Marked as scientific disagreement rather than factual inaccuracy.</p> <p>The QALY benefit of a presumptive diagnosis is applied directly when a presumptive diagnosis is made and remains throughout the time horizon until either: a) a definitive diagnosis is made, b) a false positive diagnosis is identified; or c) death occurs.</p>

				<p>reduction in the diagnostic journey in years, and resource use across the whole pathway are more relevant organisational criteria.</p> <p>Proposed adjustments</p> <ul style="list-style-type: none"> - Model a scenario in which the reduction in the rate of diagnostic laparoscopies translates into a proportional reduction in waiting time for all patients on the list. - Clearly distinguish "time to initial presentation" (modifiable by awareness-raising) from "post-negative-imaging delay" (where the tests actually intervene) in the analysis. - Correct the delay difference between technologies by addressing the false-negative artefact (see bias no. 4) and the age restriction (see bias no. 3). 	
11 - moderate	Ziwig	<i>Table 15, "Cost of treating other conditions" and "Quality of life for other conditions"</i>	<i>(p. 93-94)</i>	<p>Zero costs for comorbid conditions and absence of benefit for true negatives</p> <p>The cost of treating alternative conditions (adenomyosis, IBS, fibroids) is set to zero in the base case. The quality of life of the 57.5 % of patients without endometriosis is taken as equal to that of patients with endometriosis (base utility 0.59 from Aubry et al. 2017, endometriosis population). These patients gain no QALY benefit from</p>	<p>Marked as scientific disagreement rather than factual inaccuracy.</p> <p>Scenario analyses were run and reported in which costs were added here.</p>

		<p><i>Section 6.6</i></p>	<p><i>(p. 134)</i></p>	<p>the test: receiving a reliable diagnosis is not valued.</p> <p>Impact on the modelling</p> <p>The majority of the cohort (57.5 %) contributes to the test costs but not to the QALYs: this structurally compresses all ICERs.</p> <p>The absence of costs for alternative conditions underestimates the costs of the standard care arm (misdiagnosis, inadequate treatment) and artificially favours the comparison. Experts in France report high costs associated with the diagnostic journey and medical wandering, notably with regards to inappropriate care pathways (gastroenterology, rheumatology) owing to the complexity of symptoms.</p> <p>The Model understates the value of specificity in QALY terms: a true negative reassures the patient and reduces repeat consultations, a real benefit that cannot be captured in this model.</p> <p>Proposed adjustments</p> <ul style="list-style-type: none"> - Apply an alternative treatment cost to patients without endometriosis in the standard care arm (line 1 or 2 treatment for adenomyosis, IBS, etc.), instead of zero. - Assign a modest QALY gain (e.g. 0.02-0.05) to true-negative test results, capturing reassurance and 	
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				<p>the reduction of the diagnostic journey for patients without endometriosis.</p> <ul style="list-style-type: none"> - Test the sensitivity of the ICER to these two adjustments jointly. 	
12 - moderate	Ziwig	<p><i>Table 10, "Transvaginal ultrasound sensitivity, primary care"</i></p> <p><i>Figures 7, 11, 15 OWSA costs</i></p>	(p. 83)	<p>Primary care ultrasound sensitivity fixed at 25 %: phantom parameter</p> <p>The sensitivity of transvaginal ultrasound in primary care is fixed at 25 % (95 % CI: 12.7-41.2 %), derived from a Canadian study (Fraser et al. 2015, N=114). The EAG acknowledges that "no data have been identified for the United Kingdom". This is one of the leading cost drivers in the OWSA for all three technologies.</p> <p>Impact on the modelling</p> <p>The lower the ultrasound sensitivity, the more advantageous the new technologies appear by contrast: an excessively pessimistic parameter creates an artificial bias favouring all three technologies.</p> <p>The 25 % value comes from a non-specialist Canadian study dating from 2015, poorly representative of the current NHS Women's Health Hubs. Others references exists such as Pascoal, E., Wessels, J.M., Aas-Eng, M.K., Abrao, M.S., Condous, G., Jurkovic, D., Espada, M., Exacoustos, C., Ferrero, S., Guerriero,</p>	<p>Marked as scientific disagreement rather than factual inaccuracy.</p> <p>The data around sensitivity and specificity for all endometriosis diagnostics in primary care populations is of low quality. Scenario analyses were performed around these inputs to explore the impact they have on model outcomes.</p>

				<p>S., Hudelist, G., Malzoni, M., Reid, S., Tang, S., Tomassetti, C., Singh, S.S., Van den Bosch, T. and Leonardi, M. (2022), Strengths and limitations of diagnostic tools for endometriosis and relevance in diagnostic test accuracy research. <i>Ultrasound Obstet Gynecol</i>, 60: 309-327.</p> <p>Table 4 of the 2025 Bendifallah study demonstrates the superiority of Endotest over ultrasound. Only the average performance values are used in the model; neither the head-to-head performance against ultrasound nor the performance by endometriosis subtype is incorporated. This introduces a bias in the ICER results.</p> <p>Proposed adjustments</p> <ul style="list-style-type: none"> - Widen the ultrasound sensitivity range in the scenarios (20 % to 60 %) to cover the actual uncertainty. - Test a scenario in which the sensitivity of ultrasound in primary care equals that in secondary care (83.3 %) to assess the maximal impact. 	
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1	Endosure Inc.	11 2 nd paragraph ; 2 nd line	Clinical Evidence	<i>The second paper of the Endosure test is listed as having been a pre-print when in fact it was peer reviewed and published in a journal. I will provide a copy of the paper for completeness and accurate update of the reporting in the document.</i>	Thank you for providing the peer-reviewed version. The EAR was updated accordingly.
2	Endosure Inc.	11 2 nd paragraph ; 4th line	Clinical Evidence	<i>In referring to Specificities, it is noted that in some studies there is a specificity of 0%. There should be an accompanying explanation that In those studies there were no negative patients for evaluation, making the calculation of specificity impossible...which should be noted as such</i>	<p>The EAR was updated accordingly by including this explanation where relevant. The abstract by Tanos et al. 2025 reported a specificity of 5% in a population of 100 people with “suspected endometriosis”, where the number of negative patients was not disclosed. However, based on the reported specificity of 100%, it can be assumed that no people without the disease were evaluated, meaning that the 5% specificity value should have been reported as “unquantifiable”. This explanation is already included in the “EAG comments column” of Table 4.</p> <p>In the abstract by Andres et al. 2025, 0% specificity was reported for a population that included one person without endometriosis (in the laparoscopy reference group).</p> <p>Although the EAG agree that measuring specificity on such low numbers of negative controls lacks scientific rigour, we are obligated to present the data as they are reported in the literature.</p> <p>The EAG can reassure the company that diagnostic accuracy values used to inform the health economic model were not derived from any abstract-only publications as these represent</p>

					low-quality sources of evidence. Only sensitivities/specificities provided in RFI submissions by companies and supported by peer-reviewed published data were used in the model.
3	Endosure Inc.	11 2 nd paragraph ; 2 nd line	Clinical Evidence	<i>There is the correct notation that the technology developer led the study “representing a notable bias”. There was no such notation in the EndoTest text, where the lead author SB, was also a developer of the technology and performed confirmatory surgery on subjects...no less a notable bias...but noticeably absent in the review here and in multiple other locations! He also serves on the medical board of the company.</i>	The EAG examined the conflict-of-interest statements of the EndoTest studies more closely. No conflicts of interest were declared in the Bendifallah 2022 study; however, the supplementary disclosures for the Bendifallah 2023 and 2025 studies, do state that the lead author (SB) received consultancy fees from Ziwig and is a member of the Medical Board of Ziwig. This information was added to the relevant section of the EAR.
4	Endosure Inc.	11 3 rd paragraph	Clinical Evidence	<i>In referring to Specificities, it is noted that in some studies there is a specificity of 0%. There should be an accompanying explanation that In those studies there were no negative patients for evaluation, making the calculation of specificity impossible...which should be noted as such</i>	This was already addressed above (see response to EndoSure comment 2).
5	Endosure Inc.	13 6 th line	Evidence Gap Analysis	“For EndoSure, the additional gap of independent validation (free from <i>technology developer conflict of interest</i>) is a priority.” <i>Similar to comment 3 above, why is there no technology developer conflict noted for EndoTest too?</i>	The EAG agree that the EndoTest studies are subject to conflict of interest because they are funded by Ziwig and have a lead author who received consultancy fees from the company and is a member of the medical board. It is not the role of the EAG to weigh up one type of conflict of interest against another. As such, the relevant section of the EAR was updated with

					the sentence: “Fully company-independent validation studies are needed for all three technologies.”
6	Endosure Inc.	14 subheading 3	Key Points for Decision Makers	<i>Once again high level language about considerable conflict of interest without noting similar in other technology</i>	The EAG do not view this as a factual inaccuracy. The conflict-of-interest bias for EndoSure is considerable as stated. Although the EndoTest studies were company-funded, the two latest studies were independently validated by Monitoring Force.
7	Endosure Inc.	38 Final paragraph	5.1	“While the studies describe prospective enrolment, the extent to which consecutive or random sampling was employed is not clearly reported.” These patients were selected consecutively.	The EAG are unable to update this information in the EAR as it was not provided in the published papers. The role of the EAG is to report the information as it is presented in the literature.
8	Endosure Inc.	39 second paragraph	5.1	“However, a major concern is the conflict of interest: in both studies, the lead author (M. Noar) is disclosed as the founder of 3PCM/Endosure (the technology manufacturer). This represents a considerable source of performance bias that affects all published EndoSure diagnostic accuracy data. No external, manufacturer-independent validation study has been published. The risk of bias in this domain is judged high for both studies. The applicability concern is also judged high for the two studies, as the performance of EndoSure has not been evaluated using assessors without a commercial conflict of interest.” It is important to note that none of the	Thank you for making this distinction. The phrasing was changed in the relevant section of the EAG from “company-funded” to “investigator-sponsored”.

				Endosure were manufacturer sponsored studies. At the time these were investigator sponsored studies.	
9	Endosure Inc.	40-41	5.1	<i>I apologize if this is not a proper response but there is no mention of the potential conflict here, please see comment # 3 above.</i>	This section of the EAR was updated to highlight the conflict of interest of the lead author of the EndoTest studies. The risk of bias was also increased from 'low' to 'unclear' to reflect this.
10	Endosure Inc.	43 2 nd paragraph	5.2.2	The second paper of the Endosure test is listed as having been a pre-print when in fact it was peer reviewed and published in a journal. I will provide a copy of the paper for completeness and accuracy update of the reporting in the document.	This information was updated in the EAR.
11	Endosure Inc.	57 2 nd paragraph	5.4 Summary of Evidence	In referring to Specificities, it is noted that in some studies there is a specificity of 0%. There should be an accompanying explanation that In those studies there were no negative patients for evaluation, making the calculation of specificity impossible...which should be noted as such	This was already addressed above (see response to EndoSure comment 2).
12	Endosure Inc.	57 2 nd paragraph	5.4 Summary of Evidence	The second paper of the Endosure test is listed as having been a pre-print when in fact it was peer reviewed and published in a journal. I will provide a copy of the paper for completeness and accuracy update of the reporting in the document.	This information was updated in the EAR.

Section B - Economic model - Comments

Company Name	Issue	Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)	EAG comment
Ziwig	1	The deterministic sensitivity analysis (DSA) does not run in the current version of the model.	-	-	<p>The deterministic sensitivity analysis (OWSA) is functional, it is run by clicking the 'Run OWSA' button on the 'Results' tab. There can be issues with running the Excel macro if any of the below are true:</p> <ol style="list-style-type: none"> 1. The Excel file is not saved to the local hard drive 2. The file is not stored in a 'safe location' as defined within the local instance of Excel 3. Excel Macros are not enabled, which may be set locally by the user or centrally by the IT administrator <p>To facilitate running the Macro, the code used to create it is signed with a security certificate.</p>
Ziwig	2	The probabilistic sensitivity analysis (PSA) is operational but appears to be based on arbitrary variation ranges rather than on study-derived uncertainty.	The 95% confidence intervals reported in Bendifallah et al. 2025 could be used to parameterise the PSA distributions for Endotest sensitivity and specificity, in order to reflect the actual uncertainty	To provide a more clinically meaningful representation.	<p>If literature data for 95% confidence intervals or standard deviations were available for inputs, then these were used in the PSA. The model has multiple levels of redundancy built into it to account for many possible inputs.</p> <ol style="list-style-type: none"> 1. If the model input is equal to the default value, then the standard deviation

			around the published estimates.		and/or 95% confidence interval is used for the PSA code 2. If the model input is a value different from the default value, then the 'assumed variance' is used for the PSA calculation.
Ziwig	3	The handling of Endotest specificity in the model warrants verification, as the directional impact of varying sensitivity and specificity appears counterintuitive.	When a specificity of 100% is applied to Ziwig Endotest®, an increase in the ICER is observed; conversely, when a sensitivity of 100% is applied, a decrease in the ICER is observed. We would be grateful if the EAG could confirm that this behaviour reflects the intended model structure, and clarify the underlying mechanism.	Clarification of this point is needed to ensure correct interpretation of the sensitivity analyses and of the relative cost-effectiveness of Endotest compared with the other technologies.	This is correct: 1. Setting the test to 100% specificity only changes the outcomes coming from the population without endometriosis. As the test is more often 'correct' a small amount of money is saved from performing fewer tests (this is very minimal). There is, however, a more substantial decrease in QALYs as with a lower sensitivity there are false positive diagnoses. A diagnosis has a positive QALY impact, as the person (of course) does not know it is an incorrect diagnosis, only that they have received one. This 'incorrect diagnosis' is achieved quicker than the correct diagnosis if the test is 100% specific. The reduced QALYs drives the increase in the ICER. 2. For the sensitivity being 100%, only changes in the Endometriosis population are observed. Here we see increased QALYs as a correct diagnosis is made more quickly and lower costs as fewer tests are required (differential diagnosis avoided).

Diagnostics Advisory Committee Interests Register

Topic: Project Technologies for the rapid diagnosis of Endometriosis

NICE's declaration of interest policy can be accessed [here](#)

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Prof Thomas Clutton-Brock	Chair	Non-Financial Professional and Personal Interests	Clinical Director NIHR HRC Devices, digital and robotics	April 2024	1.12.2025	Current	Declare and Participate
Prof Thomas Clutton-Brock	Chair	Non-Financial Professional and Personal Interests	Clinical Director Medical Devices Testing and Evaluation Centre	January 2017	1.12.2025	Current	Declare and Participate
Prof Thomas Clutton-Brock	Chair	Non-Financial Professional and Personal Interests	Chair MHRA Interim Devices Working Group	November 2022	1.12.2025	Current	Declare and Participate
Prof Neil Hawkins	Vice Chair	Financial Interest	I am a director of a company that provides health technology consultancy services to pharmaceutical companies. No services have been provided to any of the listed stakeholders	February 2019	23.03.2026	Ongoing	Declare and Participate
Dr Amit Parekh	Vice Chair	N/A	Nothing to declare	-	3.2.2026	-	No further action
Dr Alex Novak	Committee Member	Financial Interest	Grants received from:	-	6.2.2026	-	Declare and Participate

			<ul style="list-style-type: none"> • National Institute of Health Research (NIHR) • Innovate UK • Small Business Research Institute • NHSX (Qure.AI) • GE Healthcare Ltd • Perspectum Diagnostics Ltd • Lunit • Radiobotics • Reporting and Imaging Quality Control • Seroxo • Abbott 				
Dr Alex Novak	Committee Member	Financial Interest	Consultancy work previously undertaken for Abbott	-	6.2.2026	2025	Declare and Participate
Dr Alex Novak	Committee Member	Financial Interest	Consultancy work previously undertaken for GE Healthcare Ltd	-	6.2.2026	2021	Declare and Participate
Dr Alex Novak	Committee Member	Non-Financial Professional and Personal Interests	Personal Appointments: <ul style="list-style-type: none"> • Standing Member of National Institute of Health and Care Excellence Diagnostics Advisory Committee • Member of Cochrane Acute and Critical Care Editorial Board • Member of National Institute of Health 	-	6.2.2026	-	Declare and Participate

			<p>Research (NIHR) Research for Patient Benefit (RfPB) Grant Panel</p> <ul style="list-style-type: none"> Member of Royal College of Emergency Medicine Research and Publications Committee 				
Dr Andre Nunes	Committee Member	N/A	Nothing to Declare	-	3.12.2025	-	No further action
Andrew Renehan	Committee Member	N/A	Nothing to Declare	-	20.5.2026	-	No further action
Amita Kanjee	Committee Member	Indirect Interest	Member of Greater Manchester Women and Girl Equality Panel	December 2023	23.3.2026	December 2025	Declare and Participate
Beena Jhoree	Committee Member	N/A	Nothing to Declare	-	20.5.2026	-	No further action
Dr Brian Shine	Committee Member	N/A	Nothing to Declare	-	3.2.2026	-	No further action
Mr Farai Goromonzi	Committee Member	N/A	Nothing to Declare	-	17.2.2026	-	No further action
Dr Hayley Sharrod-Cole	Committee Member	N/A	Nothing to Declare	-	20.5.2026	-	No further action
Prof John Cairns	Committee Member	Financial Interest	Advising Johnson & Johnson Innovative on multiple myeloma submission	May 2025	1.12.2025	May 2025	Declare and Participate
Prof John Cairns	Committee Member	Financial Interest	Advice to BeiGene on economic modelling of a treatment for small cell lung cancer	October 2024	1.12.2025	September 2025	Declare and Participate
Prof John Cairns	Committee Member	Financial Interest	Advice to Johnson & Johnson Innovative on a treatment for generalized myasthenia gravis	October 2025	1.12.2025	October 2025	Declare and Participate
Prof John Cairns	Committee Member	Financial Interest	Participating in an Office of Health Economics roundtable on severity modifiers	March 2026	8.6.2026	March 2026	Declare and Participate

Prof John Cairns	Committee Member	Financial Interest	Advising Johnson & Johnson on economic modelling for BRCA-mutated metastatic hormone-sensitive prostate cancer	May 2026	8.6.2026	Ongoing	Declare and Participate
Dr Jonathan Weir-McCall	Committee Member	Financial Interest	Private practice: Royal Papworth Private Radiology Group	1.8.2028	8.1.2025	30-Jun-2025	Declare and Participate
Dr Jonathan Weir-McCall	Committee Member	Financial Interest	Private practice: Royal Brompton Hospital	1.7.2025	8.1.2025	-	Declare and Participate
Dr Jonathan Weir-McCall	Committee Member	Non-Financial Professional and Personal Interests	President Elect and Charity Trustee, British Society of Cardiovascular Imaging (this also functions as the Specialist Interest Group of the Royal College of Radiologists).	1.9.2022	8.1.2025	-	Declare and Participate
Dr Jonathan Weir-McCall	Committee Member	Non-Financial Professional and Personal Interests	Charity Trustee, British Society of Cardiovascular Magnetic Resonance	1.9.2023	8.1.2025	-	Declare and Participate
Dr Jonathan Weir-McCall	Committee Member	Non-Financial Professional and Personal Interests	Guideline committee member, Society of Cardiovascular Computed Tomography	1.8.2024	8.1.2025	-	Declare and Participate
Dr Jonathan Weir-McCall	Committee Member	Non-Financial Professional and Personal Interests	Board of Directors, Society of Cardiovascular Computed Tomography	1.7.2023	8.1.2025	-	Declare and Participate
Dr Joy Allen	Committee Member	Financial Interest	Employee of Roche Diagnostics	August 2021	3.2.2026	Current	Conflict of interest – excluded from committee meetings

							Updated 9.6.2026
Dr Joy Allen	Committee Member	Financial Interest	"Conflict has been discussed with NICE and cannot be disclosed publicly"	August 2021	3.2.2026	-	Conflict of interest – excluded from committee meetings Updated 9.6.2026
Kate Xu	Committee Member	N/A	Nothing to Declare		22.5. 2026	-	No further action
Prof Keith Abrams	Committee Member	Financial Interest	Partner & Director, Visible Analytics Limited – HTA Consultancy company (not involved in any diagnostics projects VA are undertaking)	01.05.2019	9.6.2026	-	Declare and Participate
Prof Keith Abrams	Committee Member	Financial Interest	Consultant to Bayer – surrogacy in prostate cancer	01.09.2024	9.6.2026	-	Declare and Participate
Prof Keith Abrams	Committee Member	Financial Interest	Consultant to Roche – Bayesian dynamic borrowing	01.10.2024	9.6.2026	-	Declare and Participate
Prof Keith Abrams	Committee Member	Financial Interest	Consultant to NICE – Surrogacy in AML	01.10.2024	9.6.2026	30.01.2025	Declare and Participate
Prof Keith Abrams	Committee Member	Financial Interest	Advisory Boards – Johnson & Johnson - Relapsed Lenalidomide-Refractory Multiple Myeloma	01.02.2026	9.6.2026	-	Declare and Participate

Prof Keith Abrams	Committee Member	Financial Interest	Advisory Board - Novartis - Secondary Progressive Multiple Sclerosis	16.12.2025	9.6.2026	16.12.2025	Declare and Participate
Prof Keith Abrams	Committee Member	Financial Interest	Advisory Boards – UCB/Paraxel - antibody-positive generalised myasthenia gravis	01.12.2025	9.6.2026	-	Declare and Participate
Prof Keith Abrams	Committee Member	Financial Interest	Advisory Boards – Abbvie - acute migraine	28.10.2025	9.6.2026	-	Declare and Participate
Prof Keith Abrams	Committee Member	Financial Interest	Advisory Board - Teva/Sanofi - Inflammatory Bowel Disease (IBD) inclusive of Ulcerative Colitis (UC) and Crohn’s Disease (CD)	13.11.2025	9.6.2026	13.11.2025	Declare and Participate
Prof Keith Abrams	Committee Member	Financial Interest	Advisory Board – Deciphre/ReMap – Methods advice	12.11.2025	9.6.2026	12.11.2025	Declare and Participate
Prof Keith Abrams	Committee Member	Financial Interest	Advisory Board – Daiichi-Sankyo/SourceHE – Gastric Cancer	16.04.2026	9.6.2026	16.04.2026	Declare and Participate
Prof Keith Abrams	Committee Member	Non-Financial Professional and Personal Interests	Oct 2022 - date: NIHR i4i Cytecom Limited (a diagnostics company) via University of Warwick, value £1.3M	01.10.2022	9.6.2026	-	Declare and Participate
Prof Keith Abrams	Committee Member	Non-Financial Professional and Personal Interests	July 2024 – date: NIHR i4i OLS Real World Evidence Programme DDM Health Limited, digital company providing digital pathway Gro Health W8Buddy (in	01.07.2024	9.6.2026	-	Declare and Participate

			obesity) via University of Warwick £1.6M				
Prof Keith Abrams	Committee Member	Non-Financial Professional and Personal Interests	Member, NICE DTSU	01.10.2005	9.6.2026	-	Declare and Participate
Prof Keith Abrams	Committee Member	Non-Financial Professional and Personal Interests	Member, West Midlands (formerly Warwick Evidence) EAG Strategic Advisory Committee	01.01.2023	9.6.2026	-	Declare and Participate
Prof Keith Abrams	Committee Member	Non-Financial Professional and Personal Interests	£6.1M EU Horizon 2023 (4 years)	01.01.2023	9.6.2026	-	Declare and Participate
Prof Keith Abrams	Committee Member	Non-Financial Professional and Personal Interests	Mader J, Choudhary P, Kjær J, Haardt J, Valabhji J, Adler A, Torp-Pedersen C, Müllenborn M, Rogers G, Abrams K, Vettoretti M, Lind M, de Galan B, Holl R: <i>Real-world Evidence for Decisions in Diabetes (REDDIE)</i>	-	9.6.2026	-	Declare and Participate
Prof Keith Abrams	Committee Member	Non-Financial Professional and Personal Interests	£450K MRC/NIHR Better Methods, Better Research 2024 (3 years) Kimani P, Stallard N, Abrams KR, Metcalfe A, Chataway J: <i>Efficient and unbiased estimation in adaptive platform trials.</i>	01.10.2023	9.6.2026	-	Declare and Participate
Prof Matt Stevenson	Committee Member	N/A	Nothing to Declare		2.2.2026	-	No further action

Dr Michael MacKenzie	Committee Member	Non-Financial Professional and Personal Interests	Royal College of Physicians of Edinburgh International Executive Committee Member & Remote and Rural Health Committee Member	1.1.2023	20.5.2026	-	Declare and Participate
Mr Rashmi Kumar	Committee Member	N/A	Nothing to Declare	-	2.2.2026	-	No further action
Miss Ruth Ajayi	Committee Member	N/A	Nothing to Declare	-	27.1.2026	-	No further action
Dr Sam Creavin	Committee Member	N/A	Nothing to Declare	-	1.12.2025	-	No further action
Dr Deepthi Lavu	Professional Expert	Financial Interest	Wellcome NIHR SPCR Primary Care Clinician PhD Fellowship University of Exeter	2025	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Financial Interest	Recipient of the WONCA Europe Scholarship 2025	2025	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Financial Interest	Co-inventor of PreMetricS smartphone app	2013	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Financial Interest	General Heart Limited Shareholding	2023	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	Royal College of General Practitioners (RCGP) Nationally elected Council Member	2025	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	RCGP Clinical Adviser	2025	22.12.2025	-	Declare and Participate

Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	RCGP Women's Health Special Interest Group (SIG) member	2025	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	Deputy Faculty Lead for RCGP Tamar faculty	2025	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	Wellbeing, inclusion and culture core committee core member, APEX, University of Exeter	2024	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	Member of Royal college of Obstetricians and Gynecologists	2017	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	Diplomate Faculty of Sexual and Reproductive Healthcare	2013	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	Member of Society of Academic Primary Care	2025	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	Member of Women's Health Research Group - University of Exeter	2023	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	Member of Exeter Collaboration of Academic Primary Care (APEX), University of Exeter	2023	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	Member of the 4M - Menstruation, Menarche, Menopause and Mental Health consortium	2023	22.12.2025	-	Declare and Participate

Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	General Committee Member of Primary Care Academic Collaborative (PACT)	2025	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	Member of the National Association of Primary Care (NAPC)	2025	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Non-Financial Professional and Personal Interest	Co-author of the Paper mentioned in the evidence call. Massen et al. Temporal trends in endometriosis incidence and prevalence and symptom burden in England 2010-2020: A population-based cohort study (publication under review)	2025	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Indirect Interest	Nominated by a organisation Royal College of General Practitioners No known interest in the technology being considered or comparator product	2025	22.12.2025	-	Declare and Participate
Dr Deepthi Lavu	Professional Expert	Indirect Interest	Am a Wellcome NIHR SPCR Primary Care PhD funding recipient. Current project on Sex and ethnic inequalities in bowel cancer referrals in primary care	2025	22.12.2025	-	Declare and Participate
Miss Donna Ghosh	Professional Expert	Non-Financial Professional and Personal Interest	Principle investigator of ADDEND trial. I can confirm that the research is being led at Worcestershire Acute Hospitals NHS trust. We have secured a £3000 grant from the	November 2025	6.2.2026	2027	Declare and Participate Updated 27 May 2026

			British Society for Gynaecological Endoscopy which is paid directly to the trust for disposable equipment costs. I can confirm that I am not reviewing any funding individually.				
Miss Donna Ghosh	Professional Expert	Non-Financial Professional and Personal Interest	Honorary Secretary of the British Society for Gynaecological Endoscopy (BSGE). Position held since May 2024	May 2024	9.6.2026	-	Declare and Participate Updated
Miss Elizabeth Bean	Professional Expert	Financial Interest	NHS employed Consultant Gynecologist Barking, Havering and Redbridge University Hospitals NHS Trust	April 2024	8.2.2026	Present	Declare and Participate
Miss Elizabeth Bean	Professional Expert	Financial Interest	Director of EB Gynaecology Limited (Private practice)	April 2025	8.2.2026	Present	Declare and Participate
Miss Elizabeth Bean	Professional Expert	Financial Interest	Location of private practice - Spire Hartwood, Brentwood, Essex	July 2025	8.2.2026	Present	Declare and Participate
Miss Elizabeth Bean	Professional Expert	Financial Interest	Location of private practice - The Gynaecology Ultrasound Centre, Harley Street, London	January 2026	8.2.2026	Present	Declare and Participate
Miss Elizabeth Bean	Professional Expert	Financial Interest	Honoraria for teaching from Gedeon Richter Invited speaker. Ultrasound for the diagnosis of endometriosis: The Journey to Setting Standards. What's new in the management of endometriosis? Gedeon Richter Webinar	November 2025	8.2.2026	November 2025	Declare and Participate

Miss Elizabeth Bean	Professional Expert	Non-Financial Professional and Personal Interest	Honorary Senior Clinical Lecturer at the Institute of Health Sciences Education, Queen Mary University of London	July 2025	8.2.2026	Present	Declare and Participate
Miss Elizabeth Bean	Professional Expert	Non-Financial Professional and Personal Interest	Principal Investigator Espirit2 Research Study Barking, Havering and Redbridge University Hospitals NHS Trust	September 2025	8.2.2026	Present	Declare and Participate
Miss Elizabeth Bean	Professional Expert	Non-Financial Professional and Personal Interest	Principal Investigator REGAL Research Study Barking, Havering and Redbridge University Hospitals NHS Trust	2024	8.2.2026	2025	Declare and Participate
Miss Elizabeth Bean	Professional Expert	Non-Financial Professional and Personal Interest	Invited speaker. Ultrasound journey of endometriosis: How far we have to come and how far we have to go. Cleveland Clinic London 'A multidisciplinary perspective', The Kings Fund, London, UK	July 2025	8.2.2026	July 2025	Declare and Participate
Miss Elizabeth Bean	Professional Expert	Non-Financial Professional and Personal Interest	Invited speaker Setting standards in the ultrasound diagnosis of endometriosis (BSGE Stream). RCOG World Congress, London UK	June 2025	8.2.2026	June 2025	Declare and Participate

Miss Elizabeth Bean	Professional Expert	Non-Financial Professional and Personal Interest	Invited speaker. Hemoperitoneum is a precursor of deep endometriosis. BSGE ASM, Leeds UK.	April 2025	8.2.2026	April 2025	Declare and Participate
Miss Elizabeth Bean	Professional Expert	Non-Financial Professional and Personal Interest	Invited speaker: 'The one-stop endometriosis clinic – benefits to the surgeon and the patient.' BSGE Webinar, Online event.	February 2025	8.2.2026	February 2025	Declare and Participate
Miss Elizabeth Bean	Professional Expert	Indirect Interest	Senior council member and diagnostics portfolio chair of the British Society of Gynaecological Endoscopy (BSGE)	May 2024	8.2.2026	Present	Declare and Participate
Miss Elizabeth Bean	Professional Expert	Indirect Interest	Course organiser of the BSGE/RCOG Ultrasound for the diagnosis of endometriosis Invited speaker. The ENZIAN classification of endometriosis. Invited speaker. Endometriosis and Pregnancy	January 2026	8.2.2026	Present	Declare and Participate
Miss Elizabeth Bean	Professional Expert	Indirect Interest	Invited speaker BMUS ASM, Harrogate. Lecture title: Setting standards in the ultrasound diagnosis of endometriosis: THE BSGE Perspective	December 2025	8.2.2026	December 2025	Declare and Participate
Dr Felicity Watson	Professional Expert	Financial Interest	NHS Consultant Gynaecologist	July 2022	8.1.2026	-	Declare and Participate
Dr Felicity Watson	Professional Expert	Financial Interest	Nuffield Glasgow Consultant Gynecologist	Jan 2026	8.1.2026	-	Declare and Participate

Dr Irene Asamoah	Professional Expert	Non-Financial Professional and Personal Interest	I am the Medical Lead for a women's health digital health company (Holiya), with a focus on clinical strategy for symptom tracking, and service design. The organisation does not currently develop or market diagnostic technologies for endometriosis	-	7.1.2026	-	Declare and Participate
Miss Katie Gore	Professional Expert	Financial Interest	Co-director of The Pelvic Physios Oxford	2016	31.12.2025	Ongoing	Declare and Participate
Miss Katie Gore	Professional Expert	Financial Interest	Sporadic Consultancy work for Owen Mumford	2024	31.12.2025	Ongoing	Declare and Participate
Miss Katie Gore	Professional Expert	Financial Interest	Affiliated to the Pelvic Pain Network	2023	31.12.2025	Ongoing	Declare and Participate
Miss Katie Gore	Professional Expert	Financial Interest	Co-director of PelvicEd	2025	31.12.2025	Ongoing	Declare and Participate
Miss Katie Gore	Professional Expert	Non-Financial Professional and Personal Interest	Undertaking PhD studies in Chronic Pelvic Pain (part time)	2021	31.12.2025	Ongoing	Declare and Participate
Miss Katie Gore	Professional Expert	Indirect Interest	Oxford Brookes University	2021	31.12.2025	Ongoing	Declare and Participate
Miss Katie Gore	Professional Expert	Indirect Interest	Pelvic Obstetric Gynecology Physiotherapy POGP	2010	31.12.2025	Ongoing	Declare and Participate
Dr Sharon Dixon	Professional Expert	Financial Interest	I am a GP partner (Donnington Medical Partnership)	2009	9.1.2026	Ongoing	Declare and Participate
Dr Sharon Dixon	Professional Expert	Financial Interest	As part of my partnership role, I was a practice representative in delivering the primary care network (PCN) direct enhanced	-	1.4.2026	-	Declare and Participate

			<p>service. My primary care network was a collaboration of local GP practices, including initially 4 and now 3 local practices. It is named the South East Oxford Health Alliance. (Organisation Details)</p> <p>I ceased having a representative role in December 2025, however, as a partner, I remain part of our PCN. Our primary care network formed a limited company, to create a structure that could hold the staff contracts and centralise the organization of tasks completed as part of the NHS England PCN DES contract. At the present time, I am still named as part of that organization, although this is under transition. (SEOXHA LIMITED overview - Find and update company information - GOV.UK)</p>				Updated 1 April 2026
Dr Sharon Dixon	Professional Expert	Financial Interest	<p>I currently hold an NIHR doctoral research fellowship NIHR 301787 (What knowledge would support improving the management of teenagers with dysmenorrhoea in primary care? - NIHR Funding and Awards)</p>	January 2022	1.4.2026	December 2026	Declare and Participate Updated 1 April 2026
Dr Sharon Dixon	Professional Expert	Financial Interest	<p>I teach a seminar to Oxford University medical students, as part of their primary care clinical block, on the social determinants</p>	-	1.4.2026	-	Declare and Participate

			of health. I teach 1 or 2 seminars per year to the Oxford University Graduate entry medical students about medical sociology.				Updated 1 April 2026
Dr Sharon Dixon	Professional Expert	Non-Financial Professional and Personal Interest	I am a Royal College of General Practitioners (RCGP) college representative. I have represented the RCGP for safeguarding, female genital mutilation, and women's health related matters. I have contributed to a podcast for RCGP about adenomyosis. I have contributed to RCGP e-learning about the interface between gynaecological symptoms and domestic violence and abuse, and e-learning about the RCGP safeguarding standards	2016	9.1.2026	Ongoing	Declare and Participate
Dr Sharon Dixon	Professional Expert	Non-Financial Professional and Personal Interest	I am an unpaid member of the Endometriosis UK medical advisory panel	2024	9.1.2026	Ongoing	Declare and Participate
Dr Sharon Dixon	Professional Expert	Non-Financial Professional and Personal Interest	I am a trustee of the Sundial Centre (Centre for education on harmful practices), formerly Oxford Against Cutting	2016	9.1.2026	Ongoing	Declare and Participate
Dr Sharon Dixon	Professional Expert	Non-Financial Professional and Personal Interest	I co-founded and help co-ordinate a professional network for researchers and clinicians in primary care interested in adenomyosis and endometriosis. We hold quarterly online	2025	1.4.2026	Ongoing	Declare and Participate Updated 1 April 2026

			discussion meetings, open to any who are interested. Primary care Endometriosis and Adenomyosis Research and Learning network — Nuffield Department of Primary Care Health Sciences, University of Oxford				
Dr Sharon Dixon	Professional Expert	Non-Financial Professional and Personal Interest	I co-lead the Society for Academic Primary Care Women's Health Special Interest Group. (SAPC Women's Health Special Interest Group — Nuffield Department of Primary Care Health Sciences, University of Oxford)	-	1.4.2026	-	Declare and Participate Updated 1 April 2026
Dr Sharon Dixon	Professional Expert	Non-Financial Professional and Personal Interest	I have conducted qualitative research within primary care, about clinician perspectives on delivering endometriosis care, and pathways to diagnosis of endometriosis, and of delivering women's healthcare in general practice. This has included hearing about their perspectives on approaching and supporting endometriosis diagnosis, and things that can help or complicate this process. I have written a short summary resource for GPs about supporting people with uterine adenomyosis. I have conducted qualitative research with young people about	-	1.4.2026	-	Declare and Participate Updated 1 April 2026

			<p>their experiences of periods and period pain, including when and why they do (or do not) seek healthcare, and their experiences when they do. I have been part of a research team exploring whether having period pain as a teenager is related to the chances of having chronic pain as a young adult. I have written a short summary resource for GPs about supporting young people with period pain.</p> <p>I have reviewed evidence included in endometriosis guidance, to consider whether any of the evidence comes from primary care, and how representative the evidence is of the wider population. I have collaboratively written about the need for primary care population evidence to support new innovations and new approaches to diagnosis, and the need to ensure onward care for all, when they are diagnosed.</p> <p>I co-led a study exploring people and clinician's ideas about priority areas of women's health, where new or better technologies could be of benefit (funded by the NIHR School for Primary Care Research: NIHR SPCR: Generating a priority list of unmet needs for women's healthcare technology using a priority setting</p>				
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			<p>partnership guided approach — NIHR School for Primary Care Research).</p> <p>I have written about equity in trial inclusion and in guidance. I have not researched or written about any diagnostic tests in particular, nor reviewed these tests.</p> <p>I have never been paid by, funded by, or supported to speak or travel, by a pharmaceutical company.</p> <p>I have included a list of relevant papers I have contributed to, about endometriosis and endometriosis diagnosis below:</p> <p>Dixon S, McNiven A, Talbot A, Hinton L. Navigating possible endometriosis in primary care: a qualitative study of GP perspectives. British Journal of General Practice. 2021</p> <p>Dixon S, Evans E, Vincent K, Toye F, McNiven A, Hinton L. 'I think it is helpful... I mean it's not always helpful'—diagnostic complexity in endometriosis: a qualitative study. The British Journal of General Practice. 2025 Nov 4;75(761):e832.</p>				
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			<p>De Silva PM, Dixon S, Vekaria G. Restructuring endometriosis care. BMJ. 2024 Nov 18;387.</p> <p>Dixon S, Ranger TA, Burchardt J, Patone M, Snelling AJ, Vincent K, Hippisley-Cox J. Exploring the interface between adolescent dysmenorrhoea and endometriosis: a protocol for a cohort and nested case-control study within the QResearch Database. BMJ open. 2023 Feb 1;13(2):e069984.</p> <p>Dixon S, Mawson R, Kirk UB, Horne AW. Endometriosis: time to think differently (and together). The British Journal of General Practice. 2024 Apr 26;74(742):200.</p> <p>Karavadra B, Mawson R, Dixon S, Bak Kirk U, Horne AW. Building bridges: enhancing diagnosis and care for endometriosis across the primary-secondary care continuum. Women's Reproductive Health. 2025 Sep 9:1-9.</p> <p>Dixon S, McNiven A, Perro D, Vincent K, Marečková M. Systems approach applies to diagnosis of other conditions. bmj. 2023 Mar 29;380.</p>				
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			<p>Sharon Dixon, Katy Vincent, Jennifer Hirst and Julia Hippisley-Cox. Incidence of menstrual symptoms suggestive of possible endometriosis in adolescents: and variance in these by ethnicity and socio-economic status. British Journal of General Practice 2024; 74 (suppl1): bjgp24X737685. DOI: https://doi.org/10.3399/bjgp24X737685</p> <p>Zara Khan, Katy Vincent, Tanvi Rai and Sharon Dixon, A lack of sociodemographic participant diversity in endometriosis evidence risks unrepresentative clinical guidance: a structured review of the evidence contributing to a NICE guideline, British Journal of General Practice 2024; 74 (suppl1): bjgp24X737697. DOI: https://doi.org/10.3399/bjgp24X737697</p> <p>Dixon S, Selcuki NF, Round T, Hayward G, Vincent K. Uterine adenomyosis: an update for GPs. The British Journal of General Practice. 2023 Oct 27;73(736):524.</p> <p>Period pain (dysmenorrhea) papers: Dixon S, Hirst J, Taghinejadi N, Duddy C, Vincent</p>				
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			<p>K, Ziebland S. What is known about adolescent dysmenorrhoea in (and for) community health settings?. <i>Frontiers in Reproductive Health</i>. 2024 Jul 23;6:1394978.</p> <p>Dixon S, Taghinejadi N, Duddy C, Holloway F, Vincent K, Ziebland S. Adolescent dysmenorrhoea in general practice: tensions and uncertainties. <i>Frontiers in Reproductive Health</i>. 2024 Aug 23;6:1418269.</p> <p>Dixon S, Taghinejadi N, Holloway F, Papanikitas A, Vincent K. Supporting teenagers with period pain in general practice: clinical review. <i>The British Journal of General Practice</i>. 2024 May 31;74(743):283.</p> <p>Reid-McCann R, Poli-Neto OB, Stein K, Dixon S, Cox E, Coxon L, Fazel M, Noonan M, Sharp GC, Zondervan K, Vincent K. Longitudinal association between dysmenorrhoea in adolescence and chronic pain in adulthood: a UK population-based study. <i>The Lancet Child & Adolescent Health</i>. 2025 Nov 1;9(11):766-75.</p>				
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			<p>Femtech:</p> <p>Dixon S, Keating S, McNiven A, Edwards G, Turner P, Knox-Peebles C, Taghinejadi N, Vincent K, James O, Hayward G. What are important areas where better technology would support women's health? Findings from a priority setting partnership. BMC Women's Health. 2023 Dec 13;23(1):667.</p> <p>Research and representation papers:</p> <p>Beard E, Dixon S, Rai T, Hayward G. Ethnicity and socioeconomic status: missing in research means missing in clinical guidance. BJGP open. 2021 Jun 1;5(3).</p> <p>Rai T, Dixon S, Ziebland S. Shifting research culture to address the mismatch between where trials recruit and where populations with the most disease live: a qualitative study. BMC Medical Research Methodology. 2021 Apr 21;21(1):80.</p>				
Dr Sharon Dixon	Professional Expert	Indirect Interest	<p>I am a named co-applicant on an NIHR HSDR funded study about endometriosis (NIHR156216) Understanding and improving endometriosis experiences: a</p>	-	9.1.2026	-	Declare and Participate

			qualitative study into patient and healthcare professionals' experiences of management, diagnosis and treatment - NIHR Funding and Awards				
Dr Sharon Dixon	Professional Expert	Indirect Interest	<p>I currently hold an NIHR doctoral research fellowship NIHR 301787 (What knowledge would support improving the management of teenagers with dysmenorrhoea in primary care? - NIHR Funding and Awards)</p> <p>One output will be a public facing module about a wide range of young people's experiences of periods and period pain on the Health Experience Insights (Health Experience Insights).</p> <p>Please see below for more information about this qualitative study (Young people's experiences of period pain — Nuffield Department of Primary Care Health Sciences, University of Oxford)</p>	-	1.4.2026	-	Declare and Participate Updated 1 April 2026
Dr Sharon Dixon	Professional Expert	Indirect Interest	<p>Relevant previous talks:</p> <p>I have spoken about launching the primary care endometriosis and adenomyosis research and learning network at the 2025 national Endometriosis Research Network meeting.</p>	-	1.4.2026	-	Declare and Participate Updated 1 April 2026

			<p>I have spoken about the contribution of qualitative research to understanding in endometriosis for the World Endometriosis Society, at a Wesinar. (WESinar: Qualitative research in endometriosis - 21 January 2025 - World Endometriosis Society)</p> <p>Meetings, upcoming.</p> <p>I am an invited speaker at the British Society of Gynaecological Endoscopy (BSGE) national meeting, April 2026, about endometriosis care after diagnosis and follow up.</p>				
Miss Sujata Gupta	Professional Expert	Financial Interest	<p>Private practice (Sole trader, as director of Manchester Women's Health set up since (2019)</p> <p>I see patients with endometriosis as part of my private practice. I have no commercial partnerships with any companies</p>	August 2012	11.1.2026	Ongoing	Declare and Participate
Miss Sujata Gupta	Professional Expert	Financial Interest	<p>Intuitive – Proctor for robotic surgery (I support surgeons starting robotic surgery in gynaecology including endometriosis surgery)</p>	January 2026	11.1.2026	Ongoing	Declare and Participate
Miss Sujata Gupta	Professional Expert	Financial Interest	<p>BSGE – senior council member BSGE (British Society of Gynaecology Endoscopy) is the key national body responsible for setting standards of care for</p>	Since Apr 2022	11.1.2026	Ongoing	Declare and Participate

			endometriosis nationally. As part of the council, I am closely involved in most up to date developments in the field of endometriosis				
Miss Sujata Gupta	Professional Expert	Financial Interest	<p>BIARGS- Secretary and vice president</p> <p>British and Irish association of robotic Gynaecology Surgeons (BIARGS) aim is to set standards in robotic surgery in Gynaecology including Endometriosis. My role as society's president is to ensure all patients including patients with endometriosis benefit from latest technological advances</p>	<p>November 2023-2025</p> <p>Vice President- Nov 2025</p>	11.1.2026	Ongoing	Declare and Participate
Miss Sujata Gupta	Professional Expert	Financial Interest	<p>RCOG- Senior member on Patient information committee</p> <p>In this role, my role is to ensure that patient information is developed in a timely manner and offers clear, easy to follow and evidence based information on various gynecological Conditions</p>	Sept 2025	11.1.2026	Ongoing	Declare and Participate
Miss Sujata Gupta	Professional Expert	Financial Interest	<p>Invite speaker and Faculty on endometriosis related topics</p> <p>I am invite to speak at various national and inter-national meetings, as an expert in Endometriosis. Some of these are- BSGE, BIARGS, European Endometriosis League</p>	Since 2012	11.1.2026	Ongoing	Declare and Participate

Miss Sujata Gupta	Professional Expert	Indirect Interest	BSGE (Nominated by BSGE)	Member of society since 2008	11.1.2026	Continued	Declare and Participate
Dr Ana Cruz Ruiz	Patient Expert	N/A	Nothing to declare	-	11.2.2026	-	No further action
Miss Araya Gautam	Patient Expert	N/A	Nothing to declare	-	8.2.2026	-	No further Action Resigned 19 May 2026
Dr Emma Bolton	Patient Expert	N/A	Nothing to declare	-	8.2.2026	-	No further action