NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

Technologies for diagnosing endometriosis in primary care: early-use assessment

Guidance development process

NICE HealthTech guidance evaluates digital technologies, diagnostics and medical devices (including artificial intelligence). It provides evidence-based recommendations about how safe and effective these technologies are, and their cost effectiveness. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible treatments. NICE aims to promote innovations that meet the needs of patients and the healthcare system.

This guidance has been developed as early-use HealthTech guidance, for HealthTech products that could address an unmet need in the NHS and need more evidence to support routine use.

Find out more on the NICE webpage on HealthTech guidance.

NICE is producing this guidance on technologies for diagnosing endometriosis in primary care in the NHS in England. The diagnostics advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for consultation with the stakeholders. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the evidence.

The committee is interested in receiving comments on the following:

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- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If the committee meets again it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on technologies for diagnosing endometriosis in primary care. The recommendations in section 1 may change after consultation.

More details are available in NICE's HealthTech programme manual.

Key dates:

Closing date for comments: 5th October 2026

Third committee meeting: 18th November 2026

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1 Recommendations

Can be used during the evidence generation period

1.1 Endotest can be used in the NHS during the evidence generation period as an option to diagnose endometriosis in primary care. It can only be used if the evidence outlined in the evidence generation plan for technologies for diagnosing endometriosis in primary care is being generated.

1.2 The technology should only be used in primary care when endometriosis is suspected and:

- clinical examination of the abdomen and pelvis is normal, and
- imaging (transvaginal or transabdominal ultrasound) is negative or inconclusive for endometriosis or is declined or not suitable.

1.3 The company is responsible for ensuring that data collection and analysis take place. It must confirm that agreements are in place to generate the evidence. NICE will contact the company annually to confirm that evidence is being generated and analysed as planned. NICE may revise or withdraw the guidance if these conditions are not met.

1.4 At the end of the evidence generation period (4 years), the company should submit the evidence to NICE in a format that can be used for decision making. NICE will review the evidence and assess if the technology can be routinely adopted in the NHS.

More research is needed

1.5 More research is needed on using DotEndo, Endomkit and EndoSure to diagnose endometriosis in primary care before they can be funded by the NHS.

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What this means in practice

Can be used during the evidence generation period

Endotest can be used as an option in the NHS during the evidence generation period (4 years) and paid for using core NHS funding. During this time, more evidence will be collected to address any uncertainties. The company is responsible for organising funding for evidence generation activities.

After this, NICE will review this guidance and the recommendations may change. This should be taken into account when negotiating the length of contracts and licence costs.

Potential benefits of use in the NHS during the evidence generation period

- **Access:** Variations in ultrasound expertise may affect the accuracy of diagnosing endometriosis in primary care. Endotest is not dependent on operator expertise and may help identify endometriosis not previously detected on ultrasound. This could reduce uncertainty for women, trans men and non-binary people registered female at birth who might otherwise remain undiagnosed. Endotest may offer an alternative, non-invasive method of diagnosis.
- **System benefit:** Endotest may enable earlier diagnosis of endometriosis in primary care, through symptom management in primary care, when appropriate, or earlier referral to specialist services.
- **Patient outcomes:** Earlier diagnosis of endometriosis in primary care may enable people to get the support, treatment and care that they need sooner, through either management in primary care or prompt referral to specialist services. This may help reduce symptom burden and improve quality of life. In addition, Endotest may be an alternative to transvaginal

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ultrasound if the latter is declined or not suitable, potentially improving patient experience.

- **Equality:** Endotest may support more equitable access to diagnosis of endometriosis for women, and trans men and non-binary people registered female at birth, for whom transvaginal ultrasound is declined or not suitable, by providing an alternative diagnostic option.

Managing the risk of use in the NHS during the evidence generation period

- **Costs:** Early economic modelling shows that Endotest could be cost effective over a long time horizon. But this is uncertain because of the lack of evidence on both clinical benefits after using this test, and on quality of life before and after diagnosis.
- **Clinical risk:** The diagnostic accuracy of Endotest in primary care (including false positives and false negatives) is unclear. The test results could influence treatment decisions. This risks both overtreatment and undertreatment of endometriosis. Endotest should be used alongside standard practice and should not replace clinical judgement. Its impact on downstream patient outcomes is currently unknown.
- **Resources:** Implementation of Endotest in primary care will have resource implications. It requires healthcare professionals to be trained in its use and interpretation, and in communicating results. It also requires resources for sample collection. Positive test results from Endotest may increase referrals to secondary care because more people could be presumptively diagnosed with endometriosis.

More research is needed

There is not enough evidence to support funding DotEndo, Endomkit and EndoSure in the NHS.

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- Access to DotEndo, Endomkit and EndoSure should be through company, research or non-core NHS funding, and clinical or financial risks should be managed appropriately.

What evidence generation and research is needed

More evidence for Endotest needs to be generated on, and more research for the other technologies is needed on:

- diagnostic accuracy, including sensitivity, specificity, negative predictive value and positive predictive value, when used in primary care
- impact on the diagnostic pathway and resource use
- impact on patient-reported outcomes and patient experience
- associated training costs and cost savings as a result of avoiding downstream tests.

The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

Why the committee made these recommendations

It can take, on average, 9 years and 4 months to confirm a diagnosis of endometriosis, and longer for people from ethnic minority backgrounds. These delays may result from:

- late initial presentation
- symptoms not being recognised
- delays in the referral pathway
- variation in expertise in transvaginal ultrasound in primary care
- long waiting times for gynaecology services.

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Delays in diagnosis lead to prolonged ill health (both mental and physical) and a condition that is more difficult to treat. Diagnostic tests in primary care could enable earlier diagnosis of endometriosis and symptom management in primary care, when appropriate, or earlier referral to specialist services.

Evidence on the diagnostic accuracy of technologies for diagnosing endometriosis in primary care is limited and variable. All the studies are from secondary or tertiary care.

Evidence from multiple studies suggests that Endotest has higher diagnostic accuracy than transvaginal ultrasound done in primary care. This would help identify endometriosis if transvaginal ultrasound results are negative or inconclusive, or if transvaginal ultrasound is declined or not suitable. There is no evidence on clinical outcomes or how Endotest could affect the diagnostic pathway or resource use. Despite this, Endotest has the potential to address a high unmet need in the NHS by enabling endometriosis diagnosis in primary care.

Early economic modelling suggests that Endotest is likely to be cost effective over a 60-year time horizon. So, it is recommended for use with evidence generation.

Economic modelling also suggests that DotEndo, Endomkit and EndoSure are likely to be cost effective over the same time horizon. But the evidence on their diagnostic performance has a high risk of bias and is more limited, particularly because of a lack of external validation studies. So, more research is needed.

2 Information about the technologies

2.1 The 4 technologies for diagnosing endometriosis differ in their mechanisms: DotEndo and Endomkit are blood based, Endotest is saliva based and EndoSure is based on gastrointestinal myoelectrical activity (see table 1).

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2.2 The technologies can be used by healthcare professionals in primary care and are intended to be used alongside standard practice. Results from EndoSure are available immediately after testing. Endotest and DotEndo require sample processing in a specialist laboratory that can analyse microRNA biomarkers, whereas Endomkit requires sample processing in a standard laboratory with enzyme-linked immunosorbent assay capability. All 4 technologies require an additional appointment to discuss the results with a healthcare professional. The technologies cannot distinguish between the types of endometriosis or determine disease severity.

Table 1 Overview of technology features

Technology name (company), regulatory status	Technology features and test processing	Intended age group	Cost
Endomkit (Camlab/apDia) CE IVDR class B	Measures brain-derived neurotrophic factor and cancer antigen 125 in blood serum. Samples are sent to a laboratory and analysed using an enzyme-linked immunosorbent assay. Test results are combined with 6 clinical variables in a diagnostic algorithm.	No lower or upper age limits specified	Test kit: £1,196.26 Can be used to process between 6 samples (per-person cost of £199.38) and 42 samples (per-person cost of £28.48)
EndoSure (3CPM/Endosure) UK MDR class 2a	Measures gastrointestinal myoelectrical activity to detect abnormal electrical patterns in the gut caused by prostaglandins released by endometriosis tissue.	No lower or upper age limits specified	Test cost per person: £350 Implementation cost per person: • capital: £70.83 • training: £4.17 (Capital and training costs were assumed to be spread across 120 people)

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	Results are available immediately after testing.		
Endotest (Ziwig) CE IVDR class C To be used with a saliva collection and stabilisation kit (IVDR class A)	Detects the presence of a 109-microRNA biomarker signature of endometriosis in saliva. Samples are sent to the company's centralised laboratory with sequencing capacity.	18 to 43 years	Test cost per person: £1,381
DotEndo (DotLab) CE class C, IVDR expected in 2026	Quantifies endometriosis-specific microRNA biomarker levels in blood. Samples are sent to a laboratory and analysed using quantitative reverse transcription polymerase chain reaction.	18 to 49 years	Test cost per person: £400

Abbreviations: CE, Conformité Européenne; IVDR, In Vitro Diagnostic Regulation; MDR, Medical Device Regulation.

Sustainability

2.3 For information, Camlab's commitment to reducing greenhouse gas emissions and achieving net zero is published here: Camlab Sustainability & Environment. Ziwig's commitment to achieving net zero is published here: Ziwig's environmental responsibility. Ziwig did not disclose its Carbon Reduction Plan. Endosure and DotLab did not disclose their Carbon Reduction Plan for UK carbon emissions or their net zero commitment.

3 Committee discussion

The diagnostics advisory committee considered evidence on technologies for diagnosing endometriosis in primary care from several sources. This included evidence submitted by the companies, a review of clinical and cost evidence

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by the external assessment group (EAG), and responses from stakeholders. Full details are available in the project documents for this guidance.

The condition

3.1 Endometriosis is a chronic inflammatory disease in which tissue similar to the endometrial lining is present outside the uterus (womb). It is estimated that 10% of women, trans men and non-binary people registered female at birth who are of reproductive age in the UK have endometriosis. The most common symptom of endometriosis is chronic pelvic pain. Other symptoms include:

- period-related pain that affects 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 associated with 1 or more of the above.

Current practice

3.2 NICE's guideline on endometriosis includes the following recommendations for diagnosis and referral in primary care:

- When endometriosis is suspected, offer an abdominal and pelvic (internal vaginal) examination.
- Regardless of the examination findings, offer a transvaginal ultrasound to all people with suspected endometriosis.
- If transvaginal ultrasound is declined or unsuitable, consider a transabdominal ultrasound of the pelvis.
- Ultrasound scans should be organised by the general practice.
- A normal abdominal or pelvic examination or ultrasound does not exclude endometriosis.

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- Pharmacological treatment can start alongside the diagnosis and referral process if endometriosis is suspected.

3.3 NICE's guideline on endometriosis recommends referral to gynaecology services if:

- symptoms of endometriosis have a detrimental impact on activities of daily living
- initial treatment is not effective, not tolerated or contraindicated
- there are persistent or recurrent symptoms of endometriosis, or
- there are pelvic signs of endometriosis on examination but deep endometriosis is not suspected.

3.4 NICE's guideline on endometriosis recommends referral to a specialist endometriosis service (endometriosis centre) if there is suspected or confirmed:

- endometrioma
- deep endometriosis (including that involving the bowel, bladder or ureter), or
- endometriosis outside the pelvic cavity.

3.5 Specialist pelvic ultrasound or pelvic MRI (to assess the extent of deep endometriosis) may inform diagnosis in some cases. But if imaging findings are normal and endometriosis is still suspected, surgical laparoscopy should be considered to diagnose endometriosis.

Unmet need and innovative aspects

3.6 There is often a long wait for endometriosis to be diagnosed. There are delays in referral pathways and long waiting times for gynaecology services. Expertise in transvaginal ultrasound in primary care varies. This may result in lower diagnostic accuracy,

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leading to a missed or delayed diagnosis. There is also an unmet need for alternative, non-invasive diagnostic options.

3.7 The technologies may enable earlier diagnosis of endometriosis by providing an additional option in primary care. They do not rely on operator expertise for accuracy. Earlier decision making in the diagnostic pathway informed by the results of these tests may reduce delays to diagnosis and avoid unnecessary investigations. The committee concluded the unmet need was great enough to recommend a test for evidence generation.

Clinical effectiveness

Patient perspective

3.8 Submissions from 2 patient organisations were presented to the committee. Common themes were that non-invasive tests were generally more acceptable and that the technologies may enable faster diagnosis, treatment and referrals.

3.9 The patient experts highlighted the importance of early and accurate diagnosis of endometriosis in primary care. They stated that a presumptive diagnosis could lead to earlier access to effective treatment and improved quality of life. The technologies are not a complete solution, but they are a step towards enabling earlier diagnosis.

3.10 A patient organisation highlighted that implementing EndoSure in primary care would have logistical challenges because of the need for an additional room and staff member. The committee concluded this is a risk to the system that would be difficult to mitigate during an evidence generation period.

Healthcare professional perspective

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3.11 The clinical experts highlighted that increased diagnosis of endometriosis in primary care could lead to more referrals to secondary care gynaecology or specialist endometriosis services. This could increase the burden on secondary care services. But some referrals could be avoided if a diagnosis is made in primary care and the endometriosis can be subsequently managed there.

3.12 Imaging does not identify all types of endometriosis, particularly superficial peritoneal endometriosis. This was also highlighted by the patient experts. Additional diagnostic options in primary care could support more informed decision making, particularly when people do not want to start treatment without a diagnosis.

3.13 The clinical experts thought the technologies for diagnosing endometriosis in primary care could be used in women's health hubs. But they highlighted that service provision varies between hubs, and women's health hubs may not be available in all areas. Also, it was not clear whether the services provided by women's health hubs would be standardised, which could affect the feasibility of implementing the technologies, particularly EndoSure.

3.14 The clinical experts thought that it was reasonable to expect the technologies to perform similarly in detecting endometriosis in primary care and in secondary care. But differences in endometriosis prevalence between settings may affect diagnostic accuracy. Despite this, the clinical experts thought that people could benefit from a diagnosis in primary care, even if it is presumptive.

3.15 The clinical experts thought that the system risks associated with EndoSure would be difficult to manage during an evidence generation period. Implementing the technology in primary care

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and generating evidence would be difficult in primary care because of the infrastructure and resources needed to support its use.

3.16 The clinical experts stated that a negative result from a test in primary care should not be a reason to deny referral, if endometriosis is still suspected.

Evidence base

3.17 The evidence base comprised:

- 11 published, peer-reviewed studies, including 1 cost-effectiveness study, 1 market analysis study and 1 study reporting clinician-reported outcomes
- 5 conference abstracts, including 1 that reported patient acceptability
- 5 unpublished studies.

The committee noted that the quantity and quality of studies for each technology varied. Diagnostic accuracy was the primary outcome in 18 of the studies. No studies reported any clinical outcomes, such as time to diagnosis, time to treatment, reduction in laparoscopy rates or impact on quality of life. Most peer-reviewed studies were done outside the UK.

3.18 The committee noted that the published, peer-reviewed evidence for diagnostic accuracy for all 4 technologies came from secondary or tertiary care, where the prevalence of endometriosis is higher than in primary care. There were multiple studies from different centres for Endotest, including an independent external validation study. The evidence for DotEndo and Endomkit came from single-centre studies and the evidence for EndoSure came from studies conducted across 2 centres. DotEndo, Endomkit and EndoSure did not have external validation studies.

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Endomkit

3.19 There were 2 peer-reviewed diagnostic accuracy studies for Endomkit. These included 281 people (204 in the development cohort and 77 in the validation cohort) and 188 people in an extended analysis of the same study population. Both studies were retrospective analyses that used archived samples from a UK tertiary-care centre biobank. They both used diagnostic laparoscopy with biopsy as the reference standard. The validation cohort reported sensitivity of 46.2% and specificity of 100%. The EAG judged both studies to be at high risk of bias.

3.20 The committee concluded that the diagnostic accuracy evidence for Endomkit is too limited to be given an evidence generation recommendation and that more research is needed.

EndoSure

3.21 There were 10 diagnostic accuracy studies for EndoSure (2 peer-reviewed, 3 conference abstracts and 5 unpublished), with sample sizes ranging from 8 to 286. Two peer-reviewed, prospective studies (of 50 and 154 people) were from the same clinical research protocol. The studies reported sensitivity ranging from 91% to 96% and specificity from 95% to 96%. These sensitivity and specificity values were based on AI-derived modelling, incorporating area under the curve, symptom scores and age. The studies recruited women with suspected endometriosis who were awaiting laparoscopy in specialist centres. Both studies used diagnostic laparoscopy, with visual identification of endometriosis and histological biopsy, as the reference standard. The tests were done before the diagnostic laparoscopy. The healthcare professionals and electroviscerography technicians were blinded to each other's results and to surgical findings. The EAG judged both studies to be at high risk of bias.

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3.22 A published conference abstract of 100 people reported that most people (60%) preferred EndoSure over transvaginal ultrasound. But the committee noted that the setting was a specialised endometriosis centre, not primary care.

3.23 The committee concluded that the diagnostic accuracy evidence for EndoSure is too limited to be given an evidence generation recommendation and that more research is needed.

Endotest

3.24 There were 5 diagnostic accuracy studies for Endotest (3 peer-reviewed and 2 conference abstracts), with sample sizes ranging from 200 to 1,000. Three peer-reviewed, prospective studies (of 200, 200 and 971 people) reported sensitivity ranging from 96% to 97.3% and specificity from 94.1% to 100%. One study of 200 people was reported as an interim analysis of the same cohort included in the independently-conducted external validation study of 971 people. The studies recruited women with signs and symptoms suggestive of endometriosis. All studies used diagnostic laparoscopy with histology or MRI as the reference standard. The external validation study used transvaginal ultrasound as a reference standard, as well as diagnostic laparoscopy or MRI. Saliva samples were collected before the MRI or diagnostic laparoscopy, and microRNA signature was assessed by people blinded to the surgical or imaging findings. The EAG judged the developmental cohort study of 200 people to be at high risk of bias. However, both external validation studies were judged to have an unclear risk of bias.

3.25 The committee noted that a peer-reviewed survey of 141 German gynaecologists found limited support for using Endotest. But only 15% of those surveyed had actually used the test. This survey took place before the publication of the full external validation study.

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3.26 The committee concluded that the diagnostic accuracy evidence for Endotest is sufficient for it to be recommended for evidence generation.

DotEndo

3.27 There was 1 peer-reviewed diagnostic accuracy study for DotEndo. This prospective study of 100 women reported sensitivity of 83% (specificity-optimised threshold) and 90% (balanced threshold), and specificity of 96% (specificity-optimised threshold) and 90% (balanced threshold). The study recruited women with symptoms suggestive of endometriosis. Diagnostic laparoscopy, with visual confirmation and histological pathology, was used as the reference standard. Serum samples were collected before the diagnostic laparoscopy, and microRNA analysis was done by people blinded to the surgical findings. The EAG judged this study to be at high risk of bias.

3.28 The committee concluded that the diagnostic accuracy evidence for DotEndo is too limited to be given an evidence generation recommendation and that more research is needed

Cost effectiveness

Conceptual model

3.29 The EAG developed a de novo health economic model in which the tests were positioned in primary care after a negative or inconclusive ultrasound, or when ultrasound was declined. It compared the technologies with current care in the NHS. A Markov model was used to represent the care pathway from initial presentation through to diagnosis and management. Decision trees were used to determine outcomes for people receiving either a single diagnostic test or multiple diagnostic tests, applied to the

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relevant proportions of the population. The model used a 60-year time horizon and monthly cycles.

Model parameters

3.30 The key clinical inputs to the model were the diagnostic accuracies of the technologies, informed by the most comprehensive evidence available for each technology.

3.31 The EAG explained that health-state utility benefits from having a presumptive or definitive diagnosis after a positive test result were based on assumptions because there was no available evidence. Baseline utility was derived from a French tertiary-care study, and utility changes associated with diagnosis were based on symptom severity rather than the effect of getting a diagnosis. The committee recalled that having a diagnosis would be beneficial to the person, even if it is presumptive.

Model results

3.32 The EAG's assessment showed that all technologies were cost effective at a willingness-to-pay threshold of £20,000 per quality-adjusted life year (QALY) gained. This was the case in both the deterministic and probabilistic base cases, and over the 60-year time horizon. The committee noted that the incremental QALYs (0.03 to 0.11) and net health benefit (0.03 to 0.11) seemed modest and were not realised in the short term. All the technologies also reduced the time to presumptive diagnosis compared with current NHS practice (reduction of 0.76 years to 1.82 years) and the time to definitive diagnosis by 0.49 years to 1.22 years.

3.33 Results from one-way sensitivity analyses and scenario analyses changed the incremental cost-effectiveness ratios but not the overall interpretation. For Endomkit, the main cost and QALY drivers were the proportion of people choosing laparoscopic

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management after secondary care consultation. For EndoSure, Endotest and DotEndo, lower prevalence of endometriosis was identified as a key cost driver and was associated with higher costs. Test specificity of these 3 technologies was a key driver of QALYs, with a lower specificity leading to a higher QALY gain in the model. The EAG explained that a lower specificity will produce more false-positive results. In the model, people with a positive test result were assumed to have a presumptive diagnosis, which is associated with higher utility than having no diagnosis. The committee thought that this assumption was inappropriate. The EAG further explored a scenario in which only true-positive results would benefit from a presumptive diagnosis. This did not change the overall cost-effectiveness results from the model.

3.34 The committee noted that all tests could be cost effective in the model. But this was over a long time horizon (60 year) and was reliant on small QALY gains based on assumptions. Because of this uncertainty the committee only recommended Endotest for evidence generation because it had a full external validation study.

Equality considerations

3.35 The committee was aware of potential equality issues related to endometriosis diagnosis, use of services and access to tests in certain population groups, including:

- trans men and non-binary people registered female at birth
- young people (aged 12 to 17 years)
- women, trans men and non-binary people:
  - from ethnic minority backgrounds
  - who have a learning disability, or
  - who are uncomfortable with invasive diagnostic testing.

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No evidence was identified that addressed any of the equality issues. The committee acknowledged that the intended age limitations of Endotest and DotEndo may restrict access for people outside the indicated age range.

3.36 The committee was also aware of geographical variations in service delivery.

3.37 The committee noted that some populations may particularly benefit from using the technologies, including:

- women, trans men and non-binary people registered female at birth who find transvaginal ultrasound unacceptable, or for whom transvaginal ultrasound is not suitable
- women, trans men and non-binary people registered female at birth who do not have access to healthcare professionals in primary care with high levels of expertise in transvaginal ultrasound.

4 Committee members and NICE project team

This topic was considered by NICE's diagnostics advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Tom Clutton-Brock

Chair, diagnostics advisory committee

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NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

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