

Consultation on draft scope

Stakeholder comments table

23 April 2025 - 28 May 2025

Stakeholder	Page no.	Line no.	Comments	Developer's response
British Association for Nutrition and Lifestyle Medicine	General	General	Insulin resistance (IR) is a major driver of PCOS pathophysiology. IR assessment, especially in early stages of PCOS, and effective evidence-based lifestyle interventions are essential to reduce risk of long-term complications, including cardiovascular disease risk. Scope of this guideline should maximise interventions to improve insulin sensitivity. All comments below are to reflect IR management. Refs: 1) Zhao H, Zhang J, Cheng X, Nie X, He B. Insulin resistance in polycystic ovary syndrome across various tissues: an updated review of pathogenesis, evaluation, and treatment. J Ovarian Res. 2023 Jan 11;16(1):9. doi: 10.1186/s13048-022-01091-0. PMID: 36631836; PMCID: PMC9832677. 2) Purwar A, Nagpure S. Insulin Resistance in Polycystic Ovarian Syndrome. Cureus. 2022 Oct 16;14(10):e30351. doi: 10.7759/cureus.30351. PMID: 36407241; PMCID: PMC9665922.	Thank you for your comment. Insulin resistance and lifestyle interventions are part of the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023. The plan is to adopt the recommendations unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline.
British Association for Nutrition and Lifestyle Medicine	002	008	Amend to "1.9 Impaired glucose tolerance, insulin resistance and type 2 diabetes"	Thank you for your comment. We have used the titles as they appear in the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023. Insulin resistance was not part of the title therefore the scope has not been updated. However, insulin resistance is part of the guideline, and the recommendations related to this will be discussed by the committee.



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British Association for Nutrition and Lifestyle Medicine	003	020	New item on Infertility: 5.10 Lifestyle interventions to reduce insulin resistance Ref: 1) Lei R, Chen S, Li W. Advances in the study of the correlation between insulin resistance and infertility. Front Endocrinol (Lausanne). 2024 Jan 26;15:1288326. doi: 10.3389/fendo.2024.1288326. PMID: 38348417; PMCID: PMC10860338. 2) Li H, Tan H, OuYang Z, Hu X, Bao Y, Gao T, Hua W. Association between METS-IR and female infertility: a cross-sectional study of NHANES 2013-2018. Front Nutr. 2025 Feb 28;12:1549525. doi: 10.3389/fnut.2025.1549525. PMID: 40093882; PMCID: PMC11906314.	Thank you for your comment. We will not be updating the evidence reviews in the International evidence-based guideline for the assessment and management of polycystic ovary syndrome. If the international guideline is updated before we publish then we are likely to update our recommendations accordingly.
British Association for Nutrition and Lifestyle Medicine	Question 1	Question 1	Lifestyle interventions should be included as wrap- around care to maximise effectiveness of all treatment options.	Thank you for your comment. This will be discussed with the committee during development. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. However, we will not be updating the evidence reviews used



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				in the International guideline and nor will we be covering areas that are not included in the International guideline.
Cinnamon Days	003	010	Assessment and treatment of non-fertility This section currently suggests consideration of specific medical testing and treatments for infertility in PCOS but makes no reference to diet and lifestyle interventions for women with PCOS presenting with infertility. However, there is evidence (1 & 2) that a dietary changes, such as adoption of a low carbohydrate or ketogenic diet can result in significant improvements to reproductive hormones in women with PCOS It is therefore suggested that the scope includes diet and lifestyle change specifically within section 5 as a first line approach to the management of infertility in these patients. 1. Karniza Khalid, Saraswathy Apparow, Irma Liyana Mushaddik, Amalina Anuar, Syed A A Rizvi, Anasufiza Habib, Effects of Ketogenic Diet on Reproductive Hormones in Women With Polycystic Ovary Syndrome, Journal of the Endocrine Society, Volume 7, Issue 10, October 2023, bvad112, https://doi.org/10.1210/jendso/bvad112 Zhang X, Zheng Y, Guo Y, Lai Z. The Effect of Low Carbohydrate Diet on Polycystic Ovary Syndrome: A Meta-Analysis of Randomized Controlled Trials, Int J Endocrinol.	Thank you for your comment. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. However, we will not be updating the evidence reviews used in the International guideline and nor will we be covering areas that are not included in the International guideline.



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			2019 Nov 26;2019:4386401. doi: 10.1155/2019/4386401. PMID: 31885557; PMCID: PMC6899277.	
Department of Health and Social Care	General	General	The Department of Health and Social Care welcomes the draft scope and the decision to implement a guideline for the assessment and management of PCOS, as this was committed to in the Women's Health Strategy (2022). We support the decision to use the MONASH International evidence-based guideline for the assessment and management of polycystic ovary syndrome (2023) as a base for the NICE guidelines, and the recommendations it suggests align with government policy.	Thank you for your support.
Department of Health and Social Care	002	019	The '2.6.2 Models of care' section of the MONASH guidelines recommends 'equitable access to evidence-based primary care with pathways for escalation to integrated specialist and multidisciplinary services as required'. We would propose NICE includes reference to community and neighbourhood models of care as well as primary care in a recommended patient pathway. This would support UK government policy to 'left shift' care into the community/neighbourhood and reduce unnecessary secondary care referrals. Women's health hubs are an example of a neighbourhood health model that operates with multidisciplinary teams and offers intermediate level care.	Thank you for your comment. This will be discussed during development of the guideline. The committee will discuss cross referring to relevant national documents or policies such as NHS England » Neighbourhood health guidelines 2025/26 and NHS England » Women's health hubs when they discuss the recommendations for the NICE guideline.
Department of Health and Social Care	002	023	The 'Lifestyle Management' section of the MONASH guidelines recognises people who have PCOS and are overweight/ obese need support and options for weight management but that there may be weight stigma involved. We welcome this statement but would suggest that NICE includes a recommendation on directing women with PCOS who are	Thank you for your comment. This will be discussed during the development of the NICE guideline. We are likely to be cross referring to the NICE guideline on overweight and obesity management. The committee will also discuss cross referring to NHS resources.



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			overweight/obese to NHS support for losing weight. This can be found on the NHS website and would be a low-cost intervention.	
Ferring Pharmaceuticals	003	015	We request NICE to refer to the BFS guidelines for prevention of ovarian hyperstimulation syndrome (OHSS): British Fertility Society policy and practise guideline 2024	Thank you for your comment. NICE does not usually cross reference other organisation guidelines in its scopes. The exception here is the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 because we are proposing adapting it as a NICE guideline.
NHS England	General	General	It is comprehensive and draws in a number of areas previously not linked to PCOS, with associated guidance and management.	Thank you for your support.
Primary Care Women's Health Society	001	001	In the absence of clinical hyperandrogenism, bloods are indicated for testosterone. Is it worth considering AMH at the same time as these as this may be required if testosterone normal.? for specific population eg adolescence or those unable to have TAUSS If testosterone levels significantly raised, then patients will require further investigations for causes of this. Relevant additional investigations are not specified in the ESHRE guideline – this would be helpful for GPs. Or even a link to another relevant NICE document	Thank you for your comment. This will be discussed with the committee during development. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the International guideline. However, we will not be updating the evidence reviews used in the International guideline and nor will we be covering areas that are not included in the International guideline.
Primary Care Women's Health Society	001	008	ESHRE states higher accuracy of OGTT. Should we be trying to do this in general practice as not particularly practical	Thank you for your comment. This will be discussed with the committee during development. The plan is to adopt the



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Primary Care Women's Health Society	001	010	Management of amenorrhoea in GP – practical prescribing for GPs would be very useful here. Specific dose/duration of progestogen treatment. Which progestogen? GPs are often concerned about safety of provera with DVT risk – perhaps insert some safety data here?	recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. The costs and accuracy, as well the feasibility of these tests, will be assessed in the development of the guideline. Thank you for your comment. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. However, we will not be updating the evidence reviews used in the International guideline and nor will we be covering areas that are not included in the International guideline. Management of amenorrhoea was not part of the International guideline.
Roche Diagnostics Limited	General	General	Roche welcome the opportunity to respond to the draft scope for the new NICE guideline on the assessment and management of polycystic ovary syndrome (PCOS). This represents an area of high clinical importance, given the	Thank you for your comment and support for the development of this guideline. The committee will discuss health inequalities when adapting recommendations and detail any issues in the equalities and health impact assessment (EHIA) form.



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Stakeholder	Page no.	Line no.	significant underdiagnosis of PCOS and considerable unmet need among those affected. Rates of PCOS diagnosis remain low in the UK, estimated at only 1.3% to 2.2% (1,2), despite a prevalence of approximately 10–13% among women of reproductive age (3). Delays in diagnosis are common, with patients attending multiple clinical visits and often waiting up to two years before receiving a confirmed diagnosis (4). The underdiagnosis of PCOS can have significant long-term consequences. PCOS raises the risk of cardiovascular disease (CVD) and stroke, and is also strongly associated with mental	Developer's response
			health disorders such as depression (8-10). PCOS also increases risks of infertility, and of developing sleep apnoea, fatty liver disease and endometrial cancer. (2,7) Timely diagnosis enables for symptom management, lifestyle interventions and can reduce the impact of these long-term complications (1).	
			Health equity is a significant concern in PCOS care, with disparities in access to care and treatment particularly affecting individuals from lower socioeconomic backgrounds (6). This is compounded by the disproportionately high prevalence of PCOS in certain ethnic communities, where rates reach as high as 50% (5,6).	



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			Roche Diagnostics wish to emphasise that the international community has significantly progressed in providing support for healthcare practitioners and women with PCOS (11), and the lack of adoption in the UK could result in missed opportunities for timely diagnosis and effective management. This guideline presents a crucial opportunity to bridge that gap in order to improve health outcomes and quality of life for women living with POCS in the UK.	
			References 1. Hillman SC, et al. Polycystic ovarian syndrome: an under-recognised problem? Br J Gen Pract. 2018;68(670):244. https://doi.org/10.3399/bjgp18X696101 2. Ding T, et al. Diagnosis and management of polycystic ovary syndrome in the UK (2004–2014): a retrospective cohort study. BMJ Open. 2016;6(7):e012461. doi:10.1136/bmjopen-2016-012461	
			 NICE. Polycystic ovary syndrome. Clinical Knowledge Summaries. Available from: https://cks.nice.org.uk/topics/polycystic-ovary-syndrome/ Gibson-Helm ME, et al. Delayed diagnosis and a lack of information associated with dissatisfaction in women with polycystic ovary syndrome. J Clin Endocrinol Metab. 2017;102(2):604–12. https://pmc.ncbi.nlm.nih.gov/articles/PMC6283441/ 	



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			 Rodin DA, et al. Polycystic ovaries and associated metabolic abnormalities in Indian subcontinent Asian women. Clin Endocrinol (Oxf). 1998;49(1):91–9. doi:10.1046/j.1365-2265.1998.00492 	
			NICE. Equality and health inequalities assessment (EHIA) for PCOS: assessment and management. NICE. Available from: https://www.nice.org.uk/guidance/GID-	
			NG10436/documents/equality-and-health-inequalities 7. Gilbert EW, et al. Comorbidities and complications of polycystic ovary syndrome: an overview of systematic reviews. Clin Endocrinol (Oxf). 2018;89(6):683–99. https://doi.org/10.1111/cen.13828	
			8. Riestenberg C, et al. Health care-related economic burden of polycystic ovary syndrome in the United States: pregnancy-related and long-term health consequences. <i>J Clin Endocrinol Metab</i> .	
			2022;107(2):575–85. doi:10.1210/clinem/dgab613 9. Oliver-Williams C, et al. Risk of cardiovascular disease for women with polycystic ovary syndrome: results from a national Danish registry cohort study. <i>Eur J Prev Cardiol</i> . 2021;28(12):e39–41. doi:10.1177/2047487320939674	
			10. Yadav S, et al. Direct economic burden of mental health disorders associated with polycystic ovary syndrome: systematic review and meta-analysis. <i>Elife</i> . 2023;12:e85338. doi:10.7554/eLife.85338.	



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Roche	General	General	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC104711 60/ 11. Teede HJ, et al. Algorithm 1: Screening, diagnostic assessment, risk assessment and life stage. In: International evidence-based guideline for the assessment and management of polycystic ovary syndrome 2023. Melbourne: Monash University; 2023. Available from: Roche Diagnostics wishes to emphasise that there are five	Thank you for your comment. The plan is to adopt the
Diagnostics Limited	General	General	focus areas in the clinical section of the NHS Greener Plan Guidance, one of which is diagnostics tests and procedures (1). Offering AMH as an alternative to TUVS for the identification of PCOM in the diagnosis of PCOS has the potential to significantly reduce NHS carbon emissions. Research by the Oxford and Thames Valley Health Innovation Network using the Elecsys® AMH Plus immunoassay estimates that integrating the AMH blood test into the patients existing phlebotomy appointments contributes to an overall carbon reduction for the NHS of approximately 3000 tonnes of CO2 annually (2).	recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. The Greener plan was not part of the decision in the international guideline and is unlikely to be part of the recommendations in the NICE guideline.
			References 1. Health Innovation Kent Surrey Sussex. Polycystic ovary syndrome test has potential to improve patient experience and reduce NHS carbon footprint]. 2024. Available from: https://healthinnovation-kss.com/polycystic-ovary-syndrome-test-has-potential-	



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			to-improve-patient-experience-and-reduce-nhs-carbon-footprint/ 2. NHS England. Green plan guidance. NHS England. 2025. Available from: https://www.england.nhs.uk/long-read/green-plan-guidance/:contentReference[oaicite:3]{index=3}	
Roche Diagnostics Limited	General	General	Roche Diagnostics wishes to highlight that the current economic burden of PCOS is substantial, driven by the costs of diagnosis, ongoing management, and treatment of comorbid conditions (1). The introduction of Elecsys® AMH Plus immunoassay may represent a cost-efficient alternative to TVUS in the diagnostic pathway for PCOS, reducing the economic burden associated with a PCOS diagnosis. A health economic study has been conducted to assess the economic impact of using the Elecsys® AMH Plus immunoassay in the UK to identify PCOM as part of POCS assessment in women aged 25-45 with signs and symptoms of PCOS. Preliminary findings were presented as a poster at ISPOR 2024 (3). The manuscript for the complete analysis is currently close to publication following completion of the peer review process (2). Roche are willing to provide the manuscript to NICE in confidence, should they wish to review it prior to publication. The model estimated cost and health outcomes using a	Thank you for your comment and alerting us to this study. We will be undertaking a systematic review of the health economic literature for this guideline and will look out for this publication. We will also look at the references cited in your comment. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline.
			decision-tree structure, which assumed the 2023 International	



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Stakeholder	Page no.	Line no.	Evidence-based Guidelines were followed, and was conducted from the perspective of the UK NHS. The comparator scenario was the standard of care, where TVUS was used for assessment. The model structure and main assumptions were validated with clinical experts. Current base case results indicate that the Elecsys® AMH Plus immunoassay could lead to cost savings of approximately £284,029 per year on the total cost of PCOS diagnosis in the UK health system when compared to the use of TVUS. The model also predicted that the UK NHS would benefit by increasing the number of women correctly diagnosed with PCOS. In addition, the model predicts that the use of the Elecsys® AMH Plus immunoassay could reduce the number of cases of T2D and stroke per year, which in turn contributes to significant predicted cost savings due to reduced expenditures associated with managing these secondary comorbidities. Cost savings with the Elecsys® AMH Plus immunoassay were observed in all scenarios versus TVUS, including those with various referral rates to specialists and dropout rates from the diagnosis pathway, and even with low adherence to lifestyle recommendations (3). Overall, incorporating Elecsys® AMH Plus immunoassay could help streamline care, reduce costs, and improve outcomes for	Developer's response
			patients with PCOS.	
			References	



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			 Riestenberg C, et al. Health care-related economic burden of polycystic ovary syndrome in the United States: pregnancy-related and long-term health consequences. <i>J Clin Endocrinol Metab</i>. 2022;107(2):575–85. doi:10.1210/clinem/dgab613 Garay et al. (2025). Economic impact of the Elecsys anti-Müllerian hormone Plus immunoassay for anti-Müllerian hormone testing as part of polycystic ovary syndrome assessment in the United Kingdom. Unpublished manuscript; manuscript submitted for publication. Garay et al. (2024).Cost consequence analysis of using the Elecsys Anti-Müllerian Hormone Plus immunoassay as part of polycystic ovary syndrome assessment in the United Kingdom. <i>ISPOR Europe, November 2024</i>. Available from: https://www.ispor.org/docs/default-source/euro2024/isporeurope24garayee162poster141 823-pdf.pdf?sfvrsn=e077b5f7_0 	
Roche Diagnostics Limited	002	003	Elevated Anti-Müllerian Hormone (AMH) levels are now recognised as an alternative to transvaginal ultrasound (TVUS) for confirming polycystic ovarian morphology (PCOM) in the updated European Society of Human Reproduction and Embryology (ESHRE) Rotterdam diagnostic guideline for PCOS (1). Other national guidelines, including the Monash algorithm in Australia, have also adopted AMH for this purpose	Thank you for your comment. This will be discussed with the committee during development. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact),



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			(2). In line with this international guidance, we strongly suggest that AMH is recommended within the NICE guideline, as an alternative to TVUS to diagnose PCOM as part of the PCOS diagnostic process. We also recommend leveraging the extensive resources and expertise available through Monash regarding PCOS diagnosis and management (6) Notably, as ESHRE guidance outlines for the diagnosis of PCOM, where irregular menstrual cycles and hyperandrogenism are present, TVUS or AMH are not required for diagnosis. Importantly, in adolescents, both hyperandrogenism and ovulatory dysfunction are required, with ultrasound and AMH not yet recommended (1). Relying solely on TUVS to identify PCOM has limitations, including issues with cost, accessibility, diagnostic accuracy, and patient acceptability. TVUS is costly and invasive which may be unsuitable for some individuals and is often not feasible in primary care settings, leading to delays in diagnosis (1,3). Additionally, the procedure's accuracy can vary due to factors such as the patient's age, phase of the menstrual cycle and BMI (4,5). AMH testing offers a practical, non-invasive alternative that can be performed alongside other routine blood tests in any healthcare setting. We therefore emphasise the importance of including AMH as a diagnostic option for PCOM within the guideline.	availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. In this case we will discuss with the committee whether we need to conduct original heath economic modelling in this area.
			References	



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			 Teede HJ, et al. Recommendations from the 2023 international evidence-based guideline for the assessment and management of polycystic ovary syndrome. <i>Hum Reprod</i>. 2023;38(9):1655–73. doi:10.1093/humrep/dead156 	
			2. Teede HJ, et al. Algorithm 1: Screening, diagnostic assessment, risk assessment and life stage. In: International evidence-based guideline for the assessment and management of polycystic ovary syndrome 2023. Melbourne: Monash University; 2023.	
			Available from: https://mchri.org.au/wp-content/uploads/2023/10/Algorithm1-1.pdf	
			 Lujan ME, et al. Assessment of ultrasonographic features of polycystic ovaries is associated with modest levels of inter-observer agreement. <i>J Ovarian</i> Res. 2009;2:6. doi:10.1186/1757-2215-2-6. Available 	
			from: https://ovarianresearch.biomedcentral.com/articles/10. 1186/1757-2215-2-6 4. Anderson RA, et al. Prospective study into the value of the automated Elecsys antimüllerian hormone assay for the assessment of the ovarian growing follicle pool.	
			 Fertil Steril. 2015. doi:10.1016/j.fertnstert.2015.01.004 Parry JP, et al. [Title not provided]. Endotext [Internet]. South Dartmouth (MA): MDText.com, Inc.; 2000–2019. PMID: 25905286 	
			Monash. PCOS Guideline and Resources. Available from: https://www.monash.edu/medicine/mchri/pcos	



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Roche Diagnostics Limited	002	004	Roche Diagnostics strongly support the inclusion of AMH testing within the NICE guideline to support the diagnosis of PCOM as part of the PCOS assessment. AMH testing is a practical and non-invasive method that can be conveniently ordered alongside the other blood tests required to aid in PCOS diagnosis. AMH testing can be requested in any healthcare setting, including primary care. International guidelines, such as the updated 2023 international evidence based guidelines for the diagnosis and management of PCOS, recommend that either serum AMH or TVUS may be used to define PCOM, however, both tests should not be performed to limit unnecessary use of resources (1). Incorporating AMH into the diagnosis of PCOM can thus reduce the need for referrals for TVUS and associated follow-up appointments, streamlining the diagnostic pathway and enabling earlier diagnosis. The accuracy of TVUS can be affected by factors such as the patient's age and phase of the menstrual cycle (2). Additionally, identifying PCOM via TVUS is challenging in women with elevated BMI, a common characteristic of PCOS patients (3–4). In contrast, the AMH test uses a single cut-off to provide a clear positive or negative result for PCOM, eliminating the ambiguity often seen with ultrasound findings. Furthermore, patient preference for a non-invasive blood test over an invasive scan may improve acceptability, reduce	Thank you for your comment. This will be discussed with the committee during development. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. In this case we will discuss with the committee whether we need to conduct original heath economic modelling in this area.



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			appointment cancellations, and minimise wasted resources. The turnaround time for a blood test is often less than one week, which is significantly shorter than typical waiting times for scans, thereby helping to reduce wait lists (5,6).	
			The use of AMH is standard practice in fertility care in the UK and is therefore well-established in laboratories, with all laboratory networks in England already having access to AMH testing. As a non-acute test, AMH analysis is frequently centralised, enhancing laboratory and workforce efficiency.	
			Roche Diagnostics wishes to emphasise that there are small differences between AMH assays offered by different manufacturers; therefore, assay-specific cut-offs are necessary and should be validated individually by each manufacturer. As part of the ESHRE review for the 2023 PCOS guideline update, the committee accepted the AHRODITE study as the validated cut-offs for the CE marked Elecsys® AMH Plus immunoassay for confirmation of PCOM (7,8).	
			References 1. Teede HJ, et al. Recommendations from the 2023 international evidence-based guideline for the assessment and management of polycystic ovary syndrome. <i>Hum Reprod</i> . 2023;38(9):1655–73. doi:10.1093/humrep/dead156	



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			 Anderson et al. (2015). Prospective study into the value of the automated Elecsys antimüllerian hormone assay for the assessment of the ovarian growing follicle pool. Fertility and Sterility, 103(4), pp.1074–1080.e4. https://doi.org/10.1016/j.fertnstert.2015.01.004 	
			3. Parry, J.P. et al., Endotext [Internet]. South Dartmouth (MA): MDText.com, Inc.; 2000–2019. PMID: 25905286; Bookshelf ID: NBK279058.	
			 Nylander et al. (2017). Ovarian morphology in polycystic ovary syndrome: estimates from 2D and 3D ultrasound and magnetic resonance imaging and their correlation to anti-Müllerian hormone. Acta Radiologica, 58(8), pp.997–1004. https://doi.org/10.1177/0284185116676656 	
			5. Royal College of Obstetricians and Gynaecologists (2022) Left for too long: Understanding the scale and impact of gynaecology waiting lists. Available at: https://www.rcog.org.uk/about-us/campaigning-and-opinions/addressing-waiting-times-gynaecology/left-for-too-long/	
			6. Royal College of Obstetricians and Gynaecologists (2022) Waiting for a way forward: Voices of women and healthcare professionals at the centre of the gynaecology care crisis. Available at: https://www.rcog.org.uk/about-us/campaigning-and-opinions/addressing-waiting-times-gynaecology/waiting-for-a-way-forward/	



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			 Dietz de Loos, A., et al. Antimullerian hormone to determine polycystic ovarian morphology. Fertil Steril. 2021 Oct; 116(4):1149-1157. doi: 10.1016/j.fernstert2021.05.094. Roche Diagnostics Product Specifications. Elecsys® AMH Plus. Available from: https://diagnostics.roche.com/global/en/products/lab/elecsys-amh-plus-cps-000433.html 	
Roche Diagnostics Limited	002	005	Roche Diagnostics wishes to emphasise that there has been a significant increase in the availability of AMH testing through private providers. Without nationally supported access to AMH testing, individuals from marginalised groups, such as those identified in the CORE20PLUS5 framework, including women, ethnic minorities, and those living in socioeconomically deprived areas, may be disproportionately excluded. This risks exacerbating existing health inequalities and further limiting access to timely diagnosis and care for those already underserved. Additionally, without clear national guidance on the use of AMH for diagnosing PCOM in the UK, patients accessing the test through private providers may not receive the clinical support needed to interpret their results. It also remains unclear whether the assays being used privately are CEmarked specifically for the indication of PCOM.	Thank you for your comment. This will be discussed with the committee during development. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. In this case we will discuss with the committee whether we need to conduct original heath economic modelling in this area.



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Royal College of General Practitioners	General	General	The inclusion of ethnic variation is crucial, especially in primary care, where diagnostic thresholds may not apply uniformly across ethnic groups.	Thank you for your comment. Ethnic variation is part of the International evidence-based guideline for the assessment and management of polycystic ovary syndrome and will be discussed by the committee during guideline development. The plan is to adopt the recommendations from the International guideline unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. However, we will not be updating the evidence reviews used in the International guideline and nor will we be covering areas that are not included in the International guideline.
Royal College of General Practitioners	General	General	It would be useful to clarify whether off-label use of pharmacological treatments (e.g., spironolactone) will be discussed, and how this aligns with GMC prescribing principles for off-label use in primary care.	Thank you for your comment. The committee will consider the licensing status of all interventions in line with our guidelines manual when discussing adopting recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome.
Royal College of General Practitioners	General	General	We recommend using clear guidance on the use of metformin in pregnancy.	Thank you for your comment. This will be discussed with the committee during development. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or



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				savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. However, we will not be updating the evidence reviews used in the International guideline and nor will we be covering areas that are not included in the International guideline.
Royal College of General Practitioners	General	General	We believe there should be explicit inclusion of digital health interventions in psychological and lifestyle domains, such as CBT apps, which are increasingly used in general practice and by patients independently.	Thank you for your comment. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. However, we will not be updating the evidence reviews used in the International guideline and nor will we be covering areas that are not included in the International guideline. Digital health interventions in psychological and lifestyle domains were not part of the International guideline and therefore will not be included.
Royal College of General Practitioners	General	General	We recommend clarity on the pathway between primary and specialist services—especially for young people to avoid delayed diagnosis or support.	Thank you for your comment. This will be discussed with the committee during development. The International evidence-based guideline for the assessment



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Royal College of	General	General	We are surprised to see children aged 10y-17y as we believed	and management of polycystic ovary syndrome published in 2023 includes recommendations related to models of care. The plan is to adopt the recommendations unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. However, we will not be updating the evidence reviews used in the International guideline and nor will we be covering areas that are not included in the International guideline.
General Practitioners			that PCOS could not be diagnosed at time of menarche or early years of teenage years	because it is part of <u>International evidence-based guideline</u> for the assessment and management of polycystic ovary syndrome published in 2023.
Royal College of Nursing	General	General	The International Evidence-based Guideline for the assessment and management of polycystic ovary syndrome 2023 is a thorough and detailed resource. Delighted that NICE is proposing to adapt this document.	Thank you for your support.
Royal College of Nursing	001	007	Full support for adapting the international evidence-based guidance on PCOS 2023	Thank you for your support.
Royal College of Nursing	002	019	Full support for ensuring information needs are culturally appropriate and address health inequities, please can this be highlighted all the way through the guideline.	Thank you for your comment. Health inequalities are included as part of the Equalities and Health Impact Assessment (EHIA) from in the guideline. Additionally, the adoption of the recommendations related to this in International evidence-based guideline for the assessment and management of



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				polycystic ovary syndrome published in 2023 will be discussed by the committee. The overall approach to highlighting inequalities will be discussed during development of the NICE guideline.
Royal College of Nursing	002	032	Please can the guidance address the use of progesterone only methods as well as combined methods because the use of combined methods are contra-indicated (BMI over 35, migraine with aura etc) in many people.	Thank you for your comment. This will be discussed with the committee during development. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. The progestin only recommendation that is currently in the International guideline will be discussed by the committee. However, we will not be covering areas that are not included
Royal College of Nursing	004	010	The guideline should include recommendations for further research.	in the International guideline. Thank you for your comment. Recommendations for further research will only be considered in relation to any original work done within the guideline. However, we will discuss referring to existing research recommendations in the International evidence-based guideline for the assessment and management of polycystic ovary syndrome in the NICE guideline.



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Royal College of Physicians	General	General	Scope coverage recommendation: For women and pregnant people with PCOS, is testing for gestational diabetes during pregnancy (using the accepted 75g glucose tolerance test as per NICE NG3) indicated?	Thank you for your comment. This will be discussed by the committee during development. The guideline will cross refer to existing NICE guidance such as NG3.
Verity	General	General	The Guidelines looks like it is nested under "Fertility, pregnancy and childbirth". Is this where it will actually be? Or could it sit somewhere else more appropriate? We find there are unintended consequences of PCOS being classified / grouped primarily in a gynaecology and/or fertility category (such as lack of awareness / consideration towards nongyne/fertility symptoms (i.e. hirsutism and mental health) or long term risk (such as cardiovascular disease)	Thank you for your comment and raising this. We are looking into the best place for the guideline to sit on the NICE website.
Verity	General	General	There needs to be more detail and specific sectioning on the prevalence in ethnic variations. Within the Equality and Health Inequalities Assessment (EHIA), it states increased prevalence in (South) Asian and Eastern Mediterranean regions, but it does not acknowledge the known prevalence in women of Afro-Caribbean heritage. This should also be built out to highlight the increased health risks facing these populations, as well as cultural considerations that may impact on healthcare decisions	Thank you for your comment. Further information has been added to section 3.2 of the EHIA with regard to the prevalence and impact of PCOS in people with Black ethnicity.
Verity	General	General	We feel that there is more of a leaning towards fertility (particularly as it seems nested under the fertility section) in this outline and less focus on risk factors across the life span	Thank you for your comment. We are looking into the best place for the guideline to sit on the NICE website. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment



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Verity	General	General	We would like to see ideal model of care addressed within the Guidelines. PCOS management requires a multi-disciplinary approach, but currently the onus on management is reliant on the patient, and on individual referrals into secondary care that are not joined up	and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. The guideline is likely to include a similar number of recommendations related to fertility because we are not doing additional reviews. Thank you for your comment. This will be discussed with the committee during development. The International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 includes recommendations related to models of care. The plan is to adopt the recommendations unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. However, we will not be updating the evidence reviews used in the International guideline and nor will we be covering areas that are not included in the International guideline.
Verity	General	General	Within the EHIA document under the protected characteristics, we would like to highlight that "Pregnancy and Maternity" has no issues identified. However, it is well documented that women that are overweight face significant barriers in maternal care, are pushed towards more invasive births that carrier	Thank you for your comment. We have added details related to this to section 3.2 of the EHIA.



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			higher complication risks etc. We would like to see this acknowledged.	
Verity	002	001 - 002	We feel excess hair, acne and alopecia needs to be called out specifically or by being nested under androgens only it risks being overlooked and these symptoms have huge impact on patients self esteem and quality of life and they feel that our healthcare and healthcare professionals don't acknowledge or treat them. Having effective and efficient treatment pathways specifically for PCOS patients living with hirsutism, acne or alopecia is of critical importance in addressing health inequalities – as self-management is prohibitively expensive. This should also ensure treatment options address requirements for hair removal for Black and Brown women – again to ensure this readdresses health inequalities	Thank you for your comment. This will be discussed with the committee during development. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. In this case we will discuss with the committee whether we need to conduct original heath economic modelling in this area. Health inequalities will be discussed when adapt making or adapting recommendations.
Verity	002	004	There is a new paper from The Netherlands on AMH that we believe will be being adopted into the living version of the International Guidelines – it may be worth keeping this in mind	Thank you for your comment. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. However, we will not be updating the evidence reviews used in the International guideline and nor will we be covering areas that are not included in the International guideline. This new evidence will only be taken



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				into account in the NICE guideline if the published International guideline is updated before we publish our guideline.
Verity	002	023	Under the Lifestyle section, there should be an inclusion for lean PCOS and broader lifestyle benefits that are not related to weight management	Thank you for your comment. This will be discussed with the committee during development. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. However, we will not be updating the evidence reviews used in the International guideline and nor will we be covering areas that are not included in the International guideline.
Verity	002	General	Fatty liver is not included here	Thank you for your comment. This will be discussed with the committee during development. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023 unless there are concerns about the estimated costs or savings associated with the guideline (resource impact), availability and implementation within the NHS, health economics, health inequalities or where NICE has guidance that is within the scope of the international guideline. However, we will not be updating the evidence reviews used in the International guideline and nor will we be covering



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				areas that are not included in the International guideline. If a future update to the International guideline includes fatty liver then NICE will consider updating its guideline accordingly. We will check with Monash for any updates while we are developing the NICE guideline.
Verity	002	General	There was a lot of discussion about prevalence / link to asthma at the recent ae-PCOS conference in Copenhagen.	Thank you for your comment. The plan is to adopt the recommendations from the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023. Asthma was not part of the International guideline therefore we will not be covering it in the NICE guideline. If it gets included in a subsequent update to the international guideline then NICE will consider updating its guideline.
Verity	003	008	Pregnancy outcomes – we feel this may need a section on its own and should include: - Pregnancy complications - Miscarriage - Gestational diabetes - Breastfeeding	Thank you for your comment. We have used the titles as they appear in the international guideline. The layout of the NICE guideline will be discussed during development including where recommendations related to pregnancy should be placed. We are also likely to be referring to NICE guidelines related to pregnancy.
Verity	005	023	We would like to see GLP1's extended and approved for PCOS on the NHS	Thank you for your comment. The recommendations related to GLP1s will be discussed by the committee along with their overlap with existing NICE technology appraisals in this area. In this case it is likely that the NICE technology appraisals will take precedence over the recommendations in the International evidence-based guideline for the assessment and management of polycystic ovary syndrome published in 2023.



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