

**Suspected Cancer: recognition and referral**  
**Consultation on draft guideline - Stakeholder comments table**  
**05/01/2026 – 02/02/2026**

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SH	OUTpatients charity	EHIA	003	000	2.2 - No specific considerations were given to Gender Reassignment. Here the EIA has overlooked the potential intersection of testosterone, post-menopausal bleeding and cancer risks for trans and non-binary people who choose to retain their gynaecological organs. This needs to be considered and evidence uncertainty acknowledged.	Thank you for your comment. Gender reassignment has been considered in the EHIA which notes the lack of evidence and the committee discussed the EHIA implications in their decision making and recommendation development. The HRT included within the guideline has been added within the terms used to clarify what the recommendations include. The potential impact of gender affirming therapy and cancer risks is not within the scope of this guideline update.
SH	BAME Health Collaborative	EHIA	004	Section 1.2	<p>There is a vast, established body of public health and epidemiological literature demonstrating that disability, race, religion or belief, socioeconomic deprivation and inclusive health groups. These factors create significant inequalities.</p> <p>The suggestion that this is referencing general issues and not specific to ovarian cancer or non-site-specific-weight-loss or endometrial cancer leads to 'blind' recommendations that do not account for known barriers. The guidelines will inevitably work best for the 'standard' patient (often white, non-disabled, and health-literate)</p> <p>See Cancer research: <a href="https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/ovarian-cancer">https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/ovarian-cancer</a></p>	<p>Thank you for your comment.</p> <p>The EHIA's function in NICE guideline development is to systematically identify, assess and consider equality and health inequalities issues across the guideline development process and identify areas for action to promote equality and reduce health inequalities.</p> <p>The committee agrees that disability, ethnicity, religion or belief, socioeconomic deprivation and inclusion health status all contribute to well-recognised and substantial inequalities in cancer diagnosis and outcomes. This is an important consideration in guideline development. The evidence referenced in the EHIA document covers general issues on Equality and Health Inequalities and not specific to ovarian cancer or non-site-specific-weight-loss or endometrial cancer. A search for evidence directly relevant to these conditions was undertaken, but no suitable data were identified. This was in order to highlight</p>

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						<p>issues that could be pertinent to these population in the absence of any more specific findings.</p> <p>The committee considered equality issues throughout its discussions in the context of ovarian and endometrial cancer and non-site-specific-weight-loss. The aim was to avoid recommendations that disproportionately benefit only the 'standard' patient and to mitigate potential inequalities wherever possible.</p> <p>Thank you for sharing the link to cancer research.</p>
SH	University of Birmingham	Evidence Review – Appendix A	General	General	<p>Evidence synthesis</p> <p>We highlight that methods to evaluate diagnostic tests in the evidence synthesis are inconsistent with best practice in diagnostic test evaluation (Deeks JJ, Bossuyt PM, Leeflang MM, Takwoingi Y (editors). <i>Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy</i>. Version 2.0 (updated July 2023). Cochrane, 2023. Available from <a href="https://training.cochrane.org/handbook-diagnostic-test-accuracy/current">https://training.cochrane.org/handbook-diagnostic-test-accuracy/current</a>.)</p> <p>For the review question –  A diagnostic test accuracy review has been conducted for:</p> <ul style="list-style-type: none"> <li>• dual testing with serum CA125 and ultrasound scan compared to serum CA125 alone for detection of suspected ovarian cancer in adults to provide the Evidence underpinning recommendations 1.5.6 to 1.5.9 and 1.5.11 and research recommendation</li> </ul> <p>The diagnostic test CA125 has been evaluated at age-adjusted thresholds. However, ultrasound has been regarded as a purely descriptive and subjective test, despite the availability of robust evidence on objective scoring systems promoting standardisation</p>	<p>Thank you for your comment.</p> <p>The evidence available for this guideline reported sensitivity and specificity. Positive predictive value was also used, consistent with the approach agreed in the previous guideline update. The committee used all available metrics to review the evidence and to inform their recommendations.</p> <p>Serum CA125 and pelvic ultrasound are recommended as the initial investigations for those presenting to primary care with signs or symptoms that may be suggestive of ovarian cancer.</p> <p>The systems such as IOTA and O-RADS are used mainly in secondary care and not routinely applied in primary care. As such these systems fall outside the scope of this partial update.</p> <p>Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify</p>

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					<p>and consistently high diagnostic accuracy. For instance, the IOTA consortium has published several multicentre studies establishing distinct definitions and scores to standardise ultrasound terminology. (Timmerman et al, doi: 10.1046/j.1469-0705.2000.00287.x.) Similarly, the American college of radiologists have described the Ovarian Adnexal Data and reporting system (ORADS). (Andreotti et al, <a href="https://doi.org/10.1148/radiol.201919115">doi.org/10.1148/radiol.201919115</a>)</p> <p>Using these objective scoring criteria have been endorsed by multiple professional societies as essential to improve ultrasound quality and standardisation of reporting. (United States - National Cancer Comprehensive network guidance <a href="https://www.nccn.org/guidelines/guidelines-detail?category=1&amp;id=1453">https://www.nccn.org/guidelines/guidelines-detail?category=1&amp;id=1453</a> United Kingdom – British Gynaecological cancer society, DOI: <a href="https://doi.org/10.1016/j.ejogrb.2024.06.025">10.1016/j.ejogrb.2024.06.025</a> British Medical ultrasound society, Europe – European Society of Gynaecological Oncology, DOI: <a href="https://doi.org/10.1002/uog.23635">10.1002/uog.23635</a>)</p> <p>In providing thresholds for one test CA125 but disregarding objective scoring and triage threshold for a comparator test, NICE have failed to meet standards for evidence assessment in diagnostic accuracy and are inconsistent with international best practice for ultrasound. We submit that the evidence summary to guide the committee is therefore fundamentally flawed and the recommendations therefore are unsound.</p>	<p>people at high risk of ovarian cancer). HTG 453 includes IOTA ADNEX and other models.</p>
SH	University of Birmingham	Evidence Review – Appendix A	Methods	Table 1.1.1	<p>For the review question</p> <p>A diagnostic test accuracy review has been conducted for:</p> <ul style="list-style-type: none"> <li>• dual testing with serum CA125 and ultrasound scan compared to serum CA125 alone for detection of suspected ovarian cancer in adults</li> </ul> <p>to provide the Evidence underpinning recommendations 1.5.6 to 1.5.9 and 1.5.11 and research recommendation</p>	<p>Thank you for your comment.</p> <p>The scope of this partial update was to evaluate dual testing with CA125 and pelvic ultrasound. Evidence was not identified to support any change in the current recommendations; the committee developed a research recommendation in this area. Studies that combined CA125 and ultrasound</p>

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					<p>We highlight serious inconsistencies in the definition of index test for the evidence review.</p> <p>Index test is described as 'dual testing with serum CA125 and ultrasound scan' – but the searches have restricted inclusion to those treating CA125 and ultrasound as two separate tests and not those that COMBINE CA125 and ultrasound. However, the protocol does not specify how these studies should be handled - therefore studies that <u>COMBINE CA125 AND ultrasound should also be included.</u></p> <p>IOTA ADNEX is a risk prediction model that <u>combines CA125 values and ultrasound variables</u>, age and place of treatment to provide thresholds for management – yet, ROCKETS studies ( Lancet 2024, BMJ 2026) have been excluded despite providing information on CA125 and CA125 combined with ultrasound in the IOTA ADNEX model.</p> <p>If on the other hand, the Index test definition in the protocol excludes any models that combines CA125 and ultrasound then that should have been specified apriori– this is a key inconsistency in the protocol.</p> <p>We reiterate that the evidence summary has serious methodological concerns and therefore the recommendation is unsound.</p>	<p>into a single composite index test (such as RMI, ROMA or the IOTA ADNEX model) did not meet the protocol criteria and were therefore excluded, as these tools are primarily used in secondary care rather than primary care. Their diagnostic performance may also differ in these settings because patient populations, disease prevalence, and access to specialist imaging may vary between primary and secondary care. Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). This will include consideration of the inclusion of the ROCKETS study. HTG 453 includes IOTA ADNEX and other models.</p>
SH	Society of Radiographers	Evidence Review A	000	000	<p>Do we know how changing to a both CA125 blood test and ultrasound scan will impact on the number of referrals for ultrasound? What is thought to be the current %? There would be an impact on waiting times for ultrasound scans if additional imaging is required.</p>	<p>Thank you for your comment. The committee is not encouraging the use of both CA125 and ultrasound. Instead, the committee is</p>

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						<p>recommending age-based thresholds for serum CA125 levels.</p> <p>In forming their recommendations, the committee carefully considered the diagnostic accuracy evidence, cost-effectiveness findings and resource implications. Due to non-adherence to existing recommendations and significant variation in practice, it was not possible to estimate a reliable baseline. However, compared with a fixed threshold of <math>\geq 35</math> IU/ml, using age-based thresholds would potentially result in more ultrasound referrals for women aged over 50. Economic modelling (Wu 2025) suggests that this would require £2.4 million in additional funding, spread across primary care, inpatient care and the management of false-positive referrals. However, given that many GPs currently request an ultrasound alongside serum CA125 testing the new age-based thresholds could therefore reduce unnecessary concurrent ultrasound requests, an approach that the economic evaluation indicates is not cost effective and imposes huge burden on services.</p> <p>For women aged 40–49, no change in practice is anticipated because the thresholds remain unchanged. For those aged 39 and under, the recommendations promote clinical judgement, which may reduce unnecessary CA125 testing but could increase targeted ultrasound use.</p> <p>Given the low prevalence of ovarian cancer in these younger age groups and the already high use of ultrasound in practice, these changes are</p>
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						not expected to have a significant resource impact and may potentially result in some cost savings.
SH	British Gynaecological Cancer Society	Evidence Review A	007	008-010	<p>The evidence summary appears to regard Ultrasound as a descriptive test - this is incorrect. In current practice, there are multiple methods of objectively assessing risk at ultrasound that are commonly used. These include the u score which assesses specific features on ultrasound, or more precise definitions established by the International Ovarian tumour analysis group (IOTA) or Ovarian-Adnexal reporting and data system (ORADS). These objective methods reduce the variability of interpretation of ultrasound and enable robust investigations of diagnostic performance.</p> <p>Currently no guidance on ultrasound interpretation is provided - this is the equivalent of requesting CA125 but not specifying a threshold for abnormality. What is considered abnormal ultrasound by the committee?</p> <p>Multiple papers, including ROcKeTS (Lancet Oncology, 2024, BMJ January 2026) have evaluated the use of structured, quality assured ultrasound using various risk prediction models and scores. ROcKeTS finds that the most accurate test for Ovarian cancer in post-menopausal and premenopausal women is ultrasound, when performed in a structured manner and assessed through a risk prediction model called IOTA ADNEX. A cost consequence analysis of seven diagnostic strategies for Ovarian cancer finds a two-step strategy with IOTA ADNEX to provide the best balance between cost and cancer death ( BJOG 2025)</p> <p>Importantly, ROcKeTS explicitly set out to address the question of the best diagnostic test in primary care and in secondary care, recruiting predominantly from urgent suspected cancer referrals, recognising that a trial of CA125 plus ultrasound in primary care would need to be extremely large and likely unfeasible to deliver due to the rarity of Ovarian cancer.</p>	<p>Thank you for your comment.</p> <p>The scope of this partial update was to evaluate dual testing with CA125 and pelvic ultrasound. Evidence was not identified to support any change in the current recommendations; the committee developed a research recommendation in this area. Studies that combined CA125 and ultrasound into a single composite index test (such as RMI, ROMA or the IOTA ADNEX model) did not meet the protocol criteria and were therefore excluded, as these tools are primarily used in secondary care rather than primary care.</p> <p>Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). This will include consideration of the inclusion of the ROcKeTS study. HTG 453 includes IOTA ADNEX and other models.</p> <p>The diagnostic test accuracy of ultrasound is not within the scope of this guideline update.</p>

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					ROCKeTS sought to assess deliverability of tests in real life in a robust diagnostic test accuracy study where all available tests were evaluated and ultrasound models were evaluated in the hands of NHS sonographers rather than experts.	
SH	British Gynaecological Cancer Society	Evidence Review A	007	008-010	<p>The guidance declares ROCKeTS studies ( Lancet Oncology 2024) out of scope as ' - Study does not contain any relevant index Tests. Index test focuses on the accuracy of risk prediction models for diagnosing ovarian cancer and not the identification of age and serum CA125 thresholds or <b>dual testing with serum CA125 and ultrasound.</b>'.</p> <p>This is flawed - ROCKeTS study represents the highest quality evidence to date on the diagnostic test accuracy of CA125 and all available tests for ovarian cancer including structured, quality assured ultrasound delivered by NHS sonographers. Both ultrasound (IOTA ADNEX ultrasound, IOTA simple rules) and CA125 results are presented in Fig 2 ( main results) of the Lancet Oncology paper. DOI: <a href="https://doi.org/10.1016/S1470-2045(24)00406-6">10.1016/S1470-2045(24)00406-6</a> for postmenopausal women and Figure 3 of the BMJ 2025 paper.</p> <p>ROCKETs recruited approximately 2400 patients; the majority ( 67%) were recruited through the urgent suspected cancer pathway from primary care and is therefore relevant to this guidance. ROCKeTS is prospective, multi centre, accurately assessing how tests perform in routine clinical practice. Results of CA125 and ultrasound ( IOTA simple rules, IOTA ADNEX, ORADS) ARE presented in the study. So, to declare ROCKeTS study out of scope of the evidence summary due to index tests is an error.</p> <p>The protocol for the evidence review describes Population as in scope if 80% of the population in a study were from primary care – please detail the evidence for this justification?</p>	<p>Thank you for your comment.</p> <p>Studies that combined CA125 and ultrasound into a single composite index test (such as RMI, ROMA or the IOTA ADNEX model) did not meet the protocol criteria and were therefore excluded, as these tools are primarily used in secondary care rather than primary care.</p> <p>Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). This will include consideration of the inclusion of the ROCKeTS study. HTG 453 includes IOTA ADNEX and other models.</p> <p>The 80% threshold was set and agreed by the committee to ensure that the evidence reflected a predominantly primary care population, as the guideline focuses on suspected cancer referral in primary care. If at least 80% of participants in a study were recruited from primary care, the findings are considered sufficiently representative of that setting.</p>

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SH	University of Birmingham	Evidence Review A	007	008-010	<p>Evidence summary – no studies were included to address the question of dual testing of serum CA125 and ultrasound compared to CA125 alone.</p> <p>Here, the evidence summary considers Sundar, Sudha, Agarwal, Ridhi, Davenport, Clare et al. (2024) Risk-prediction models in postmenopausal patients with symptoms of suspected ovarian cancer in the UK (ROCKeTS): a multicentre, prospective diagnostic accuracy study. The Lancet. Oncology 25(10): 1371-1386 – as out of scope because ‘ <b>Study does not contain any relevant index tests.</b> Index test focuses on the accuracy of risk prediction models for diagnosing ovarian cancer and not the identification of age and serum CA125 thresholds or dual testing with serum CA125 and ultrasound.’</p> <p>This exclusion decision based on the assumption that ultrasound is a descriptive rather than an objective test is fundamentally flawed.</p> <p>ROCKeTS was commissioned by the National Institute of Health and Care Research NIHR HTA 13/13/01 to address the question – which is the best diagnostic test for Ovarian cancer in primary care and secondary care. ROCKeTS evaluated all commonly available tests including CA125 and multiple models and scores of ultrasound including IOTA simple rules, IOTA ADNEX model, ORADS in comparison to the current standard of care test – Risk of Malignancy index which <i>combines</i> CA125 and ultrasound in a prospective, high quality, head to head comparison study of approximately 2400 participants.</p> <p>Recruitment of ROCKeTS was predominantly through the urgent suspected cancer pathway (67%) and finds consistent results across premenopausal (BMJ 2025) and postmenopausal women (2024, Lancet Oncology). Both papers present comparison results</p>	<p>Thank you for your comment.</p> <p>The scope of this partial update was to evaluate dual testing with CA125 and pelvic ultrasound. Evidence was not identified to support any change in the current recommendations; the committee developed a research recommendation in this area.</p> <p>Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). This will include consideration of the inclusion of the ROCKeTS study. HTG 453 includes IOTA ADNEX and other models.</p> <p>The Davenport et al (2022) Cochrane review was identified by the search and subsequently excluded at title and abstract as the paper considers CA125 and ultrasound within four tests (RMI, ROMA, IOTA and ADNEX) which as not usually undertaken in primary care are outside the scope of this guideline update.</p>

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					<p>for CA125 and ultrasound assessed through all commonly used scoring systems.</p> <p>Results for the specific cohort of women referred through urgent suspected cancer pathway are entirely consistent with the cohort recruited across urgent suspected cancer pathway, elective referrals from primary care and emergency admissions (data available on request).</p> <p>In agreeing the study design, the NIHR HTA acknowledged that answering the question on diagnostic testing for Ovarian cancer in a relatively unselected population (the group referred through urgent suspected cancer pathway to secondary care) offered the best balance between feasibility of study recruitment and numbers needed to address this question. Recruiting a prospective study in primary care to address the question of dual testing of CA125 with ultrasound versus CA125 alone would require several thousand women and would be a very expensive trial.</p> <p>We highlight that disregarding a meticulously conducted head-to-head comparison study commissioned by the NIHR to identify the best diagnostic testing strategies for ovarian cancer diagnosis undermines recommendations for practice.</p> <p>We also highlight that a Cochrane review by Davenport et al, which investigated the accuracy of ultrasound and biomarker tests for the diagnosis of ovarian cancer in symptomatic women <a href="https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011964.pub2/full#CD011964-sec-0027">https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011964.pub2/full#CD011964-sec-0027</a> has not been considered for inclusion.</p> <p>Respectfully, we point out that the way the scope has been defined and the protocol has been written has resulted in restriction to two included studies and one cost effectiveness analysis to those from</p>	

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					one research group alone resulting in a highly selective evidence synthesis.	
SH	Target Ovarian Cancer	Evidence Review A	032	008	We fully support the committee's proposal to develop a research recommendation on dual-testing with serum CA125 and ultrasound, we believe the recommendation should cover patients from all age groups.	Thank you for your comment.
SH	BAME Health Collaborative	Evidence Review A	057	032	<p>We are concerned that this recommendation may inadvertently reflect the exclusion of ethnic minorities from the significant evidence base informing this guideline, which may lead to risks of systematic bias and poor health outcomes.</p> <p>The demographic composition of the studies used to define the &gt;5%/6-month threshold.</p> <p>Whether differential diagnosis pathways or risk adjustments have been considered for ethnic minority patients.</p> <p>A commitment to inclusive research and guideline reviews that ensure future recommendations are valid for all populations.</p>	<p>Thank you for your comment.</p> <p>It is not clear what part of evidence review A you are referring to or which recommendation within the guideline document.</p> <p>We think you are referring to the evidence review which focused on unexplained weight-loss. The recommendation referred to is inclusive of ethnic minorities as it applies to all people aged 60 or over with unexplained weight loss.</p> <p>The mean <math>\geq 5\%</math> weight loss within a six-month period is defined in the Nicolson et al 2024 study and whilst it included 326240 it did not break this down by ethnicity, but it is UK based.</p> <p>The committee recognised the importance of ensuring that the recommendations are applicable to all population groups. An Equality and Health Inequalities Assessment (EHIA) was developed as part of this update to identify any potential equality or health inequality issues. The committee explicitly considered these matters throughout its discussions.</p>
SH	Target Ovarian Cancer	Evidence Review A	General	General	We note that the questions for review, and the data included in the evidence review don't consider data published from the ROCKeTS study, which demonstrates the utility of IOTA ADNEX ultrasound protocol in the diagnosis of ovarian cancer. Given that ultrasound is a key diagnostic test for ovarian cancer in primary care, particularly	<p>Thank you for your comment.</p> <p>The use of systems such as IOTA and O-RADS are used mainly in secondary care and not routinely applied in primary care. As such these are outside the scope of this update.</p>

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					<p>in patients aged 39 and below, we feel it is remis to not have a more specific recommendation in place.  <a href="https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(24)00406-6/fulltext">https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(24)00406-6/fulltext</a>  <a href="https://www.bmj.com/content/392/bmj-2024-083912">https://www.bmj.com/content/392/bmj-2024-083912</a></p> <p>Considering the data published by ROCKeTS we would like to see inclusion of a research recommendation for further research into quality assured ultrasound/ultrasound models in primary care, including integration of AI technology to support analysis and reporting of ultrasound results.</p>	<p>Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). This will include consideration of the inclusion of the ROCKeTS study. HTG 453 includes IOTA ADNEX and other models.</p>
SH	University of Birmingham	Evidence Review A	Protocol	Table 1.1.1	<p>For the review question - What is the diagnostic accuracy of dual testing with serum CA125 and ultrasound scan for the detection of suspected ovarian cancer compared to serum CA125 alone in adults for referral via a suspected cancer pathway?</p> <p><b>Population</b> is defined as Adults (≥18 years old) presenting to primary care* with symptoms that suggest ovarian cancer. *When a paper includes populations from primary and secondary care and the data cannot be disaggregated if at least 80% of the population are from primary care.  Please provide evidence to justify the 80% cut-off. This appears to be a cut-off designed to limit inclusion of studies rather than a genuine effort to synthesise existing evidence, and has inappropriately excluded evidence largely collected from studies undertaken in patients sent by GPs straight to urgent suspected cancer referral units.</p> <p>Whilst the most applicable population would originate from primary care, an approach to searching and inclusion that is inclusive of high-quality evidence, regardless of setting, would be a more robust evidence base from which to make decisions about inclusion and synthesis, particularly given the rarity of high quality test accuracy studies in populations with low prevalence. With</p>	<p>Thank you for your comment.  The 80% threshold was set and agreed by the committee to ensure that the evidence reflected a predominantly primary care population, as the guideline focuses on suspected cancer referral in primary care. If at least 80% of participants in a study were recruited from primary care, the findings are considered sufficiently representative of that setting.  The identification of secondary metastatic cancer is out of the scope of this update.</p>

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					<p>knowledge of the evidence base across primary and secondary care, informed decisions about inclusion and subgroup analysis could be made, trading off applicability and internal validity.</p> <p><b>Diagnosis of interest</b> is defined as - Different age thresholds and different serum CA125 thresholds in adults presenting with symptoms that suggest ovarian cancer in primary care  This cannot be the Diagnosis of interest – rather the diagnosis of interest should be Invasive Ovarian cancer with sensitivity analysis to include secondary metastatic cancer to the ovary.</p>	
SH	AMMF	Evidence Review B	021	007-009	<p>This document indicates that introducing an age threshold of 60 and over to this recommendation will be associated with 131 cases of cancer missed per year in England, in adults aged 18-59. Has there been any analysis of which cancer types are most likely to be missed? We would be concerned that rare and less common cancers are more likely to be missed because of this change in guidance, further exacerbating the inequity of outcomes when compared with more common cancers.</p>	<p>Thank you for your comment.  The types of cancers that are identified in people with unexplained weight loss on its own and no other signs and symptoms was not reported in the literature. The committee did note that they may be more indicative of advanced (stage 4) cancer in people under the age of 60.</p>
SH	AMMF	Evidence Review B	024	020-022	<p>This document indicates that the committee were reassured that the recommendation includes provisions to carry out assessments for additional symptoms, signs, or findings for patients presenting with unexplained weight loss. Our interpretation of the draft guidance is that these recommendations only explicitly apply to people aged 60 and over with unexplained weight loss. The guidance should be more explicit in recommending that adults aged 18-59 with unexplained weight loss who do not meet the criteria for referral should still be reviewed.</p> <p>Cholangiocarcinoma typically presents with few, vague symptoms, and may not present with additional signs or symptoms until advanced stages. Therefore, we feel it is important to emphasise</p>	<p>Thank you for your comment.  The committee discussed that unexplained weight loss on its own was rare (this discussion can be found in the related evidence review). They also noted that this guideline (<a href="#">NICE guideline on suspected cancer: recognition and referral</a>) also contains recommendations on safety netting.</p>

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					that assessments for additional signs should be carried out for all adults with unexplained weight loss.	
SH	OUTpatients charity	Evidence Review C	004	008	Inclusion criteria – Although attempting to be inclusive by discussing <u>adults</u> taking HRT, it only covers oestrogen and progesterone, ignoring the potential effect of testosterone on bleeding risk (either due to withdrawal bleed due to low levels, vaginal atrophy or hyperplasia/cancer).	Thank you for your comment. Gender reassignment has been considered in the EHIA which notes the lack of evidence and the committee discussed the EHIA implications in their decision making and recommendation development. The HRT included within the guideline has been added within the terms used to clarify what the recommendations include. The potential impact of gender affirming therapy and cancer risks is not within the scope of this guideline update.
SH	The International Ovarian Tumor Analysis group	General	General	General	We note that no member of the committee for this guidance has specific expertise in gynaecological ultrasonography in relation to the examination of ovarian tumours. This is important as ultrasound is an integral part of the diagnostic pathway being considered – with an elevated CA 125 triggering an ultrasound scan. This is a “two step” approach that must be considered in total. We feel that a gynaecologist with expertise in ultrasound would add value to the group.	Thank you for your comment. The committee includes a radiologist with an academic background, who is also an interventional radiologist.
SH	The International Ovarian Tumor Analysis group	General	General	General	The guideline covers the test performance of CA125 thresholds in detail – based on retrospective studies. However, there are no prospective studies showing that the pathway being proposed works when used in “real world” clinical practice	Thank you for your comment. The protocol did include prospective studies, and any prospective evidence would have been considered. However, no prospective studies meeting the inclusion criteria were identified.
SH	The International Ovarian Tumor Analysis group	General	General	General	The pathway is a two-step test. Using thresholds of CA125 will create significant numbers of false positive test results at step one – requiring an ultrasound scan at step 2, and it is cited that this may happen in primary care. However, the guidelines do not state how these scans should be performed and what approach will be used to classify an ovarian mass if one is found on the scan. The recently published Rockets study shows clearly that the IOTA	Thank you for your comment and the references provided Serum CA125 and pelvic ultrasound are recommended as the initial investigations for those

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					<p>ADNEX model is the best test for this purpose when used in a real-world clinical setting in the NHS – see references below:</p> <p><u>Risk-prediction models in postmenopausal patients with symptoms of suspected ovarian cancer in the UK (ROCKeTS): a multicentre, prospective diagnostic accuracy study.</u> Sundar S, Agarwal R, Davenport C, Scandrett K, Johnson S, Sengupta P, Selvi-Vikram R, Kwong FL, Mallett S, Rick C, Kehoe S, Timmerman D, Bourne T, Van Calster B, Stobart H, Neal RD, Menon U, Gentry-Maharaj A, Sturdy L, Ottridge R, Deeks J; ROCKeTS collaborators. <i>Lancet Oncol.</i> 2024 Oct;25(10):1371-1386. doi: 10.1016/S1470-2045(24)00406-6.</p> <p><u>Diagnostic tests for ovarian cancer in premenopausal women with non-specific symptoms (ROCKeTS): prospective, multicentre, cohort study.</u> Sundar S, Agarwal R, Scandrett K, Davenport C, Van Calster B, Johnson S, Sengupta P, Selvi-Vikram R, Kwong FL, Mallett S, Rick C, Kehoe S, Timmerman D, Bourne T, Stobart H, Neal RD, Menon U, Gentry-Maharaj A, Sturdy L, Ottridge R, Deeks JJ; ROCKeTS collaborators. <i>BMJ.</i> 2026 Jan 28;392:e083912. doi: 10.1136/bmj-2024-083912.</p> <p>A recent systematic review demonstrated the performance of the IOTA ADNEX model and concluded “If a strategy independent of operator expertise is preferred, the ADNEX model is recommended”. This is highly relevant when considering carrying out a test in primary care. See reference below:</p> <p><u>Diagnostic accuracy of ultrasound models for assessment of ovarian tumors: systematic review and meta-analysis.</u> Lems E, Koch AH, Delvaux EJLG, Leemans JC, Bongers MY, Lok CAR, Ramaekers BL, Geomini PMAJ. <i>Ultrasound Obstet Gynecol.</i> 2025 Dec 4. doi: 10.1002/uog.70135.</p>	<p>presenting to primary care with signs or symptoms that may be suggestive of ovarian cancer.</p> <p>The use of systems such as IOTA and O-RADS are used mainly in secondary care and not routinely applied in primary care. As such these systems fall outside the scope of this partial update.</p> <p>Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). HTG 453 includes IOTA ADNEX and other models.</p>

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SH	The International Ovarian Tumor Analysis group	General	General	General	<p>Ultrasound is a critical part of the pathway. Unfortunately, there is nothing in the guidance that comments on the need for appropriate training and what this might look like. Recommending that patients with a raised CA125 “undergo ultrasound” without making it clear that the second step approach to characterising a mass should be ADNEX and what training is required for such scans to be carried out (particularly in primary care) is problematic in our view. The ADNEX model holds performance in a low-risk population. Although not tested in the ROCKETS study, the IOTA two step approach also works well in this scenario (see reference below)</p> <p><u>Validation of ADNEX and IOTA two-step strategy and estimation of risk of complications during follow-up of adnexal masses in low-risk population.</u> Pascual MA, Vancraeynest L, Timmerman S, Ceusters J, Ledger A, Graupera B, Rodriguez I, Valero B, Landolfo C, Testa AC, Bourne T, Timmerman D, Valentin L, Van Calster B, Froyman W. <i>Ultrasound Obstet Gynecol.</i> 2024 Sep;64(3):395-404. doi: 10.1002/uog.27642.</p>	<p>Thank you for your comment and the reference. Serum CA125 and pelvic ultrasound are recommended as the initial investigations for those presenting to primary care with signs or symptoms that may be suggestive of ovarian cancer. The use of systems such as IOTA and O-RADS are used mainly in secondary care and not routinely applied in primary care. As such these systems fall outside the scope of this partial update.</p> <p>Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). HTG 453 includes IOTA ADNEX and other models.</p>
SH	The International Ovarian Tumor Analysis group	General	General	General	<p>The psychological impact of testing for cancer in this context is not commented on. Data from the ROCKETS study has shown that overall, 1355/2596 (52.1%) and 1781/2596 (68.6%) experienced moderate-to-severe distress and anxiety, respectively, at recruitment. Younger age and emergency presentations had higher distress levels. The clinical category for anxiety and distress remained unchanged/worsened in 76% of respondents at 12 months, despite a non-cancer diagnosis (see reference below). This is a major issue. What is the societal cost of the distress caused by these women who are being triaged using CA125, where maybe 80-97% of women with a raised CA 125 level will not have cancer? Yet they will be told they have a positive CA 125 level and then must wait for a scan. This seems potentially damaging given the knowledge we have about psychological</p>	<p>Thank you for your comment and the reference provided.</p> <p>This update used new evidence with the aim of improving the accuracy of CA125 at a PPV of 3% to help guide the use of an ultrasound scan. Evidence was sought on the dual approach but none was identified and a research recommendation has been made. We also note the references regarding the ROCKETS study which would fall outside the scope of this guideline update which focuses on the initial primary care pathway, These scoring systems are not routinely used in primary care and therefore, models such as ADNEX and IOTA fall outside the scope of this update. The societal cost associated with the</p>

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					<p>distress. The psychological distress of patients in the pathway should be considered in the guideline.</p> <p><u>Investigating harms of testing for ovarian cancer - psychological outcomes and cancer conversion rates in women with symptoms of ovarian cancer: A cohort study embedded in the multicentre ROCKeTS prospective diagnostic study.</u> Kwong FL, Kristunas C, Davenport C, Aggarwal R, Deeks J, Mallett S, Kehoe S, Timmerman D, Bourne T, Stobart H, Neal R, Menon U, Gentry-Maharaj A, Sturdy L, Ottridge R, Sundar S; ROCKeTS collaborators. <i>BJOG</i>. 2024 Sep;131(10):1400-1410. doi: 10.1111/1471-0528.17813.</p>	<p>distress experienced by women with suspected cancer symptoms is outside the scope of this update.</p> <p>Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). HTG 453 includes IOTA ADNEX and other models.</p>
SH	NICE GP Reference Panel	Guideline	000	000	A note about collation of GP Reference panel comments. Some comments were on recommendations outside the scope of the update. I have not included irrelevant ones, but have included a couple which I felt may inform amendments to the new updates (JT)	Thank you for the clarification
SH	The International Ovarian Tumor Analysis group	Guideline	002	009-011	The guideline states "Make a referral to a gynaecological cancer service using a <a href="#">suspected cancer pathway referral</a> if physical examination identifies ascites and/or a pelvic or abdominal mass (which is not obviously uterine fibroids)." The view of the IOTA group is that most clinicians in primary care and indeed most in secondary care would not be able to discriminate reliably between fibroids (particularly if pedunculated) and many ovarian masses. We feel that in the event of a palpable pelvic mass, an ultrasound scan is required to correctly identify the pathology present.	<p>Thank you for your comment.</p> <p>The recommendation referred to in this comment, is not within the scope of this update.</p> <p>Topics for inclusion in possible future updates can be suggested via NICE's topic suggestion process. <a href="#">Prioritising our guidance topics   NICE</a></p>
SH	British Gynaecological Cancer Society	Guideline	003	009-011	<b>Relevant recommendations:</b> 1.5.1, 1.5.2, 1.5.6–1.5.10 BGCS has concerns regarding the assumption, implicit within recommendation 1.5.1, that primary care clinicians (and, in some cases, non-specialist secondary care clinicians) can reliably distinguish a pelvic mass due to uterine fibroids from ovarian pathology on physical examination alone.	<p>Thank you for your comment.</p> <p>The recommendation referred to in this comment is not within the scope of this update.</p> <p>Topics for inclusion in possible future updates can be suggested via NICE's topic suggestion process. <a href="#">Prioritising our guidance topics   NICE</a></p>

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					<p>In clinical practice, a smooth ovarian cyst and a smooth uterine fibroid—particularly a broad ligament or pedunculated fibroid—may be indistinguishable on bimanual examination. Reliance on examination findings alone to determine referral risks both unnecessary referrals and delayed diagnosis. BGCS proposes that, where a pelvic mass is identified in primary care, GPs should be explicitly supported to request <b>both a pelvic ultrasound and serum CA125 testing prior to referral</b>, rather than defaulting to referral based on examination findings alone. This approach would:</p> <ul style="list-style-type: none"> <li>• Align with real-world practice, where secondary care will typically arrange ultrasound and CA125 as first-line investigations;</li> <li>• Reduce time to diagnosis by enabling earlier risk stratification;</li> <li>• Allow secondary care services to triage appropriately, including direct-to-CT pathways where indicated;</li> <li>• Reduce unnecessary outpatient appointments and associated patient anxiety for those with benign pathology (for example, fibroids) who may avoid referral altogether.</li> </ul> <p>Such an approach would improve diagnostic efficiency without increasing overall investigation burden.</p>	
SH	Society of Radiographers	Guideline	003	017	The phrase “ <i>persistent abdominal distension (often referred to as ‘bloating’)</i> ” risks misinterpretation. Persistent bloating should be used within referrals, otherwise bloating should not be used in this	Thank you for your comment. The recommendations which are referred to in this comment, is not within the scope of this update.

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					context as to combat subjectivity. The document should clarify that intermittent or functional bloating should not trigger referral.	
SH	NICE GP Reference Panel	Guideline	004	008	<i>Rec 1.5.4 (out of scope/update) - mean safety netting?</i>	Thank you for your comment. The recommendation which is referred to in this comment, is not within the scope of this update.
SH	Target Ovarian Cancer	Guideline	004	019	<p>Recommendation 1.5.6 We are concerned that this recommendation is vague and does not support decision making in primary care. If CA125 is not to be used in isolation it needs to be explicit which test(s) it should be used alongside, if the recommended test is ultrasound then it should be made clear here.</p> <p>The recommendation is not saying 'don't use serum CA125' but rather do not use in isolation, in the current context some guidance is required to indicate when a GP should consider acting upon a CA125 result.</p>	<p>Thank you for your comment. The recommendations have been revised for greater clarity. This has included combining into one recommendation noting not to use CA125 in this group and to consider an ultrasound scan. An additional recommendation has been added to note that in this group if the ultrasound scan is normal that other causes should be investigated and a return to the GP advised if symptoms become more frequent, persistent or both.</p>
SH	NICE GP Reference Panel	Guideline	004	019	<p>Rec 1.5.6 what does the last sentence mean? It seem superfluous and unhelpful in it's present wording</p>	<p>Thank you for your comment. Even though ovarian cancer is uncommon in women, and in trans men and non-binary people with female reproductive organs aged 39 and under, the committee remained concerned about the risk of missing it because it is often diagnosed late. For this reason, the committee considered it important to include an additional safeguard in the recommendation.</p>
SH	BAME Health Collaborative	Guideline	004	019	Rec 1.5.6 – No concerns	Thank you for your comment.
SH	Cancer Research UK	Guideline	004	019-024	Rec 1.5.6 – we understand the rationale to not recommend CA125 in isolation for those aged 39 years and under, as the diagnostic accuracy is poor and ovarian cancer is rare in younger people. The	<p>Thank you for your comment. The recommendations have been revised for greater clarity. This has included combining into</p>

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					recommendation outlining how to investigate those in that age bracket with signs and symptoms of suspected ovarian cancer requires further clarity. The recommendation states 'do not use serum CA125 measurement in isolation for decision making', which leaves ambiguity as to whether CA125 should still be used concurrently with ultrasound, or whether those aged 39 and under presenting with symptoms in the guidelines should be investigated with ultrasound only. If the recommendation is to not use CA125 in this age bracket, we propose removing recommendation 1.5.6.	one recommendation noting not to use CA125 in this group and to consider an ultrasound scan. An additional recommendation has been added to note that in this group if the ultrasound scan is normal that other causes should be investigated and a return to the GP advised if symptoms become more frequent, persistent or both.
SH	Society of Radiographers	Guideline	004	025	<p>1.5.7 – What is the rationale for scanning Abdomen and Pelvis? Sonographers would consider an ultrasound scan of the abdomen to include all the upper abdominal organs including the liver, biliary system, spleen, pancreas, aorta, IVC, kidneys.</p> <p>If the clinical question relates to ovarian pathology and the abdomen is only for ascites, this needs to be made clearer, e.g. ultrasound of the pelvis and assessment for ascites.</p> <p>Scanning for both the abdomen and pelvis would require a 40 minute appointment rather than a 20 minute appointment. It would also require the patient to starve in advance of their appointment. At a time when ultrasound waiting lists are higher than ever and the national shortage of sonographers and radiologists is increasing; this will impact on other patients accessing ultrasound services and getting timely diagnosis.</p> <p>If cancer is diagnosed, the patient would undergo a CT scan for staging.</p>	<p>Thank you for your comment.</p> <p>These recommendations are outside the scope of this update.</p> <p>Topics for inclusion in possible future updates can be suggested via NICE's topic suggestion process. <a href="#">Prioritising our guidance topics   NICE</a></p>
SH	Target Ovarian Cancer	Guideline	004	025	<p>Recommendation 1.5.7</p> <p>We are concerned that this recommendation may inadvertently eliminate all test options in primary care for people aged 39 and under presenting with symptoms. The recommendation implies that an ultrasound is optional. In the context of recommendation 1.5.6</p>	<p>Thank you for your comment.</p> <p>The recommendations have been revised for greater clarity. This has included combining into one recommendation noting not to use CA125 in this group and to consider an ultrasound scan. An</p>

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					which cautions against CA125 in isolation there is no option other than ultrasound. We would recommend 'arrange' rather than 'consider' in line with recommendation 1.5.9. The recommendation would also benefit from an indication regarding routine or urgent ultrasound, if ovarian cancer is suspected then we would expect 'urgent'.	additional recommendation has been added to note that in this group if the ultrasound scan is normal that other causes should be investigated and a return to the GP advised if symptoms become more frequent, persistent or both.
SH	Target Ovarian Cancer	Guideline	004	025	Recommendation 1.5.7 We believe this recommendation could be further strengthened by the inclusion of safety netting guidance like those outlined in recommendation 1.5.11 ie investigate other potential causes and advise a return to the GP	Thank you for your comment. The recommendations have been revised for greater clarity. This has included combining into one recommendation noting not to use CA125 in this group and to consider an ultrasound scan. An additional recommendation has been added to note that in this group if the ultrasound scan is normal that other causes should be investigated and a return to the GP advised if symptoms become more frequent, persistent or both.
SH	Target Ovarian Cancer	Guideline	004	025	Recommendation 1.5.7 The PPV of the new age-adjusted CA125 thresholds exceed 3%. As such, this statement should be revised to <b>"urgent ultrasound"</b> . This is consistent with recommendations for other cancers in NG12 where a 3% PPV is used as the threshold for urgent cancer investigation, such as ultrasound for gallbladder.	Thank you for your comment. This has been amended in the revised wording around this recommendation.
SH	NICE GP Reference Panel	Guideline	004	025	Rec 1.5.7 The recommendation to 'consider ultrasound' for under-40s is ambiguous. Is this a Direct Access Ultrasound (routine/urgent) or a Suspected Cancer Pathway (2WW) referral? Clarifying this pathway is vital to prevent rejected referrals.  Can 1.5.2 and 1.5.7 be integrated?	Thank you for your comment. This has been amended in the revised wording around this recommendation.

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SH	NICE GP Reference Panel	Guideline	004	025	Rec 1.5.7 Is this a routine or urgent ultrasound? Routine USS pelvis/abdomen in my region takes ~3m at present. If urgent, then there should be a recommendation that localities have a pathway for urgent USS (if this isn't already mentioned somewhere)	Thank you for your comment. This has been amended in the revised wording around this recommendation.
SH	BAME Health Collaborative	Guideline	004	025	Rec 1.5.7: The recommendation should be strengthened by replacing 'consider' with 'must' or 'should' to provide clinicians with clear and unambiguous guidance regarding their expected duty	Thank you for your comment. The recommendations have been revised for greater clarity. This has included combining into one recommendation noting not to use CA125 in this group and to consider an ultrasound scan. An additional recommendation has been added to note that in this group if the ultrasound scan is normal that other causes should be investigated and a return to the GP advised if symptoms become more frequent, persistent or both.
SH	British Gynaecological Cancer Society	Guideline	004	025-027	The guideline defines persistent symptoms as occurring "particularly more than 12 times per month" (recommendation 1.5.2). BGCS is concerned that this phrasing may inadvertently suggest that women should wait several months before presenting or re-presenting, potentially contributing to delayed diagnosis.  BGCS recommends revising the wording to: "persistent or frequent symptoms – particularly more than three times per week" This reflects an equivalent symptom frequency while encouraging earlier presentation and re-presentation, particularly where initial investigations are normal. Given that late diagnosis remains a major challenge in ovarian cancer outcomes, clarity in symptom thresholds is essential.	Thank you for your comment. The recommendation, which is referred to in this comment, is not within the scope of this update. However, the guideline already defines the meaning of persistent symptoms (see Terms used in this guideline section) and makes clear that the precise period will vary according to severity and associated features, as assessed by the health professional. There is no suggestion that people should wait a prolonged period before presenting or re-presenting to their GP.

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SH	Cancer Research UK	Guideline	004	025-027	<p>Rec 1.5.7 – as ultrasound is potentially the only proposed investigation for those aged 39 years and under with signs and symptoms of ovarian cancer, removing 'Consider' from the recommendation could provide greater clarity for health professionals, reduce variation in referral activity and support decision-making. It may be worth combining recommendations 1.5.6 and 1.5.7 to provide one clear recommendation on the most appropriate action in those aged 39 years and under. For example:</p> <p><b>Option 1</b> (if CA125 is not recommended for this group): For women, and trans men and non-binary people with female reproductive organs who are aged 39 and under, CA125 is not an accurate indicator of ovarian cancer risk. Although the risk of ovarian cancer is low, it remains a clinical concern and is often diagnosed late. Arrange an ultrasound scan of the abdomen and pelvis for those aged 39 and under with persistent symptoms that suggest ovarian cancer (see recommendations 1.5.1 to 1.5.5).</p> <p><b>Option 2</b> (if CA125 is recommended for this group): For women, and trans men and non-binary people with female reproductive organs who are aged 39 and under, CA125 is not an accurate indicator of ovarian cancer risk. Although the risk of ovarian cancer is low, it remains a clinical concern and is often diagnosed late. Arrange CA125 measurement and an ultrasound scan of the abdomen and pelvis concurrently for those aged 39 and under with persistent symptoms that suggest ovarian cancer (see recommendations 1.5.1 to 1.5.5).</p>	<p>Thank you for your comment.            The recommendations have been revised for greater clarity. This has included combining into one recommendation noting not to use CA125 in this group and to consider an ultrasound scan. An additional recommendation has been added to note that in this group if the ultrasound scan is normal that other causes should be investigated and a return to the GP advised if symptoms become more frequent, persistent or both.</p>
SH	The International Ovarian Tumor Analysis group	Guideline	004	028-029	<p>The guideline recommends that clinicians measure CA125 in primary care for women, and trans men and non-binary people with female reproductive organs aged 40 and over. In other words – do NOT carry out an ultrasound scan. We would suggest that the test performance of CA125 in the 39-50 age group remains poor as women remain pre-menopausal. This will lead to higher false positive test results. We would suggest that all premenopausal</p>	<p>Thank you for your comment.            The question of dual testing with serum CA125 and ultrasound for suspected ovarian cancer was included in the scope of this update. However, no evidence was identified, and therefore no recommendation on dual testing can be made. For those 39 and under, CA125 is not used in isolation</p>

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					women as a minimum should have a scan as a first line test. Our view is that this should be offered to postmenopausal women as well, however the data in premenopausal women does not support using CA125 as a first stage test.	and an ultrasound may be considered where symptoms are persistent. For those aged 40 and over, CA125 should be measured and, if the relevant threshold is reached, an ultrasound arranged. Although the PPV for women aged 40–49 falls below the preferred threshold, it still shows moderate to high sensitivity, and the committee considered this with concerns about late diagnosis, choosing to retain the ≥35 U/ml threshold for this group.
SH	BAME Health Collaborative	Guideline	004 -005	028	Rec 1.5.8– No concerns	Thank you for your comment.
SH	British Gynaecological Cancer Society	Guideline	004-005	General	<p><b>Relevant recommendations:</b> 1.5.6–1.5.9; Table 1; Rationale and impact section (paragraphs 9–26)</p> <p>BGCS welcomes the recommendation not to use CA125 in isolation for decision-making in women aged 39 and under (recommendation 1.5.6), recognising the low specificity and risk of false reassurance in this group.</p> <p>However, BGCS notes that the evidence presented demonstrates that the standard CA125 threshold of 35 IU/ml also has a <b>positive predictive value below 3% in women aged 40–49</b>, which does not meet NICE's usual threshold for urgent cancer investigation. The rationale for retaining CA125 testing in this age group appears to be based on an assumption that ultrasound is only requested following an abnormal CA125 result.</p> <p>This assumption does not reflect current UK primary care practice. In the experience of BGCS members, <b>GPs almost invariably request pelvic ultrasound concurrently with CA125</b>, both to streamline patient management and to avoid the need for additional appointments. As a result:</p>	<p>Thank you for your comment.</p> <p>The question of dual testing with serum CA125 and ultrasound for suspected ovarian cancer was included in the scope of this update. However, no evidence was identified, and therefore no recommendation on dual testing can be made. The research recommendation was made to encourage further work in this area that may provide data to support future recommendation development.</p> <p>For those 39 and under, CA125 is not used in isolation... For those aged 40 and over, CA125 should be measured and, if the relevant threshold is reached, an ultrasound arranged. Although the PPV for women aged 40 - 49 falls below the preferred threshold, it still shows moderate to high sensitivity, and the committee considered this with concerns about late diagnosis, choosing to retain the ≥35 U/ml threshold for this group.</p>

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					<ul style="list-style-type: none"> <li>• The health economic modelling based on sequential testing is unlikely to reflect real-world practice;</li> <li>• The perceived risk of missed malignancy due to reliance on CA125 thresholds in the 40–49 age group is overstated.</li> </ul> <p>BGCS therefore suggests that the guideline be updated to better reflect actual clinical pathways by recommending:</p> <ul style="list-style-type: none"> <li>• <b>Ultrasound as the primary investigation for women aged 18–49 with persistent symptoms suggestive of ovarian cancer</b>, with CA125 measured only if ultrasound findings are abnormal; and</li> <li>• <b>Concurrent CA125 and ultrasound testing in women aged 50 and over</b>, where CA125 has greater diagnostic utility and reflects established practice.</li> </ul> <p>This approach would improve diagnostic accuracy, better align with existing workflows, and avoid unnecessary reliance on a low-specificity biomarker in younger women.</p>	
SH	British Gynaecological Cancer Society	Guideline	004-005	General	The BGCS are of the understanding that currently CA125 assays are non-standardised and there is considerable overlap in normal ranges for assays used at different hospitals such that a level of 35 on one assay may correspond to a level of 20 or 60 on another assay. Thus, should NICE proceed with greater emphasis given to the exact value of the CA125 in relation to age related values we would recommend that there is standardisation and requirements set out as to the appropriate assay to use. This will ensure equity	Thank you for your comment. The consideration of the standardisation of the assay used is outwith the remit of this guideline. The previous recommendation from 2011 also stated a CA125 level so there is an assumption that standardisation of CA125 measurement will have been established.

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					<p>across different geographic populations and ensure levels are comparable across the country.</p> <p>The BGCS welcome the move towards age adjusted values for CA125 testing however we note that laboratory reporting systems will require updating, and there may be a need for national messaging to ensure consistency and avoid confusion among primary care clinicians.</p>	
SH	Society of Radiographers	Guideline	005	002	<p>For postmenopausal women/people is an age limit required? Should this be postmenopausal patients regardless of age i.e. 1 year post LMP</p>	<p>Thank you for your comment.</p> <p>The assumption is that this comment refers to the recommendations on endometrial cancer, as this is where the age threshold of 55 is introduced. The age limit is required because there are different recommendations for those under and over 55 with unexplained post-menopausal bleeding that cannot be attributed to hormone replacement therapy (HRT). The recommendation referred to in this comment, is not within the scope of this update.</p>
SH	Greater Manchester Cancer Alliance	Guideline	005	003	<p>I appreciate that no cost effectiveness data on dual tests. But extrapolation of impact of IOTA plus Ca125 likely to improve QALY as would identify more malignant ovarian lesions. Are we missing opportunity to advocate IOTA simple as ultrasound scan analysis – feedback from sonographer / ED leads is that this should be easily achieved for all sonographers who already do TVUSS.</p>	<p>Thank you for your comment.</p> <p>The focus of the guideline is on the initial primary care pathway, where a raised CA125 triggers an ultrasound, rather than on risk prediction models and ultrasound scoring systems that require specific training; and these scoring systems are not routinely used in primary care.</p> <p>Therefore, models such as IOTA fall outside the scope of this update.</p> <p>Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). HTG 453 includes IOTA ADNEX and other models.</p>

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SH	Society of Radiographers	Guideline	005	003	1.5.9 – see comment number 4 (comment regarding 1.5.7)	
SH	NICE GP Reference Panel	Guideline	005	003	<p>Rec 1.5.9 To ensure practicality, the guideline should explicitly recommend that laboratory reporting systems be updated to auto-flag 'Abnormal' based on these specific age ranges. GPs should not be expected to manually cross-reference a look-up table for every result.</p> <p>Does menopause status affect CA-125? My understanding is that pre-menopause, CA-125 can be physiologically raised and also vary with menstrual cycle. Are the thresholds the same pre- and post-menopause?</p> <p>Re: Ovarian Cancer, it is useful to have different thresholds for CA 125, depending on age</p> <p>A single test for CA 125 might not be useful, but to consider a repeat test and to monitor the trend might also indicate ovarian cancer.</p> <p>If there is a Family History of ovarian cancer, screening for ovarian cancer needs to happen, irrespective of CA 125 level.</p> <p>Ca125: One key question will be – 'do we need to do a retrospective exercise to find the people with a Ca125 which would have been above the new thresholds but was less than the old one?'</p>	<p>Thank you for your comment. The comment related to operational processes within laboratory systems are not within NICE's remit.</p> <p>Any possible impact of menopause status and stage in the menstrual cycle of CA125 is not directly in the scope of this update. The update did consider age ranges and the PPV of CA125 for endometrial cancer for these ages ranges. This included ages which would typically be pre, during and post-menopausal ages.</p> <p>Details on the risk of ovarian cancer and family history can be found in <a href="#">Ovarian cancer: identifying and managing familial and genetic risk (NG241)</a>.</p>
SH	BAME Health Collaborative	Guideline	005	003	.5.9: The UK is an ethnically diverse population, yet the proposed threshold appears to assume biological uniformity across ethnic groups. Evidence from international settings, including the United	<p>Thank you for your comment. The systematic review of the evidence included two papers that were UK-based and included a</p>

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					<p>States, suggests that diagnostic thresholds may differ by population characteristics. It is therefore important to consider whether a single threshold risks reduced sensitivity in some ethnic minority groups.</p> <p>If a standardised threshold is retained, NICE should explicitly recommend further research focusing on ethnic minority women and trans men who later present with advanced-stage ovarian cancer despite previously testing below the threshold. This would help determine whether current thresholds contribute to delayed diagnosis and poorer outcomes in these populations.</p>	total of 393,058 participants. The larger paper (Arendse et al 2025 [n=342278]) provided a breakdown of participants by ethnicity with a total of 14.4% (n=49138) identifying as Asian/Asian British, Mixed, Black/Black British or Other ethnicity. The EHIA has been updated to highlight the point raised and the committee has considered equality issues throughout its discussions in the context of ovarian and endometrial cancer and non-site-specific-weight-loss.
SH	Cancer Research UK	Guideline	005	003-005	<p>Rec 1.5.9 – we support the recommendation of age-based thresholds for CA125, based on high-quality, recent evidence<sup>1</sup>.</p> <p>Consider whether a recommended ultrasound scan following an above threshold CA125 result should be defined as an urgent direct access ultrasound (within two weeks). Evidence demonstrates that a person's risk of cancer following an 'above threshold' CA125 (defined as &gt;35 U/ml in this study) is ~10%<sup>1</sup>, which would warrant either urgent referral or investigation as per NICE NG12 risk threshold.</p>	Thank you for your comment. This has been amended in the revised wording around this recommendation.
SH	The International Ovarian Tumor Analysis group	Guideline	005	007-009	<p>The guidance states "If the ultrasound suggests ovarian cancer, make a referral to a gynaecological cancer service using a <a href="#">suspected cancer pathway referral</a> [2011]." As stated above, the guidance should clearly outline what criteria or approach is to be used to characterise a mass if seen on ultrasound to reduce false positive test results.</p>	Thank you for your comment. Reading and characterising the ultrasound scan fall outside the scope of the guideline update.
SH	Greater Manchester Cancer Alliance	Guideline	005	010	<p>Gynae PWB, GMCA are drafting pathway for raised ca125 with normal pelvic scan. (Happy to share if needed.) We reviewed Scottish, Welsh and GIRFT guidance on this and all agree interval rpt of Ca125. This should also be included here along with recognition of other cancer causes and benign disease like heart</p>	Thank you for your comment. Raised CA125 with a normal pelvic ultrasound falls outside the scope of the guideline update, as the review question did not consider whether or when to repeat CA125 after a normal ultrasound. The

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					failure. Don't need to stipulate frequency of rpt as no solid evidence but peer opiion ranges 8 weeks- 4 months.	committee noted the guideline safety netting recommendations (see Safety netting section) and that clinical judgement underpins all decision making.
SH	Target Ovarian Cancer	Guideline	005	010	Recommendation 1.5.11 A study included within the NICE evidence review (Funston et al 2020) indicates that around 20% of women over 50 with a CA125 above the current threshold but without ovarian cancer, have another cancer type. There is a real opportunity to highlight this within NG12 so that GPs consider the possibility of other cancers. Recommend re-wording this section so that it explicitly states that in those with a CA125 above the new thresholds but a normal ultrasound scan, identify any potential causes of the symptoms "including other types of cancer". <a href="https://pubmed.ncbi.nlm.nih.gov/33112854/">https://pubmed.ncbi.nlm.nih.gov/33112854/</a>	Thank you for your comment. The consideration of CA125 for other cancer types is not within the scope of this update. Topics for inclusion in possible future updates can be suggested via NICE's topic suggestion process. <a href="#">Prioritising our guidance topics   NICE</a>
SH	Target Ovarian Cancer	Guideline	005	010	Recommendation 1.5.11 This recommendation will pose a challenge for some in general practice where a symptoms and suspicion of ovarian cancer persist, but urgent cancer referral is not supported by diagnostic test results.	Thank you for your comment. Recommendations are always intended to be used alongside clinical judgement. Where symptoms persist but test results do not support urgent referral, clinicians should continue to use their clinical judgement, and the guideline also includes safety netting recommendations.
SH	BAME Health Collaborative	Guideline	005	010	1.5.11 The inclusion criteria that a normal ultrasound or does not meet the CA125 threshold should have a more defined pathway that is not open to subjective interpretation. See: 'More frequent': From once a week to daily. 'Persistent: Symptoms that used to come and go but are now constant. 'Return to the GP': This is not necessarily a new referral back to the start; it is a clinical review to reassess the risk. The GP may then repeat CA125/ultrasound (as changes over time are significant), or consider referral based on the new or worsened clinical picture.	Thank you for your comment. Recommendations are always intended to be used alongside clinical judgement. Where symptoms persist but test results do not support urgent referral, clinicians should continue to use their clinical judgement, and the guideline also includes safety netting recommendations.

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SH	British Gynaecological Cancer Society	Guideline	005	010-016	<p>BGCS considers the guidance on managing women with an elevated CA125 and a normal pelvic ultrasound (recommendation 1.5.11) to be insufficiently detailed for safe and consistent practice. We recommend that the guideline explicitly include:</p> <ul style="list-style-type: none"> <li>• Recognition of common non-gynaecological causes of raised CA125 (for example, cardiopulmonary disease, gastrointestinal pathology, inflammatory conditions);</li> <li>• Suggested baseline investigations, such as chest X-ray, echocardiography where clinically indicated, and faecal occult blood testing;</li> <li>• Clear guidance on repeating CA125 testing (for example, at 6 weeks) to assess trends rather than relying on a single value;</li> <li>• Consideration of repeat ultrasound or cross-sectional imaging if symptoms persist.</li> </ul> <p>In addition, BGCS recommends explicit guidance for <b>significantly raised CA125 levels</b> (for example &gt;100–150 IU/ml in women aged 50 and over), recognising the increased likelihood of non-ovarian malignancy or primary peritoneal cancer. In some regions, women with markedly elevated CA125 are appropriately referred via non-site-specific symptom (NSS) pathways, and such practice should be acknowledged within national guidance.</p>	<p>Thank you for your comment. The consideration of CA125 for other cancer types is not within the scope of this update. Topics for inclusion in possible future updates can be suggested via NICE's topic suggestion process. <a href="#">Prioritising our guidance topics   NICE</a></p>

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SH	Cancer Research UK	Guideline	005	010-016	Rec 1.5.11 – we support the inclusion of safety netting recommendations for those who do not meet CA125 thresholds for further investigation, or for those who have a raised CA125 with normal ultrasound. Ovarian cancer generally presents with non-specific symptoms, which overlap with many other cancers, particularly colorectal cancer. There is also evidence demonstrating that the incidence of non-ovarian cancers in women with a CA125 <35 U/ml is 2% (most commonly lower GI and breast), and in women with a CA125 ≥35 U/ml is ~12% (most commonly lower GI, pancreas, lung and endometrial) <sup>1</sup> . More detailed safety netting information should be included to reduce missed opportunities in this group, such as specific cancer sites to be aware of, investigations or referral pathways to consider e.g. non-specific symptom pathways.	Thank you for your comment. The consideration of CA125 for other cancer types is not within the scope of this update. Topics for inclusion in possible future updates can be suggested via NICE's topic suggestion process. <a href="#">Prioritising our guidance topics   NICE</a>
SH	The International Ovarian Tumor Analysis group	Guideline	005	013-016	<p>The guidance states “If the serum CA125 does not meet the threshold outlined in recommendation 1.5.9, or meets the threshold but with a normal ultrasound scan:</p> <ul style="list-style-type: none"> <li>• identify any other potential causes of the symptoms, and investigate as appropriate, and</li> <li>• if no other cause is identified, advise a return to the GP if the symptoms become more frequent and/or persistent.”</li> </ul> <p>The above scenario is not unusual. We think much clearer guidance is needed here. If a pathway is created that is certain to lead to false positive test results and predictably leave many women with unexplained raised CA125 results – then we believe that NICE should set out what actions should be taken. Should the CA125 be repeated at an interval? should full breast and upper abdominal assessment be arranged? Clinicians will be extremely concerned leaving a woman with a raised CA 125 and no explanation and no follow up. NICE in our view should be clear on what guidance expects.</p>	Thank you for your comment. Repeating CA125 falls outside the scope of the guideline update, which focuses on people presenting to primary care with symptoms suggestive of ovarian cancer. The committee noted the guideline safety netting recommendations (see Safety netting section) and that clinical judgement underpins all decision making.

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SH	NICE GP Reference Panel	Guideline	005	015	<p>Rec 1.5.11            If the CA125 is raised but the ultrasound is normal, what is the follow-up? The guideline needs a clear safety-netting statement for this specific false positive cohort.</p> <p>I appreciate that there is always a balance to be struck between precision and practicality. The relatively complex thresholds for ca125 as part of a two step process are likely to be difficult to implement in practice. AI/software developments may make this easier but we are still some distance away.</p> <p>The committee recognised that in practice ca125 and ultrasound were often requested simultaneously which probably reflects some uncertainty about the process and a recognition that there may be potential for diagnoses to be missed because blood results might be misinterpreted and the difficulties with continuity and follow up. While these are essentially structural problems within primary care, they will affect ability to work to these recommendations.</p> <p>I also have a question about the recommendation for ultrasound as a first step for those under 40. I see that the relatively low incidence of cancer in this group makes ca125 less reliable but in those 40 and over, will not the absolute number of people missed by ca125 screening still be significant? Maybe this is a misunderstanding on my part and the ca125 is perhaps a more sensitive test in the older age groups.</p> <p>Ovarian cancer: The clarification of the benefits/risks of isolated CA125 vs. an ultrasound is most welcome.</p> <p>At 1.5.11 referral is not recommended if CA125 meets threshold but USS is normal. Given USS is a subjective testing modality, are there any recommendations for repeat scans at an interval, if the threshold is raised? Why are we measuring CA125 if referral on a 2ww is based on USS results?</p>	<p>Thank you for your comment.</p> <p>Repeating pelvic ultrasound falls outside the scope of the guideline update, which focuses on people presenting to primary care with symptoms suggestive of ovarian cancer.</p> <p>Recommendations are always intended to be used alongside clinical judgement to ensure that ongoing concerns are appropriately addressed. The committee noted the safety netting recommendations (see Safety netting section).</p> <p>For those 39 and under, CA125 is not used in isolation and an ultrasound may be considered where symptoms are persistent. For those aged 40 and over, CA125 should be measured and, if the relevant threshold is reached, an ultrasound arranged. Although the PPV for women aged 40–49 falls below the preferred threshold, it still shows moderate to high sensitivity, and the committee considered this with concerns about late diagnosis, choosing to retain the <math>\geq 35</math> U/ml threshold for this group.</p>

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SH	University of Oxford	Guideline	006	001-007, 019-023	<p><b>Endometrial cancer.</b> We are glad to see the inclusion of considering the uncertainties and need for evidence about how to approach managing unscheduled bleeding on HRT. We value framing this as a need for diagnostic accuracy because of the importance of considering best use of services and resources and also recognising the impact of tests and experience of investigating bleeding on those with lived experience.</p> <p>In a context of increasing use of HRT, our clinical experience and observation is that this is accompanied by a parallel increase in the number of people seeking care for unscheduled bleeding, and an increased number of people being investigated with ultrasound scans and hysteroscopy. It is hard when advising them to know how to contextualise risk of cancer in the context of HRT treatment, aware that this might differ from risk associated with post-menopausal bleeding without exogenous hormonal treatment. We are also concerned about the number of people who have repeated episodes of bleeding, and repeated investigations.</p> <p>We were glad to see your planned evidence review, addressing this question, which we agree is critical. As part of the workplan of the NIHR Cancer Awareness Screening and Early Diagnosis Policy Research Unit, we are currently undertaking a primary research epidemiological study which will offer valuable information relevant to your evidence review. We are establishing the risk of endometrial cancer in patients presenting with unscheduled bleeding in women on peri or post-menopausal HRT with oestrogen and progestogens, using the ORCHID-E database. Our objectives are to describe incidence of unscheduled bleeding in women on HRT compared to those not on HRT, and the patterns of onward urgent suspected cancer referrals within one year of referral.</p>	<p>Thank you for your comment.</p> <p>The decision not to include “any cancer” in the population was made because of the nature of this guideline. The focus is on people presenting to primary care for the first time with symptoms suggestive of endometrial cancer.</p> <p>The references provided do not meet the inclusion criteria for the review question.</p> <p>Thank you for the additional information on the ongoing study.</p> <p>Topics for inclusion in possible future updates can be suggested via NICE’s topic suggestion process. <a href="#">Prioritising our guidance topics   NICE</a></p>

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					<p>However, we have the following comments in response to the consultation:</p> <ul style="list-style-type: none"> <li>a. We do not understand the decision to remove “any cancer” from your population under study and would be glad of further detail and context for this decision. While anyone with a history of an oestrogen-dependent cancer would not normally take HRT, many people with other cancers might, and it is also important to understand their risk and information needs? (Cardwell CR, Ranger TA, Labeit AM, Coupland CA, Hicks B, Hughes C, McMenamin Ú, Mei XW, Murchie P, Hippisley-Cox J. Hormone replacement therapy and cancer mortality in women with 17 site-specific cancers: a cohort study using linked medical records. British Journal of Cancer. 2024 Sep 7;131(4):737-46.) Although we recognise a rationale for excluding people with a history of breast cancer, we do note that there is evidence (panorama) that women with a history of breast cancer might take HRT through private providers or under oncology guidance.</li> <li>b. We recognise your aspiration to explore the risk associated with repeated episodes of bleeding. While our study will explore repeated episodes of referral, we note that in using routinely collected electronic health record data, we will not be able to address this question. While we will have dates for consultations where unscheduled bleeding is coded, this could represent either a discrete episode, or a disclosure and coding of repeated or prolonged bleeding experienced before consultation, and without access to free text data, our study will not reliably be able to ascertain this or discriminate.</li> </ul>	

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SH	OUTpatients charity	Guideline	006	003	Rec 1.5.12 – While the statement is inclusive of trans men and non-binary people, nowhere in the document is it considered whether HRT applies to testosterone therapy.	Thank you for your comment. Gender reassignment has been considered in the EHIA which notes the lack of evidence and the committee discussed the EHIA implications in their decision making and recommendation development. The HRT included within the guideline has been added within the terms used to clarify what the recommendations include. The potential impact of gender affirming therapy and cancer risks is not within the scope of this guideline update.
SH	NICE GP Reference Panel	Guideline	006	003	1.5.12 The guideline needs to explicitly state that PMB (no HRT) remains an automatic 2WW whereas HRT bleeding requires a risk assessment as defined by BMS. Define unscheduled vs post-menopausal terminology.  Endometrial cancer: The direct link to BMS guidance is welcome and provides better standardisation across the board.	Thank you for your comment. Further definitions of unexplained postmenopausal bleeding and unscheduled vaginal bleeding on HRT have been added to ensure clarity around the recommendations and to make sure that people with unexplained postmenopausal bleeding not associated with HRT are referred via the suspected cancer pathway (see Terms used in this guideline section).
SH	NICE GP Reference Panel	Guideline	006	003	1.5.12 <b>Comment separated as I think is commenting on the BMS guidance itself</b>  <i>Assessment: Lower Genital tract swab...If px taking HRT presents with unscheduled bleed, I doubt many GPs would even think about this.</i>  <i>When to investigate: "... offer adjustments in the progestogen or HRT preparation. ". I would like more specific and detailed meaning of "adjustments".</i>	Thank you for your comment. These comments refer to the content of the BMS guideline, which while this guideline is acknowledged within the recommendations the content of the BMS guideline is outside the remit of NICE.

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					<p><i>"...weaning off HRT..." - as above. Too vague. What time scale?</i></p> <p><i>How should it be investigated?</i></p> <p><i>"...and measures ≤ 4 mm with ccHRT or ≤ 7 mm with sHRT, can be reassured that the risk of endometrial cancer is low. ". I doubt if px will be easily reassured by advice alone without further tests . If results are 3.9mm or 6.9mm respectively, how do you suggest we approach this? I doubt if any GP would simply reassure in this situation</i></p>	
SH	BAME Health Collaborative	Guideline	006	003	<p>1.5.12: Abnormal bleeding on HRT in women aged 55 and over is also a red flag</p> <p>Please note there is evidence that any episode of post-menopausal bleeding requires prompt and direct referral for specialist assessment to rule out endometrial cancer, regardless of the patient's age or the bleed's characteristics.</p>	<p>Thank you for your comment.</p> <p>Further definitions of unexplained postmenopausal bleeding and unscheduled vaginal bleeding on HRT have been added to ensure clarity around the recommendations and to make sure that people with unexplained postmenopausal bleeding not associated with HRT are referred via the suspected cancer pathway (see Terms used in this guideline section).</p>
SH	NICE GP Reference Panel	Guideline	006	008	<p><i>Rec 1.5.13 (out of scope/update)</i></p> <p><i>- do you mean pelvic ultrasound?</i></p> <p><i>- do you mean rapid diagnostic clinic if symptoms are vague?</i></p>	<p>Thank you for your comment.</p> <p>The recommendation which is referred to in this comment, is not within the scope of this update.</p> <p>Topics for inclusion in possible future updates can be suggested via NICE's topic suggestion process.</p> <p><a href="#">Prioritising our guidance topics   NICE</a></p>

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SH	Society of Radiographers	Guideline	006	011	Should 'vaginal discharge' be 'vaginal bleeding'? Not all discharge would be concerning for endometrial cancer	Thank you for your comment. The recommendation which is referred to in this comment, is not within the scope of this update. The discussion when this recommendation was developed referred to vaginal discharge. Topics for inclusion in possible future updates can be suggested via NICE's topic suggestion process. <a href="#">Prioritising our guidance topics   NICE</a>
SH	OUTpatients charity	Guideline	006	020	Rec 1.5.14 – While the statement is inclusive of trans men and non-binary people, nowhere in the document is it considered whether HRT applies to testosterone therapy. Further, it may be unclear to those taking testosterone under 55 who still have a uterus and ovaries, when they become menopausal, as they will experience amenorrhoea from around 4 months of testosterone use. From the scan literature, oestradiol, progesterone and ovarian activity vary between individuals according to multiple factors including type of testosterone preparation and concordance. FSH and LH levels are typically also in the postmenopausal female range. AMH would be confirmatory but not of use if equivocal.	Thank you for your comment. Gender reassignment has been considered in the EHIA which notes the lack of evidence and the committee discussed the EHIA implications in their decision making and recommendation development. The HRT included within the guideline has been added within the terms used to clarify what the recommendations include. The potential impact of gender affirming therapy and cancer risks is not within the scope of this guideline update.
SH	BAME Health Collaborative	Guideline	006	020	1.5.14: Abnormal bleeding on HRT is not age-specific and is also a red flag Please note there is evidence that any episode of post-menopausal bleeding requires prompt and direct referral for specialist assessment to rule out endometrial cancer, regardless of the patient's age or the bleed's characteristics	Thank you for your comment. Further definitions of unexplained postmenopausal bleeding and unscheduled vaginal bleeding on HRT have been added to ensure clarity around the recommendations and to make sure that people with unexplained postmenopausal bleeding not associated with HRT are referred via the suspected cancer pathway (see Terms used in this guideline section).
SH	Society of Radiographers	Guideline	006	024-030	As the NICE guidance on unscheduled bleeding on HRT does not include a clear recommendation, we suspect this will cause confusion, as the BMS guidance referred to is already in	Thank you for your comment. The committee discussed that the BMS recommendations are largely based on informal

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					widespread use. Would it be prudent to add a caveat to say that until further research is available NICE are not making a specific recommendation?	consensus and expert opinion, as there is limited evidence in this area. They recognised that the BMS guidance is a useful resource in practice. Considering this, the committee developed a research recommendation and agreed to raise awareness of the BMS guideline. We do not incorporate the wording into this guideline.
SH	Cancer Research UK	Guideline	006	024-030	Rec 1.5.15 – consider adding more detail about what the British Menopause Society ' <a href="#">Management of unscheduled bleeding on hormone replacement therapy (HRT)</a> ' guideline outlines e.g. information about when somebody experiencing unscheduled bleeding on HRT, combined with various risk factors may require investigation, to support health professional decision-making.	Thank you for your comment. The committee discussed that the BMS recommendations are largely based on informal consensus and expert opinion, as there is limited evidence in this area. They recognised that the BMS guidance is a useful resource in practice. Considering this, the committee developed a research recommendation and agreed to raise awareness of the BMS guideline. We do not incorporate the wording into this guideline.
SH	Society of Radiographers	Guideline	006	025	Unclear wording – what is there limited evidence of?	Thank you for your comment. This links to the remainder of the recommendation on unscheduled bleeding for those taking HRT. As noted in the links in the guideline further details can be found in the evidence review and committee discussion underpinning this recommendation.
SH	OUTpatients charity	Guideline	006	025	Rec 1.5.15 – The BMS guideline does not discuss unscheduled bleeding in trans men and non-binary people on testosterone, only those taking oestrogen-containing HRT. There remains a theoretical increased risk of endometrial hyperplasia and cancer in trans men on testosterone due to aromatisation to its oestrogen and the potential suppression of the progesterone access. This fits with data in women with PCOS and high androgens. Small convenience samples looking at prevalence of endometrial hyperplasia and cancer have not established whether this is the case and have mostly looked at premenopausal age individuals. A	Thank you for your comment. Gender reassignment has been considered in the EHIA which notes the lack of evidence and the committee discussed the EHIA implications in their decision making and recommendation development. The potential impact of gender affirming therapy and cancer risks is not within the scope of this guideline update.

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					large Dutch study did not find an increased risk but the median age of hysterectomy in that study was 28 (DOI: <a href="https://doi.org/10.1016/j.eclinm.2025.103248">10.1016/j.eclinm.2025.103248</a> ). It also contains many of the most relevant references for other literature) In the UK, progesterone is not routinely prescribed alongside testosterone unless individuals do experience persistent unscheduled bleeding with therapeutic testosterone levels, and no evidence of malignancy, or those require it for contraception. No equivalent consensus guideline exists and I would be happy to work with NICE to develop this in consensus until further evidence is available.	
SH	NICE GP Reference Panel	Guideline	006	025	<p>Rec 1.5.15                      Embed [BMS guidelines] don't link. Referring to external guidance creates issues during busy clinics. Please embed the flowchart and the 6-month rule and management into the NG12 summary tables. External links often break or sit behind paywalls and logins.</p> <p>The BMS guidance often relies on Transvaginal Ultrasound (TVS) to measure endometrial thickness. Does the current radiology workforce have the capacity for the increased volume of scans this might generate if GPs are following the BMS 'thickened endometrium' criteria strictly?</p> <p>the British Society of the Menopause Guideline about HRT and unscheduled bleeding is useful, but difficult to remember or to implement.</p> <p>Postmenopausal women with risk factors for endometrial cancer need to be counselled prior to starting HRT and maybe be offered an ultrasound prior to starting HRT.</p>	<p>Thank you for your comment. The committee noted that the BMS recommendations are largely based on informal consensus and expert opinion, as there is limited evidence in this area. They recognised that the BMS guidance is a useful resource in practice. Considering this, the committee developed a research recommendation and agreed to raise awareness of the BMS guideline. Therefore, we do not incorporate the wording into this guideline.</p> <p>By raising awareness of the BMS guideline and encouraging clinical consideration, this may reduce unnecessary referrals for women experiencing unscheduled bleeding on HRT.</p> <p>Postmenopausal women taking HRT who have risk factors for endometrial cancer are addressed within the <a href="#">Menopause: identification and management (NG23)</a> guideline. Counselling and risk assessment prior to initiating HRT fall outside the scope of this guideline.</p>

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SH	BAME Health Collaborative	Guideline	006	025	<p>1.5.15: Rec 1.5.6 – We strongly believe that this recommendation lacks a patient-centred approach. While the evidence is indeed limited for this population, the prudent clinical imperative is clear.</p> <p>The standard of care should shift from an age-based or identity-based rule to a physiology-based rule</p>	<p>Thank you for your comment.</p> <p>The committee carefully considered all available evidence on the topic when making recommendations.</p> <p>The committee recognised the importance of ensuring that the recommendations are applicable to all population groups. An Equality and Health Inequalities Assessment (EHIA) was developed as part of this update to identify any potential equality or health inequality issues. The committee considered these matters throughout its discussions.</p>
SH	British Gynaecological Cancer Society	Guideline	006	025-030	<p>BGCS welcomes the explicit acknowledgement of the evidence gap regarding unscheduled bleeding on HRT and the decision to signpost clinicians to the joint British Gynaecological Cancer Society (BGCS) and British Menopause Society (BMS) guidance. Specific comments:</p> <ul style="list-style-type: none"> <li>We agree that, in the absence of robust evidence, referencing BGCS/BMS guidance is a pragmatic approach that reflects current clinical practice.</li> <li>It is important that the guideline clearly communicates the distinction between post-menopausal bleeding and unscheduled bleeding on HRT, to minimise inappropriate urgent referrals while maintaining vigilance for malignancy.</li> <li>BGCS strongly supports the associated research recommendation to establish diagnostic accuracy</li> </ul>	<p>Thank you for your comment.</p>

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					thresholds for referral in this population, given the increasing prevalence of HRT use and the potential impact on gynaecological cancer services.	
SH	Cancer Research UK	Guideline	006	Endometrial	<p>Rec 1.5.12 + 1.5.14 - consider whether recommendations 1.5.12 and 1.5.14 could be encompassed into one recommendation that does not specify age but focuses on all those who are experiencing post-menopausal bleeding which cannot be attributable to HRT, to provide greater clarity for health professionals.</p> <p>Menopause usually occurs between 45 and 55 years of age, with the average age in the UK is 51<sup>ii</sup>.</p> <p>Data from a large primary care database shows that in England the rate of symptom reporting of PMB in those aged 40-49 years is relatively low (9.1 per 100,000) compared to in the 50-59 years age category (145.7 per 100,000) (Source: <a href="#">Unpublished data, ORCHID-E dataset, March 2025</a>).</p> <p>This suggests that removing the age criteria and focusing on menopause and HRT status is unlikely to lead to a significant increase in referral rates, as the majority of those experiencing PMB are within or very near to the age that endometrial cancer risk increases (~55 years). It may reduce missed opportunities in the timely recognition and referral of those presenting with PMB who go through menopause at a slightly younger age.</p> <p>The endometrial cancer risk associated with age could be noted as part of recommendation 1.5.15, to provide further information to support decision-making without determining a referral criteria.</p>	<p>Thank you for your comment.</p> <p>The committee also added further definitions of unexplained postmenopausal bleeding to ensure clarity around the recommendations and to make sure that people with unexplained postmenopausal bleeding not associated with HRT are referred via the suspected cancer pathway (see Terms used in this guideline section).</p> <p>The age criterion was introduced and agreed by the previous guideline committee, and these recommendations are outside the scope of this partial update.</p>

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SH	British Gynaecological Cancer Society	Guideline	006	General	<p>The guideline continues to recommend transvaginal ultrasound (TVS) as the primary investigation for suspected endometrial cancer but does not acknowledge evidence that endometrial thickness measurement is less reliable in Black women.</p> <p>BGCS recommends explicit guidance stating that <b>endometrial thickness on ultrasound should not be used to exclude endometrial cancer in Black women</b>. This is due to the high chance of other uterine pathology making the interpretation of the endometrium less accurate. The BGCS would recommend a referral via a suspected cancer pathway should be based on symptoms irrespective of ultrasound findings in this group, to avoid diagnostic inequity.</p> <p>Furthermore, data from diagnostic test accuracy studies of high vaginal/endocervical swabs using methylated DNA (similar to the FIT test for colorectal cancer) has better negative predictive value (NPV) than TVS, especially in those more likely to have serous cancer (older women and black women). The WID-easy test is licenced for those with abnormal bleeding aged over 45 years. This is being evaluated in pilot implementation studies, although data exist from DTA studies. (e.g. DOI: 10.1200/JCO.22.00266; DOI: 10.1002/ijc.34275; DOI: 10.1002/ijc.34406; DOI: 10.3390/diagnostics14040417). Given the recommendation to consider inclusion of those &lt;55 for CWT, which would overwhelm services with those who do not have cancer, the BGCS would suggest allowing centres to consider this as an alternative, with USS reserved for those with a positive WID-easy test (since 50% with a positive test have an endometrial cancer and 25% who do not have endometrial cancer will have an ovarian cancer) as well as hysteroscopy. Those with negative WID-easy test have extremely low incidence of cancer and hysteroscopy/endometrial biopsy should only be considered (via urgent not CWT pathway) in those with persistent bleeding or risk factors for endometrial cancer</p>	<p>Thank you for your comment.</p> <p>The consideration of the findings of ultrasound scans is outside the scope of this update.</p> <p>Topics for inclusion in possible future updates can be suggested via NICE's topic suggestion process. <a href="#">Prioritising our guidance topics   NICE</a></p>

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					(1 major or 3 minor as per BMS/BGCS unscheduled bleeding on HRT guidance) as these patients are more likely to have hyperplasia, polyps or atrophic changes. TVS will not add to the diagnosis and increase costs, unless symptoms concerning for ovarian cancer or pelvic mass.	
SH	British Gynaecological Cancer Society	Guideline	006	General	<p>The NHS England Documents referring to the <b>Faster Diagnostic pathways</b> and specifically the 'Implementing a timed gynaecology cancer diagnostic pathway' document, outlines a '28 day best practice diagnosis pathway'. In this document it suggests that women referred with suspected endometrial cancer should have a clinical examination and ultrasound and this should happen between <b>day -3 and day 0</b> of the diagnostic pathway, with day 0 being the day of referral.</p> <p>If a GP follows the proposed NICE guidance as it stands, the ultrasound will not be requested until the patient attends secondary care (after day 0) adding significant delay into the pathway. The NICE guidance as proposed is not compatible with meeting the <b>28-day faster diagnosis target</b>.</p> <p>The BGCS recommends that NICE consider harmonising the pathways to recommend direct access ultrasound for women both under and over 55, with referral determined by imaging findings and clinical assessment. This would be consistent with the NICE recommendations for women presenting with visible haematuria or new vaginal discharge and would be both consistent and compatible with the NHS England guidance.</p>	Thank you for your comment. Implementation of the NHSE pathway is not in the scope of this NICE update.
SH	Breast Cancer Now	Guideline	008	003-010	We believe that NICE should recognise that non-specific symptoms such as unexplained weight loss and loss of appetite can be red flags not just for primary cancers, but also for advanced or metastatic cancers, including metastatic breast cancer.	Thank you for your comment. <a href="#">NICE guideline on suspected cancer: recognition and referral</a> is not specific for primary cancers. This guideline was developed to identify symptoms predictive of cancer in general.

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					<p>We believe that there is strong evidence that non-specific symptoms such as unexplained weight loss and unexplained loss of appetite are signs that a person's primary breast cancer may have metastasised to the liver, abdomen or bones.</p> <p><b>Evidence:</b> <a href="#">Clinical features, diagnosis, and staging of newly diagnosed breast cancer - UpToDate</a>  <a href="#">Symptom Management in Metastatic Breast Cancer - PMC</a>  <a href="#">Incidence and patterns of distant metastases for patients with early-stage breast cancer after breast conservation treatment - PubMed</a>  <a href="#">Metastatic spinal cord compression (MSCC) recognition signs and symptoms :: UK Acute Oncology Society</a></p>	
SH	Breast Cancer Now	Guideline	008	003-010	<p>We are concerned by the decision to limit unexplained weight loss as a symptom of concern to patients who are aged 60 or over. Whilst unexplained weight loss in people over 60 is more likely to be caused by non-cancer pathologies, we believe that the guideline should recognise that in people with a history of breast cancer it may indicate metastatic breast cancer and should prompt an assessment regardless of age.</p> <p>If this is not reflected in the guidance, then we are concerned that it may lead to a delay in referral for women under 60 presenting with weight loss who previously had primary breast cancer and whose symptoms may be due to metastatic breast cancer.</p> <p>As highlighted by the National Audit of Metastatic Breast Cancer (NAoME) State of the Nation report, there is incomplete data available on the number of people diagnosed with metastatic breast cancer. This makes it difficult to assess if unexplained weight loss is less likely to be a symptom of metastatic breast cancer for people under the age of 60. We would recommend that NICE delay the introduction of this age threshold until more data is</p>	<p>Thank you for your comment. The recommendations relating to breast cancer within this guideline are not in the scope of this update. The evidence reviewed was for those with unexplained weight loss. This guideline also includes safety netting recommendations.</p> <p>Topics for inclusion in possible future updates can be suggested via NICE's topic suggestion process. <a href="#">Prioritising our guidance topics   NICE</a></p>

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					available on metastatic breast cancer diagnosis and the age range of diagnosis after experiencing weight loss.	
SH	University of Oxford	Guideline	008	003-011	<p><b>Unexpected Weight Loss.</b> We welcome the incorporation of recently published data from Nicholson (2024) on the risk across multiple cancers in patients presenting to primary care with unexpected weight loss. A major consideration when investigating this cohort is to ensure that they are not referred multiple times to site specific cancer pathways by making use of dedicated pathways for non-specific symptoms, called NHS Rapid Diagnostic Centres. We therefore feel the proposed guidance is not aligned with the optimal NHS investigation of this cohort. Could the committee consider the following modifications:</p> <ul style="list-style-type: none"> <li>a. Nicholson (2024) presents an aggregated increased risk of cancer across multiple cancer sites. The risk of each individual cancer, even with additional symptoms taken into account, will often not reach the 3% referral threshold. It is the aggregated cancer risk across multiple sites that is important. *We therefore consider that the recommended urgent referral pathway for patients with unexpected weight loss should be a NHS Rapid Diagnostic Centre with broad investigation for non-specific symptoms.</li> <li>b. The recommendation limits investigation of unexpected weight loss to patients age 60 years and over, then asks to check for additional symptoms to guide choice of USC pathway. *We recommend that patients should be referred if they present with or without additional symptoms if they are 60 years or over and have unexpected weight loss (to a NHS Rapid Diagnostic Centre investigating across cancer sites)</li> </ul>	<p>Thank you for your comment. Please find responses to each of your points below:          The recommendation has been updated to include a non-specific symptoms pathway referral as well as the suspected cancer pathway referral. The evidence identified does not support the inclusion of this recommendation for those under 60. The committee note that recommendations should be used alongside clinical review and also noted the safety netting recommendations within the guideline.          The committee agreed that a potential benefit of this recommendation would be to identify those people with cancer more rapidly. Furthermore, there was a consensus in the committee that introducing age thresholds for unexplained weight loss may minimise the number of inappropriate referrals for people without cancer, while maximising the number of appropriate referrals for people with cancer.</p>

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					c. The recommendation for patients younger than 60 years could be strengthened. Nicholson (2024) outlines the scenarios in which the aggregated risk of cancer across multiple sites exceeds 3% when a patient presents to primary care with unexpected weight loss and additional symptoms. It also shows that even when unexpected weight loss is combination with other 'localising' symptoms there is a broad range of cancers diagnosed, many of which are not associated with the additional 'localising' symptom. *We therefore ask for a clearer recommendation that patients under 60 years of age with unexpected weight loss in combination with the symptoms/signs/results that push the aggregated cancer risk over 3% should be eligible for investigation by Rapid Diagnostic Centres.	
SH	NICE GP Reference Panel	Guideline	008	004	Rec 1.13.2 To improve the 'Positive Predictive Value' (PPV) of these referrals, the guideline should list mandatory 'filter tests' (e.g., HbA1c for diabetes, TFTs for hyperthyroidism, coeliac screen) that must be performed <i>before</i> a 2WW referral. This prevents cancer clinics from seeing undiagnosed diabetics.  Why is the cut-off strictly 60? Is there a safety net for a 55-year-old with 10% weight loss and negative bloods? Please clarify the pathway for the 50-60 age group—should they receive a 'Direct Access CT' rather than a full cancer referral?  Define unexplained - Please clarify if 'unexplained' implies that a GP must have ruled out depression, dietary changes, or benign causes <i>clinically</i> first, or if the objective >5% loss is sufficient to warrant referral regardless of psychosocial context.	Thank you for your comment. The specific tests to be performed are out of scope of this guideline. The evidence showed that positive predictive values of 3% or above were seen in people aged 60 and over who presented in primary care with unexplained weight loss (a mean loss of more than 5% of body weight within a 6-month period). The committee agreed that a potential benefit of this recommendation would be to identify those people with cancer more rapidly. Furthermore, the committee agreed that introducing age thresholds for unexplained weight loss may minimise the number and related stress to the individual of inappropriate referrals, while maximising the

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					<p>what does 'mean weight loss' mean? Surely it's just 5% weight loss?</p> <p>Weight loss: I think this is most welcome, and will hopefully look to identify difficult-to-treat cancers earlier, though I feel a public health campaign focussed on weight loss/looser clothes must be considered in tandem. I appreciate this is outside of NICE's remit but we need to patients to come forward, too.</p> <p>Weight loss: You have stipulated 5% in 6 months. Probably a more common scenario is going to be someone coming for their annual review who has lost 5% since the last check 12 months ago. You won't know if that 5% weight loss is over 12 months or 6 months, although the patient might be able to give you some idea. Is it worth factoring that into the guidelines?</p>	<p>number of appropriate referrals for people with cancer.</p> <p>There is a definition of 'unexplained' as part of the section terms used in this guideline.</p> <p>The 6-month period was added to the recommendation based on the evidence included.</p>
SH	BAME Health Collaborative	Guideline	008	004	.1.13.2 The 6-month timeframe for assessing unexplained weight loss in older adults, implying it might be too lenient and delay cancer diagnosis. The guideline is often misinterpreted as some cancers are very aggressive, for example, the pancreas.	<p>Thank you for your comment.</p> <p>The 6-month period was added to the recommendation based on the evidence included related to unexplained weight loss.</p>
SH	AMMF	Guideline	008	004 - 011	<p>Rec 1.13.2 – Introducing an age threshold of 60 and over to this recommendation will result in some cancers being missed and diagnosed late in adults aged 18-59.</p> <p>We are concerned that a disproportionately large number of missed cancers will be rare and less common cancers, such as cholangiocarcinoma (bile duct cancer, one of the biliary tract cancers), because they typically present with few vague and non-specific symptoms until advanced stages. A report on health inequalities for people with rare and less common cancers by Cancer52 (<a href="#">link</a>) revealed that over a third (34%) of respondents to their patient survey said they had visited their GP three or more times before being referred for a diagnosis, which is double the</p>	<p>Thank you for your comment.</p> <p>The evidence showed that positive predictive values of 3% or above were seen in people aged 60 and over who presented in primary care with unexplained weight loss (a mean loss of more than 5% of body weight within a 6-month period). The committee agreed that a potential benefit of this recommendation would be to identify those people with cancer more rapidly. Furthermore, the committee agreed that introducing age thresholds for unexplained weight loss may minimise the number of inappropriate referrals for people</p>

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					<p>cancer average. Introducing an age threshold for investigating unexplained weight loss could exacerbate this inequality.</p> <p>Analysis of 32,251 cholangiocarcinoma patient records in England between 2001-2018 revealed that more than one-in-five patients (22.7%) were under 65 years old at diagnosis (<a href="#">link</a>). Incidence of cholangiocarcinoma is growing rapidly in younger adults, with many cases occurring in people who are otherwise healthy (i.e. no underlying liver disease or known risk factors). As such, they may not present with other symptoms associated with an increased risk of cancer until their disease has advanced.</p> <p>If Liver Function Tests (LFTs) are requested for all adults with unexplained weight loss as a safety netting measure, it may reduce the number of cholangiocarcinoma cases that could be missed, although LFTs will not be abnormal for all cholangiocarcinoma patients.</p>	<p>without cancer, while maximising the number of appropriate referrals for people with cancer. The committee discussed that they consider unexplained weight loss on its own to be rare. They also noted that the guideline contains recommendations on safety netting. The committee noted that recommendations should be used alongside safety-netting to reduce the risk of missed cancers (including rare cancers).</p>
SH	British Gynaecological Cancer Society	Guideline	008	004-011	<p>BGCS supports the introduction of age and weight-loss thresholds for unexplained weight loss in adults aged 60 and over. We agree that this may improve referral precision and reduce unnecessary investigations in lower-risk populations.</p> <p>However, we emphasise the importance of:</p> <ul style="list-style-type: none"> <li>• Clear communication to primary care that this recommendation does not preclude referral or investigation in younger adults where clinical concern exists.</li> </ul>	<p>Thank you for your comment. The committee discussed that they consider unexplained weight loss on its own to be rare. They also noted that the guideline contains recommendations on safety netting.</p>

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					<ul style="list-style-type: none"> <li>Robust safety-netting arrangements to ensure that patients outside the defined thresholds are reviewed appropriately if symptoms persist or evolve.</li> </ul>	
SH	Cancer Research UK	Guideline	008	004-011	<p>Recc 1.13.2 – we welcome updates to the non-specific symptom recommendations based on recent, high-quality evidence.</p> <p>It may be useful to note non-specific symptoms pathway in this recommendation as a potential investigation option, to align with available pathways and potentially expedite diagnosis via avoiding multiple site-specific referrals.</p> <p>We know that those who present with non-specific symptoms, such as unexplained weight loss, typically experience longer times to diagnosis, later stage diagnosis, and diagnosis via emergency presentation<sup>iii</sup>, so providing as much guidance as possible to health professionals regarding available routes to diagnosis could support timely referral.</p> <p>We understand the age threshold suggested for investigation of unexplained weight loss aligns with the point at which risk exceeds the 3% threshold. For those aged &lt;60 years presenting with unexplained weight loss as a single symptom, they do not meet criteria for any site specific pathway based on the updated recommendation. It is worth noting in the guidelines if there is significant clinical concern in this patient group to consider investigation via non-specific symptom pathways, to support health professional decision-making.</p> <p>An example of the updated recommendation could be: 'carry out assessment for additional information that may clarify which cancer and offer urgent investigation or suspected cancer referral.'</p>	<p>Thank you for your comment. The recommendation has been updated to include a non-specific symptoms pathway referral.</p> <p>The committee discussed that they consider unexplained weight loss on its own to be rare. They also noted that the guideline contains recommendations on safety netting.</p>

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					<p>Consider referral to a non-specific symptom pathway if does not fit any site specific criteria and available in your area'</p> <p>We support more specific guidance where possible in referral guidelines and agree that a 5% UWL is regarded as clinically meaningful, warranting further investigation. As weight is infrequently recorded in primary care, consider whether referral criteria should note GP concern about weight loss as well as the proportion of weight lost, as patients may present with unquantified UWL e.g. loose fitting clothes or in response to family concern<sup>iv</sup>.</p>	
SH	AMMF	Guideline	008	006-007	Unexplained weight loss can be an early symptom of each of the biliary tract cancers - cholangiocarcinoma, gallbladder cancer and ampullary cancer – and so these should be included in the list of cancer types for which this can be a symptom.	<p>Thank you for your comment.</p> <p>The committee retained the list of potential cancer sites from the available evidence in 2015. The committee in 2015 acknowledged that the included list of potential cancer sites was a function of which cancers had been studied and that the symptoms may be due to cancers for which no evidence was (as yet) available. This is why they added the word 'including' to reflect that the list of potential cancers was not exhaustive.</p>
SH	Greater Manchester Cancer Alliance	Guideline	008	007	Unexplained wgt loss is associated also with gyane cancers esp ovarian. Needs to be included.	<p>Thank you for your comment.</p> <p>The committee retained the list of potential cancer sites from the available evidence in 2015. The committee in 2015 acknowledged that the included list of potential cancer sites was a function of which cancers had been studied and that the symptoms may be due to cancers for which no evidence was (as yet) available. This is why they added the word 'including' to reflect that the list of potential cancers was not exhaustive.</p>

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SH	Breast Cancer Now	Guideline	010	018	<p>As stated in the scope, the draft updated guideline does not include an update to section 1.14.3, which covers the information given to patients with suspected cancer and their families.</p> <p>However, we believe that this list of further information should include "information and support charities". There are many cancer charities in the UK who provide free advice and support for patients with cancer or have suspected cancer symptoms. We know at Breast Cancer Now that the advice and support that we provide to breast cancer patients and their families is often invaluable. For example, in 2023/24 we supported 836 people living with metastatic breast cancer and over 4,500 people with primary breast cancer through our services.</p> <p>One patient told us that "The (Younger Women Together) residential (organised by Breast Cancer Now) has been life changing for me. It helped me to come to terms with my diagnosis."</p> <p>Explicitly referencing these services in NICE guidelines would recognise their established role in supporting patients in their cancer journey and will strengthen and better promote the offer available to patients and their families.</p>	<p>Thank you for your comment.</p> <p>The recommendation, which is referred to in this comment, is not within the scope of this update.</p>
SH	Greater Manchester Cancer Alliance	Guideline	011	025	I know grey box but Advice and Guidance is not included as option of contacting specialist. Is this intentional?	<p>Thank you for your comment.</p> <p>Advice and guidance on contacting specialists is not within the scope of this update.</p>
SH	The International Ovarian Tumor Analysis group	Guideline	013	Table 6	The PPV of CA125 in some populations is so low that one might question the point of the test. In table 6 it states a PPV of about 3% - meaning 97% of women referred for a scan will have no adnexal pathology. This is critically important. No data is presented to indicate the likely outcome of false positive pathology following a scan and what to do about it. There seems to be a presumption that this PPV of only 3% is not potentially harmful. This again emphasises the relative lack of information about ultrasound use in	<p>Thank you for your comment.</p> <p>For those 39 and under, CA125 is not used in isolation and an ultrasound may be considered where symptoms are persistent. For those aged 40 and over, CA125 should be measured and, if the relevant threshold is reached, an ultrasound arranged. Although the PPV for women aged 40–49 falls below the preferred threshold, it still shows moderate to high sensitivity, and the committee</p>

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					the guidance. For the < 50-year-old age group the false negative rate is 37% for a CA125 cutoff of 35. This is concerning.	considered this with concerns about late diagnosis, choosing to retain the ≥35 U/ml threshold for this group.
SH	BAME Health Collaborative	Guideline	014	005	Agree with recommendations	Thank you for your comment.
SH	BAME Health Collaborative	Guideline	014	005	Agree with recommendations	Thank you for your comment.
SH	Cancer Research UK	Guideline	014	005-008	Consider providing signposting or a definition of what is considered 'expected settling-in timing' for PMB on HRT, either by linking into the definition of unexplained vaginal bleeding on HRT, or referencing evidence and recommendations from the British Menopause Society ' <a href="#">Management of unscheduled bleeding on hormone replacement therapy (HRT)</a> ' guidelines.	Thank you or your comment. The terms used does include further explanation of unscheduled vaginal bleeding on HRT, this includes within the first 6 months of starting HRT, or within 3 months of changing a dose or preparation. Any other aspects of HRT use are outwith the scope of this update.
SH	OUTpatients charity	Guideline	014	009	"Unscheduled vaginal bleeding on HRT" – This paragraph alludes to two types of hormone replacement therapy (sequential/continuous combined) that relate to oestrogen and progesterone but does not discuss testosterone, which is also a hormone. Testosterone does need to be tackled somewhere. This may mean using "GAHT" – gender affirming hormone therapy, to differentiate and perhaps make it easier to deal with the differences.	Thank you for your comment. Gender reassignment has been considered in the EHIA which notes the lack of evidence and the committee discussed the EHIA implications in their decision making and recommendation development. The HRT included within the guideline has been added within the terms used to clarify what the recommendations include. The potential impact of gender affirming therapy and cancer risks is not within the scope of this guideline update.
SH	Society of Radiographers	Guideline	014	012-013	Should this be "commonly occurs", rather than "can". Unscheduled bleeding can occur at any time when taking HRT. It <i>can</i> occur within the first 6 months of starting HRT, or within 3 months of changing a dose or preparation.	Thank you for your comment. This has been considered but remains as can as the frequency of occurrence was not considered.

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SH	The International Ovarian Tumor Analysis group	Guideline	014	020-025	<p>As seen in screening studies – a strategy of using CA125 as a first stage test is likely to miss most early-stage cancers – which remain important. Although clearly a different population – the Kings ovarian cancer screening study (reference below) showed a sensitivity of 33% for a two-step approach with CA125 as its first step. We believe it will be difficult to recruit to a trial when it is known that the index test being assessed has this level of performance.</p> <p><u>Results from an ultrasound-based familial ovarian cancer screening clinic: a 10-year observational study.</u> Taylor A, Bourne TH, Campbell S, Okokon E, Dew T, Collins WP. <i>Ultrasound Obstet Gynecol.</i> 2003 Apr;21(4):378-85. doi: 10.1002/uog.65.</p>	<p>Thank you for your comment. Ovarian cancer screening falls outside the scope of the guideline update.</p>
SH	The International Ovarian Tumor Analysis group	Guideline	014	020-025	<p>We believe there are some important research questions that need to be answered. There is a need for the real-world performance of ultrasound to be evaluated in primary care. The index test would be the use of IOTA ADNEX or the IOTA two step strategy – as discussed above. Two further important areas also need to be examined – one is the impact of appropriate education for ultrasonography in the primary care setting and the second is the possible impact of AI. The ADNEX AI approach has shown good test performance, and this approach has huge potential in primary care (See reference below). The ROCKETS study has shown that a pragmatic real-world study on ultrasound can be carried out successfully and provide the required evidence to change practice. The same approach in our view should be taken in primary care.</p> <p><u>ADNEX-AI: automated extraction of ultrasound predictors for interpretable ovarian cancer risk stratification.</u> Geysels A, Garofalo G, Timmerman S, Ceusters J, Buonomo F, Fischerová D, Testa AC, Moro F, Sladkevicius P, Jokubkiene L, Van Holsbeke C, Kudla M, Czekierdowski A, Epstein E, Groszmann Y, Blaschko M, Bourne T, De Moor B, Valentin L, Van Calster B, Timmerman D, Froyman</p>	<p>Thank you for your comment. Thank you for your comment and the reference. The use of systems such as IOTA and O-RADS are used mainly in secondary care and not routinely applied in primary care. As such these systems fall outside the scope of this partial update. Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). HTG 453 includes IOTA ADNEX and other models</p>

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					W.NPJ Precis Oncol. 2025 Dec 11;10(1):18. doi: 10.1038/s41698-025-01215-x.	
SH	British Gynaecological Cancer Society	Guideline	014	021-025	<p>Research recommendations currently include evaluation of the dual use of CA125 and ultrasound in primary care versus sequential testing. We highlight that answering this question would need an extremely large prospective trial in primary care ( several thousand participants) – inferring results from a well conducted prospective study from an urgent suspected cancer referred population is much more feasible and has already been conducted ( ROCKeTS).</p> <p>Research recommendations to evaluate ultrasound risk prediction models and scores that can provide objective risk assessment in primary care are explicitly needed.</p> <p>Artificial intelligence models have great promise in accurate estimation of Ovarian cancer risk ( Geysels et al NPJ 2025, <a href="https://www.nature.com/articles/s41698-025-01215-x">https://www.nature.com/articles/s41698-025-01215-x</a>, Epstein, Nature Medicine, <a href="https://www.nature.com/articles/s41591-024-03329-4">https://www.nature.com/articles/s41591-024-03329-4</a> ). An additional research recommendation to evaluate AI enabled ultrasound in primary care is needed.</p>	<p>Thank you for your comment.</p> <p>Thank you for your comment and the reference. Serum CA125 and pelvic ultrasound are recommended as the initial investigations for those presenting to primary care with signs or symptoms that may be suggestive of ovarian cancer. The use of systems such as IOTA and O-RADS are used mainly in secondary care and not routinely applied in primary care. As such these systems fall outside the scope of this partial update.</p> <p>Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). HTG 453 includes IOTA ADNEX and other models</p> <p>The use of AI enabled ultrasound in primary care falls outside the scope of this update.</p>
SH	University of Birmingham	Guideline	014	021-025	<p>Research recommendations currently include evaluation of the dual use of CA125 and ultrasound in primary care versus sequential testing. We highlight that answering this question would need an extremely large prospective trial in primary care (several thousand participants). Inferring test accuracy in primary care from a well conducted prospective study from an urgent suspected cancer referred population was an approach accepted by NIHR as a more pragmatic and efficient use of research funds; findings from this prospective study have already been reported (ROCKeTS).</p>	<p>Thank you for your comment.</p> <p>Serum CA125 and pelvic ultrasound are recommended as the initial investigations for those presenting to primary care with signs or symptoms that may be suggestive of ovarian cancer. The use of systems such as IOTA and O-RADS are used mainly in secondary care and not routinely applied in primary care. As such these systems fall outside the scope of this partial update.</p> <p>Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify</p>

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					<p>Research recommendations from ROCKETS include the need for evaluation of ultrasound risk prediction models and scores that can provide objective risk assessment in primary care.</p> <p>Artificial intelligence models have great promise in accurate estimation of Ovarian cancer risk ( Geysels et al NPJ 2025, <a href="https://www.nature.com/articles/s41698-025-01215-x">https://www.nature.com/articles/s41698-025-01215-x</a>, Epstein, Nature Medicine, <a href="https://www.nature.com/articles/s41591-024-03329-4">https://www.nature.com/articles/s41591-024-03329-4</a> ). An additional research recommendation to evaluate AI enabled ultrasound in primary care is needed.</p>	<p>people at high risk of ovarian cancer). HTG 453 includes IOTA ADNEX and other models                      The use of AI enabled ultrasound in primary care falls outside the scope of this update.</p>
SH	Cancer Research UK	Guideline	014	021-025	<p>We agree with the research recommendation that further evidence is required to understand the impact of dual testing CA125 and ultrasound on patient outcomes. The dual-testing approach is already implemented in Scotland, and is recommended in their latest guideline update, published in 2025.</p> <p>Wu et al (2025)<sup>v</sup> demonstrates using a dual testing approach detects more cancers, and the <a href="#">British Gynaecological Cancer Society (BGCS) Practice Recommendations</a> note this approach may be more sensitive for earlier diagnosis. However, dual testing requires significantly more referrals and secondary care investigations and was not deemed to reach the NICE cost-effectiveness threshold of £30,000 per QALY gained.</p> <p>Summary of the results are outlined below:</p> <ul style="list-style-type: none"> <li>for those aged &lt;50 years, concurrent age-adjusted CA125 thresholds and U/S detect 59-60% of ovarian cancers, while referring 1.1-1.2% of the cohort into secondary care. This is compared to dual testing, which detects 92-96% of ovarian cancers, while referring 18-23% of the cohort into secondary care.</li> </ul> <p>for those aged &gt;50 years, concurrent, age-adjusted CA125 and U/S detect 90% of ovarian cancers while referring 5.7-5.8% of the cohort into secondary care. This is compared to dual testing, which</p>	<p>Thank you for your comment and additional information.</p> <p>The scope of this partial update included an evaluation of dual testing with CA125 and pelvic ultrasound. The committee was aware of the economic evidence you refer to and used it to inform the concurrent age-specific CA125 thresholds. The committee was also aware that the modelling study included a comparator strategy incorporating dual testing, which as you state was found not to be not cost effective and to have significant resource implications. Given the lack of effectiveness evidence, the committee considered that modelling evidence alone was insufficient to support any change to the current recommendations. As a result, the committee developed a research recommendation in this area.</p>

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					detects 97-98% of ovarian cancers, while referring 21-23% of the cohort into secondary care.	
SH	OUTpatients charity	Guideline	015	001	Research Recommendations: Unscheduled bleeding on HRT – This statement should be broader to talk about “different types of HRT” or to explicitly include testosterone if it is not being used under this definition.	Thank you for your comment. Gender reassignment has been considered in the EHIA which notes the lack of evidence and the committee discussed the EHIA implications in their decision making and recommendation development. The HRT included within the guideline has been added within the terms used to clarify what the recommendations include. The potential impact of gender affirming therapy and cancer risks is not within the scope of this guideline update.
SH	Cancer Research UK	Guideline	015	001-004	We agree with this research recommendation, and would welcome additional detail such as considering age, and HRT status.	Thank you for your comment. The related evidence review includes a research recommendation protocol outline, this includes suggestions to stratify evidence by a number of groups, including peri and post menopausal, age, and other factors.
SH	The International Ovarian Tumor Analysis group	Guideline	016	016-017	This section refers to likely increased ultrasound use. This again emphasises the importance of the guidance being clear on how the scans should be carried out and how any masses if found should be characterised. Unless clarity is provided on this, we are concerned that ultrasound scans may be misinterpreted leading to unforeseen test and economic outcomes.	Thank you for your comment. The details of how scans should be carried out and how any masses found should be characterised fall outside the scope of the guideline update.
SH	University of Birmingham	Guideline	Equality and Health Inequalities assessment	General	The committee acknowledges that CA125 in younger women is not an accurate indicator.  In ignoring the substantial evidence on ultrasound scoring and tests that combine CA125 and ultrasound to provide objective risk assessment, the draft NICE guideline fails to meet standards of equality of care for younger women.	Thank you for your comment. Serum CA125 and pelvic ultrasound are recommended as the initial investigations for those presenting to primary care with signs or symptoms that may be suggestive of ovarian cancer.  The use of systems such as IOTA and O-RADS are used mainly in secondary care and not

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						<p>routinely applied in primary care. As such these systems fall outside the scope of this partial update.</p> <p>Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). HTG 453 includes IOTA ADNEX and other models. The question of dual testing with serum CA125 and ultrasound for suspected ovarian cancer was included in the scope of this update. However, no evidence was identified, and therefore no recommendation on dual testing can be made.</p>
SH	British Society of Gastrointestinal and Abdominal Radiology	Guideline	General	General	Ovarian and endometrial cancer do not fall within the remit of our society, so not reviewed/commented on	Thank you for your comment.
SH	British Society of Gastrointestinal and Abdominal Radiology	Guideline	General	General	a new and updated recommendation on non-site-specific weight loss (recommendation 1.13.2): We have reviewed the bits that we have expertise on and are content.	Thank you for your comment.
SH	Society of Radiographers	Guideline	General	General	There are concerns about the potential increase in gynaecological ultrasound referrals and resource gap (ultrasound practitioners particularly sonographers and ultrasound appointment slots), which have been acknowledged in the draft guideline.	Thank you for your comment.
SH	Society of Radiographers	Guideline	General	General	A comment was raised about the ovarian cancer pathway for the under 40s. As there is evidence that CA125 in the under 40 age category is not a sensitive test for ovarian malignancy, is there evidence to suggest that the straight-to-ultrasound pathway is better?	Thank you for your comment. Ultrasound scan is recommended for those under 39 with persistent symptoms that suggest ovarian cancer and for those 40 and over with CA125 levels at the various age group bandings.

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					The guideline offers no quantifiable evidence on whether straight-to-ultrasound improves cancer detection, reduces time to diagnosis, or leads to significant over-investigation. While there is a comment regarding activity change, there does not appear to be a strong acknowledgement regarding the impact this will have on services generally, particularly on downstream effects on service capacity, potentially slowing cancer diagnostic pathways.	Ultrasound scan is the established next step and assessing whether a straight-to-ultrasound pathway is better was outside the scope of this update. Given the low prevalence of ovarian cancer in those under 39 years these changes are not expected to have a significant resource impact.
SH	Target Ovarian Cancer	Guideline	General	General	Overall Target Ovarian Cancer welcomes the recommendation 1.5.9 on age related thresholds for women aged 40 and over. We consider that, overall, the thresholds will support clinical decision making better than a universal threshold of 35IU/ml.	Thank you for your comment.
SH	Target Ovarian Cancer	Guideline	General	General	We consider that recommendations 1.5.6 and 1.5.7 have the potential to give GPs more leverage to request and insist upon ultrasound imaging for patients where there is a suspicion of ovarian cancer as referral is no longer contingent on a raised serum CA125.	Thank you for your comment. Ultrasound scan is recommended for those under 39 with persistent symptoms. Given the low prevalence of ovarian cancer in those under 39 years these changes are not expected to have a significant resource impact.
SH	Target Ovarian Cancer	Guideline	General	General	We urge NICE to prioritise an update of CG122 as a matter of urgency, in line with the changes to NG12 1.5.6 – 1.5.11 so that the primary care community are receiving consistent guidance based on the latest evidence.	Thank you for your comments. The relevant recommendations in CG122 will be amended in line with this guideline on publication.
SH	Breast Cancer Now	Guideline	General	General	More widely, we believe that NICE should distinguish between symptoms that are suggestive of a possible primary cancer diagnosis, and symptoms that may indicate metastatic disease in people with a previous primary cancer diagnosis. In addition to the cancers listed in the Suspected Cancer guideline, these symptoms can also be red flags for advanced cancers, including metastatic breast cancer.  We would recommend either a dedicated section on metastatic cancers, or clearer framing within the existing Suspected Cancer guideline, to address the symptoms that may indicate that a	Thank you for your comment. Suspected breast cancer symptoms are not within the scope of this update. Topics for inclusion in possible future updates can be suggested via NICE's topic suggestion process. <a href="#">Prioritising our guidance topics   NICE</a>

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					<p>patients' cancer has spread. This will allow non-specific symptoms such as unexplained weight loss and a loss of appetite to be framed in the context of disease progression, rather than being combined with lists that concern early-stage cancers.</p> <p>Our research indicates the impact of this gap on clinical practice. 34% of primary healthcare professionals told us that they do not have a good understanding of the signs and symptoms of metastatic breast cancer and could benefit from further guidance<sup>1</sup>. In addition, 44% of GPs also told us that linking non-specific symptoms with metastatic breast cancer was the biggest challenge they faced in identifying patients with potential metastatic breast cancer<sup>2</sup>.</p> <p>It is vital that primary healthcare professionals are supported to recognise these symptoms, as patients with a previous primary breast cancer often do not feel equipped to recognise these themselves. The yearly National Cancer Patient Experience Survey results have consistently found that breast cancer patients don't feel that they were given enough information about the possibility and signs of their cancer coming back or spreading. Until this year's survey, it was the cancer site with the lowest score for this question.</p>	
SH	British Gynaecological Cancer Society	Guideline	General	General	BGCS supports the overall direction of the guideline update, particularly the committee's emphasis on preserving clinical judgement, avoiding false reassurance, and strengthening safety-netting. We welcome the transparent discussion of evidence	Thank you for your comments.

<sup>1</sup> Synergy Healthcare Research commissioned by Breast Cancer Now (2024). Primary Care Attitudes to Secondary Breast Cancer Market Research. Fieldwork conducted December 2024. Sample size was 200 GPs and 50 Practice Nurses across the UK. (unpublished survey)

<sup>2</sup> Same as above

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					<p>limitations and the inclusion of research recommendations where gaps persist.</p> <p>However, we highlight several areas where clarification, caution, or further consideration may be warranted to ensure patient safety, equity of access, and consistency of practice across primary and secondary care.</p>	
SH	British Gynaecological Cancer Society	Guideline	General	General	BGCS supports the overall intent of the guideline update but recommends targeted amendments to improve diagnostic efficiency, reflect real-world practice, address inequities, and ensure internal consistency. We would welcome continued engagement with NICE during finalisation and implementation.	Thank you for your comment.
SH	University of Birmingham	Guideline	General	General	<p>The evaluation has inappropriately been restricted to evidence by both test technologies and the point in the clinical pathway where tests are used.</p> <p>The guideline has focused on treating biomarker CA125 as the only relevant triage test, for which only 2 studies have been found. The alternative use of ultrasound as a triage test has been ignored and all relevant studies excluded, despite the substantial evidence of the accuracy of Ultrasound scoring systems for Ovarian cancer.</p> <p>The guideline has inappropriately focused on investigations in primary care and thus omitted evidence of the accuracy of test technologies which can be delivered in urgent suspected cancer referral units (and can be delivered in NHS Community Diagnostic Centres) which are key in NHS pathways.</p> <p>This has led to the evaluations missing a significant part of the evidence base, including the NIHR HTA ROCKeTS study, prioritised and commissioned by NIHR to provide evidence for this NICE Guideline and meet NHS patient needs.</p>	<p>Thank you for your comment and the reference provided.</p> <p>Serum CA125 and pelvic ultrasound are recommended as the initial investigations for those presenting to primary care with signs or symptoms that may be suggestive of ovarian cancer. The use of systems such as IOTA and O-RADS are used mainly in secondary care and not routinely applied in primary care. As such these systems fall outside the scope of this partial update.</p> <p>Risk prediction models applied in secondary care fall outside the scope of this partial update.</p> <p>Consideration is currently being given via NICE's prioritisation process on a possible update of HTG 453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). HTG 453 includes IOTA ADNEX and other models.</p>

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					<p>The relevant evidence base is available in a 2022 Cochrane review; which summarises 59 relevant studies:</p> <p>1) Davenport C, Rai N, Sharma P, Deeks JJ, Berhane S, Mallett S, Saha P, Champaneria R, Bayliss SE, Snell KI, Sundar S. Menopausal status, ultrasound and biomarker tests in combination for the diagnosis of ovarian cancer in symptomatic women. Cochrane Database Syst Rev. 2022 Jul 26;7(7):CD011964. doi: 10.1002/14651858.CD011964.pub2;</p> <p>The ROCKeTs post-menopausal study - A multicentre, prospective diagnostic accuracy study with 1242 recruited newly presenting post-menopausal female patients aged 16–90 years with non-specific symptoms and raised CA125 or abnormal ultrasound results (or both) who had been referred via rapid access( urgent suspected cancer pathway), elective clinics, or emergency presentations from 23 NHS hospitals in the UK.</p> <p>2) Sundar S, Agarwal R, Davenport C et al. (2024) Risk-prediction models in postmenopausal patients with symptoms of suspected ovarian cancer in the UK (ROCKeTS): a multicentre, prospective diagnostic accuracy study. The Lancet. Oncology 25(10): 1371-1386. DOI: <a href="https://doi.org/10.1016/S1470-2045(24)00406-6">10.1016/S1470-2045(24)00406-6</a>;</p> <p>And the ROCKeTs post-menopausal study - A multicentre, prospective diagnostic accuracy study with 1211 recruited newly presenting pre-menopausal female patients with non-specific symptoms and raised CA125 or abnormal ultrasound results (or both) who had been referred via rapid access ( urgent suspected cancer pathway), elective clinics, or emergency presentations from 23 NHS hospitals in the UK.</p>	

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					<p>3) Sundar S, Agarwal R, Scandrett K, Davenport C, Van Calster B, Johnson S et al. Diagnostic tests for ovarian cancer in premenopausal women with non-specific symptoms (ROCKeTS): prospective, multicentre, cohort study BMJ 2026; 392 :e083912 doi:10.1136/bmj-2024-083912</p> <p>It is unclear, but very concerning, that the NICE Guideline process appears to have failed. As experts in the clinical field, evidence synthesis and test evaluation, we recommend that the Guideline process is re-started from the point assessing the guideline questions, through to the evaluation synthesis and health economic evaluations. Below, we discuss some of the details, but the problems are far greater than that can be modified by text changes in the Guideline.</p>	
SH	University of Birmingham	Guideline	General	General	<p>Impact on Implementation – Cancer Research UK data shows that cancer conversion from an urgent suspected cancer referral across all ages is 2.9% of over 280,000 women referred from primary care in 2022/23 falling below the 3% PPV established by NICE. (CRUK <a href="https://crukcanerintelligence.shinyapps.io/EarlyDiagnosis/?urn=&amp;utm_medium=email&amp;utm_source=mcmp&amp;utm_campaign=22CIN4&amp;utm_content=22CIN4001&amp;utm_team=Cancer%20Intelligence_IN_22CIN4_July2022">https://crukcanerintelligence.shinyapps.io/EarlyDiagnosis/?urn=&amp;utm_medium=email&amp;utm_source=mcmp&amp;utm_campaign=22CIN4&amp;utm_content=22CIN4001&amp;utm_team=Cancer%20Intelligence_IN_22CIN4_July2022</a>)</p> <p>We have previously highlighted the low conversion rate of 1% in women under 40 years and the severe anxiety and distress experienced by younger women referred through this pathway. Kwong et al. 2024 – ROCKeTS substudy <a href="https://doi.org/10.1111/1471-0528.17813">doi.org/10.1111/1471-0528.17813</a></p>	<p>Thank you for your comment. The guideline update therefore sought to establish age-specific serum CA125 thresholds. The broader psychological impact of cancer testing falls outside the scope of this update.</p> <p>Serum CA125 and pelvic ultrasound are recommended as the initial investigations for those presenting to primary care with signs or symptoms that may be suggestive of ovarian cancer. The use of systems such as IOTA and O-RADS are used mainly in secondary care and not routinely applied in primary care. As such these systems fall outside the scope of this update. Consideration is currently being given via NICE's prioritisation process on a possible update of HTG</p>

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					<p>A key contribution to unnecessary referral is <u>the absence of NICE NG12 recommendation on structured ultrasound triage</u> – resulting in many women with physiological ovarian cysts being referred through this pathway.</p> <p>In not taking this opportunity to address evidence gaps in previous NICE guidance, the committee risk further increasing referrals, reducing the cancer conversion rate, wastage of NHS resource by increasing secondary care referrals and most importantly causing unnecessary severe anxiety and distress to women referred through this pathway.</p> <p>We reiterate that the evidence summary is flawed and therefore the draft guideline is unsound.</p>	453 (was DG31 Tests in secondary care to identify people at high risk of ovarian cancer). HTG 453 includes IOTA ADNEX and other models
SH	NICE GP Reference Panel	Guideline	General	General	<p>I realise it is contentious, and a NICE style decision, but I wish the recs could be written without the repetition of the long form of "women, and trans men and non-binary people with female reproductive organs" - it really reduces readability. Why can't NICE just state at the beginning, "when referring to women in the recommendations this is used a shorthand for women, and trans men and non-binary people with female reproductive organs"?</p> <p>The guideline is well balanced; clear and the update is important</p> <p>The revised recommendations are likely to support more consistent and confident referral decisions and promote earlier and more appropriate investigation of patients with non-specific but higher-risk presentations.</p> <p>In particular, the new recommendation on unexplained weight loss in adults aged 60 and over is helpful. By defining weight loss more explicitly and linking it to action, the guidance should encourage more objective weight measurement (including patient-reported weights in remote consultations), clearer documentation of weight trends over time, and a more systematic assessment for</p>	<p>Thank you for your comment.</p> <p>NICE uses gender inclusive language when possible to be inclusive of people who do not identify with the sex they were registered with (or assigned) at birth Most of the recommendations in the guideline are not sex-specific and are written as 'people'. We do appreciate that spelling out the populations covered in full can make recommendations longer. The specific wording that we have used for sex-specific recommendations is line with the <a href="#">NICE Style Guide's section on sex and gender</a>, which is based on extensive user research.</p> <p>We are also aware that the language we use around sex and gender is rapidly evolving, and your feedback has been passed to our colleagues who work on the Style Guide for consideration.</p>

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					associated symptoms, rather than reliance on subjective impression alone. Given the incidence of cancer in this age group, this is a timely and proportionate update.	
SH	Royal College of Nursing	Guideline	General	General	Membership list: it is not clear if any of the committee members have experience in the clinical signs of cancers in the child or young person given the guidance declares it is for children, young people and adults.	Thank you for your comment. This update does not include any recommendations for children. When children's recommendations are updated, NICE ensures appropriate representation on the committee.
SH	Royal College of Nursing	Guideline	General	General	Acknowledge that this is a specific update for prostate, ovarian and endometrial cancers which are rare in the under 24s (NICE's upper age range for young people), particularly prostate cancer. However, ovarian tumours do present in young women, particularly during puberty and given this can be difficult to identify, the guidance could offer advice for primary care providers about recognising clinical signs/symptoms of these cancers, given other diagnostic tests are not reliable in the younger age ranges.	Thank you for your comment. The concern relating to the difficulties of diagnosis in younger women was noted by the committee and they included within the recommendation the clinical concern and risk of late diagnosis for this group. Recommendations are used alongside clinical judgement. Where symptoms persist but test results do not support urgent referral, clinicians should continue to use their clinical judgement and safety netting (see Safety netting section).
SH	Royal College of Nursing	Guideline	General	General	Whilst they have mentioned within the non-updated guidance that parents and carers should be listened to, it is important to add that young people with gynaecological problems may present without parents and may require time and additional support (such as question prompts) to declare concerns as potential novices in managing their own health needs independent of parents.	Thank you for your comment. Barriers young people may face when seeking care for gynaecological symptoms are not in the scope for this update. The guideline has not explicitly outlined the issue you have raised, NG12 already cross refers to one of NICE's foundational guidelines on ' <a href="#">Babies, children and young people's experience of healthcare</a> ' (NG204) which describes good patient experience for babies, children and young people, and makes recommendations on how it can be delivered..

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SH	Royal College of Nursing	Guideline	General	General	For the Gynae cancer section, it would be good to have some clarification around if a Ca125 has been ordered despite not being recommended if aged 39 or under (i.e. from another clinician or department) and if would then continue to follow the guidance - whilst it states ultrasound needed if persistent symptoms, often Ca125 may be added as precaution and therefore the guidance would suit reflecting if this test was ordered in this age group, whether clinicians disregard this result or continue with the next steps as per the guidance.	Thank you for your comment. The recommendation notes that CA125 measurement should not be used in isolation for decision making for ovarian cancer in those under 39 years. This acknowledges that it may have been ordered but notes the inaccuracy of the measurement in this group.
SH	Royal College of Nursing	Guideline	General	General	Symptoms of concerns in adults - it states for 1.13.2 that if weight loss symptoms then further investigations should be carried out, whilst appreciate may be out of the scope of the document, it does not state which investigations which would be useful for less experienced clinicians such as MUST score, bloods, medication reviews etc.	Thank you for your comment. The specific tests to be performed are out of scope of this guideline. The specific tests are listed as part of the <a href="#">NHS Rapid cancer diagnostic and assessment pathways</a> .
SH	Cancer Research UK	Guideline	General	Ovarian	Consider whether the flow of the guideline could help with the clarity of recommendations. Previous unpublished qualitative research, commissioned by Cancer Research UK <sup>3</sup> , found that time is a key barrier for GPs when utilising referral guidelines, and guidelines that are concise and easily accessible are more likely to be used. The guideline format could be simplified and follow the decision-making process for this cancer site such as: symptoms that warrant CA125, CA125 thresholds, when an ultrasound is warranted, when an urgent suspected cancer referral is warranted, and safety netting recommendations.	Thank you for your comment. We are currently developing a new content management system which will aim to present our guidelines content in a componentised and easily searchable format. It would be helpful if you could share the research with the team, and we can use this to inform the platform that we are developing.
SH	British Gynaecological Cancer Society	Methods	General	General	BGCS notes that there is no consultant radiologist or sonographer in the committee to provide expert input in the additional value of ultrasound. Furthermore there is only one general obstetrician and gynaecologist on the panel and none of the panel members appear to have expertise or an interest in gynaecological cancer or gynaecological cancer diagnostics.	Thank you for your comment. The committee includes a radiologist with an academic background, who is also an interventional radiologist. As this guideline is based within primary care and considers investigations within primary care and

<sup>3</sup> Qualitative interviews and focus groups of a representative sample of 48 GPs across the UK.

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					The BGCS would recommend a consultant radiologist, sonographer and a gynaecologist with an interest in gynaecological cancer or gynaecological cancer diagnostics and/or a representative of the BGCS be involved in future drafts of this guidance.	onwards referral processes the majority of the committee are those who work within primary care.
SH	University of Birmingham	Methods	General	General	We note that there is no consultant radiologist or sonographer in the committee to provide expert input on the potential value of ultrasound.	Thank you for your comment. The committee includes a radiologist with an academic background, who is also an interventional radiologist. As this guideline is based within primary care and considers investigations within primary care and onwards referral processes the majority of the committee are those who work within primary care.
SH	The Royal College of General Practitioners	Guideline	General	General	The College welcomes the updated draft guideline, which reflects evolving evidence and aligns well with contemporary primary care practice. We particularly value the explicit acknowledgement of areas of clinical uncertainty, for example in the assessment of younger people with suspected ovarian cancer and in cases of unscheduled bleeding in those using HRT. This recognition is both realistic and supportive for frontline clinicians, who frequently manage diagnostic ambiguity and would benefit from guidance that reflects the complexities of real-world decision making.	Thank you for your comment.
SH	The Royal College of General Practitioners	Guideline	General	General	We recognise that the guideline changes do not seem to take account of people with a learning disability who may not <ul style="list-style-type: none"> <li>• have anyone to articulate their symptoms for them if they cannot</li> <li>• may not recognise symptoms <a href="#">mac16332-er-e06-signs-of-cancer.pdf</a></li> <li>• may experience diagnostic overshadowing</li> </ul>	Thank you for your comment. This update focuses on the diagnostic accuracy of dual testing with CA125 and ultrasound, age thresholds, and unscheduled vaginal bleeding in adults taking HRT for the detection of suspected cancer. Whilst the recommendations developed as part of this update don't directly outline the consideration of people with a learning disability the introduction to this guideline highlights that

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					<ul style="list-style-type: none"> <li>• have earlier onset of these cancers and menopause, syndromic underlying causes</li> <li>• not have clear family history</li> <li>• evidence                             <ul style="list-style-type: none"> <li>○ <a href="#">Cancer diagnoses, referrals, and survival in people with a learning disability in the UK: a population-based, matched cohort study - The Lancet Regional Health – Europe</a></li> </ul> </li> </ul> <p><a href="#">Avoidable Cancer Deep Dive</a> from LeDeR reviews</p>	healthcare professionals should follow other NICE guidelines for people delivering care. NG12 refers to guideline 108 Decision-making and mental capacity which aims to help health and social care practitioners support people to make their own decisions where they have the capacity to do so. It also helps practitioners to keep people who lack capacity at the centre of the decision-making process. Barriers that people with a learning disability may face, in relation to equality and health inequalities, are also addressed in the EHIA document and the committee considered equality issues throughout its discussions when updating NG12. Barriers such as new symptoms that may be attributed to an existing disability or long-term condition rather than investigated as a possible new illness. People with learning disabilities may also present cancer symptoms in atypical ways, and practical barriers such as limited transport and lack of available carers can further delay diagnosis
SH	The Royal College of General Practitioners	Guideline	004	General	<p>The College agrees that the recommendation not to use CA125 in isolation in people aged 39 and under is appropriate and reflects valid concerns about the potential for false reassurance in this group.</p> <p>We suggest that it would be helpful for the guideline to include a recommended timescale for ultrasound scanning in this context. Clear expectations around timing would support timely diagnosis and help ensure that commissioners and providers of ultrasound services can be held accountable for avoidable delays. As this referral appears to precede entry into a suspected cancer referral pathway, clarity on urgency is particularly important.</p>	<p>Thank you for your comment.</p> <p>The recommendation has been clarified to note urgent, direct access.</p> <p>Diagnostic accuracy of vaginal versus abdominal ultrasound is not within the scope of this update.</p>

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					We also recommend clarifying whether transvaginal ultrasound should be considered the preferred or more accurate initial investigation compared with transabdominal ultrasound, where appropriate. Providing this level of detail would support more consistent clinical decision making and optimise diagnostic accuracy in primary care.	
SH	The Royal College of General Practitioners	Guideline	005	General	<p>The College welcomes the recommendations on age-specific CA125 thresholds, which are clinically helpful and have the potential to improve risk stratification in primary care. However, we note that implementation may be challenging unless laboratory reporting systems clearly flag age-adjusted thresholds. NICE may therefore wish to emphasise the importance of aligned pathology reporting and decision-support prompts within GP clinical systems to support safe and consistent application in practice.</p> <p>We also welcome the emphasis on safety netting when CA125 levels do not meet referral thresholds. We suggest that the guideline could be strengthened by including a brief recommendation that practices document agreed follow-up timeframes, as variation in safety-netting practice is common and clearer documentation would support continuity and reduce the risk of delayed diagnosis.</p> <p>We remain concerned that delays in accessing ultrasound scans in primary care, once a raised CA125 has been identified, may contribute to delayed diagnosis. Given that the scan request appears to precede entry into a suspected cancer referral pathway, it would be helpful for the guideline to acknowledge this potential bottleneck and reinforce the importance of timely access to imaging.</p>	<p>Thank you for your comment. Operational processes within laboratory systems are not within the scope of this update. The guideline defines the meaning of persistent symptoms (see Terms used in this guideline section) and notes that the precise period will vary according to severity and associated features, as assessed by the health professional.</p> <p>Recommendations are intended for use alongside clinical judgement. Where symptoms persist but test results do not support urgent referral, clinicians should continue to use their clinical judgement and safety netting (see Safety netting section) to ensure that ongoing concerns are appropriately addressed.</p>
SH	The Royal College of General Practitioners	Guideline	006	General	The College recognises that signposting to British Menopause Society (BMS) guidance is a pragmatic approach in the context of limited evidence. However, we note that reliance on external guidance may introduce variability in interpretation and application.	<p>Thank you for your comment. The committee noted that the BMS recommendations are largely based on informal consensus and expert opinion, as there is limited</p>

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					NICE may therefore wish to consider including a brief summary of key practical thresholds or principles within the guideline itself to support consistency for clinicians working in primary care. We also found that the wording in this section (line 25) could be clearer. It is currently ambiguous as to whether NICE is formally recommending that clinicians follow BMS guidance or whether this is intended as optional supplementary information. Greater clarity on NICE's position would be helpful to avoid uncertainty and support confident clinical decision making.	evidence in this area. They recognised that the BMS guidance is a useful resource in practice. Considering this, the committee developed a research recommendation and agreed to raise awareness of the BMS guideline. We do not incorporate the wording into this guideline.
SH	The Royal College of General Practitioners	Guideline	008	General	The College welcomes the introduction of a defined threshold for unexplained weight loss (>5% over 6 months) in people aged 60 and over, as this provides helpful clarity for clinicians and supports more consistent decision making in primary care. It would be useful for the guideline to acknowledge the practical realities of assessing weight change in routine care, particularly the extent to which clinicians may need to rely on patient-reported weight loss rather than documented serial measurements. Clarifying how best to interpret and act on patient-reported changes, especially where objective data are unavailable, would enhance the applicability of this recommendation in everyday practice.	Thank you for your comment. Recommendations are always intended to be used alongside clinical judgement, such as where patient-reported weight loss rather than serially documented measures may need to be used.

Organisation name – Stakeholder or respondent	Disclosure on tobacco funding / links	Comments/Action

*\*None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

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<sup>i</sup> Funston G, Hamilton W, Abel G, Crosbie EJ, Rous B, Walter FM. [The diagnostic performance of CA125 for the detection of ovarian and non-ovarian cancer in primary care: A population-based cohort study](#). PLoS Med. 2020 Oct 28;17(10):e1003295. doi: 10.1371/journal.pmed.1003295

<sup>ii</sup> British Menopause Society. [What is the menopause?](#) January 2026.

<sup>iii</sup> Pearson C, Poirier V, Fitzgerald K, Rubin G, Hamilton W. Cross-sectional study using primary care and cancer registration data to investigate patients with cancer presenting with non-specific symptoms. BMJ Open. 2020;10(1):e033008.

<sup>iv</sup> Martinez-Gutierrez J, De Mendonca L, Ly P, Lee A, Hunter B, Manski-Nankervis JA, et al. A scoping review of unexpected weight loss and cancer: risk, guidelines, and recommendations for follow-up in primary care. BJGP Open. 2024;8(4).

<sup>v</sup> Wu, R., Arendse, K.D., Hamdani, T., Walter, F.M., Crosbie, E.J., Mihaylova, B. and Funston, G. (2025). Cost-effectiveness of CA125- and age-informed risk-based triage for ovarian cancer detection in primary care. *British Journal of Cancer*. doi:https://doi.org/10.1038/s41416-025-03166-3.

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