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Recommendations from the international evidence-based guideline for the assessment and management of polycystic ovary syndrome

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Study Question: What is the recommended assessment and management of women with polycystic ovary syndrome (PCOS), based on the best available evidence, clinical expertise, and consumer preference?

Summary Answer: International evidence-based guidelines including 166 recommendations and practice points, addressed prioritized questions to promote consistent, evidence-based care and improve the experience and health outcomes of women with PCOS.

What Is Known Already: Previous guidelines either lacked rigorous evidence-based processes, did not engage consumer and international multidisciplinary perspectives, or were outdated. Diagnosis of PCOS remains controversial and assessment and management are inconsistent. The needs of women with PCOS are not being adequately met and evidence practice gaps persist.

Study Design, Size, Duration: International evidence-based guideline development engaged professional societies and consumer organizations with multidisciplinary experts and women with PCOS directly involved at all stages. Appraisal of Guidelines for Research and Evaluation (AGREE) II-compliant processes were followed, with extensive evidence synthesis. The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework was applied across evidence quality, feasibility, acceptability, cost, implementation and ultimately recommendation strength.

Participants/Materials, Setting, Methods: Governance included a six continent international advisory and a project board, five guide-line development groups, and consumer and translation committees. Extensive health professional and consumer engagement informed guideline scope and priorities. Engaged international society-nominated panels included pediatrics, endocrinology, gynecology, primary care, reproductive endocrinology, obstetrics, psychiatry, psychology, dietetics, exercise physiology, public health and other experts, alongside consumers, project management, evidence synthesis, and translation experts. Thirty-seven societies and organizations covering 71 countries engaged in the process. Twenty face-to-face meetings over 15 months addressed 60 prioritized clinical questions involving 40 systematic and 20 narrative reviews. Evidence-based recommendations were developed and approved via consensus voting within the five guideline panels, modified based on international feedback and peer review, with final recommendations approved across all panels.

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Participants of the International PCOS Network are listed in the Appendix.

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Main Results and the Role of Chance: The evidence in the assessment and management of PCOS is generally of low to moderate quality. The guideline provides 31 evidence based recommendations, 59 clinical consensus recommendations and 76 clinical practice points all related to assessment and management of PCOS. Key changes in this guideline include: i) considerable refinement of individual diagnostic criteria with a focus on improving accuracy of diagnosis; ii) reducing unnecessary testing; iii) increasing focus on education, lifestyle modification, emotional wellbeing and quality of life; and iv) emphasizing evidence based medical therapy and cheaper and safer fertility management.

Limitations, Reasons for Caution: Overall evidence is generally low to moderate quality, requiring significantly greater research in this neglected, yet common condition, especially around refining specific diagnostic features in PCOS. Regional health system variation is acknowledged and a process for guideline and translation resource adaptation is provided.

Wider Implications of the Findings: The international guideline for the assessment and management of PCOS provides clinicians with clear advice on best practice based on the best available evidence, expert multidisciplinary input and consumer preferences. Research recommendations have been generated and a comprehensive multifaceted dissemination and translation program supports the guideline with an integrated evaluation program.

Study Funding/Competing Interest(S): The guideline was primarily funded by the Australian National Health and Medical Research Council of Australia (NHMRC) supported by a partnership with ESHRE and the American Society for Reproductive Medicine. Guideline development group members did not receive payment. Travel expenses were covered by the sponsoring organizations. Disclosures of conflicts of interest were declared at the outset and updated throughout the guideline process, aligned with NHMRC guideline processes. Full details of conflicts declared across the guideline development groups are available at https://www.monash.edu/medicine/sphpm/mchri/pcos/guideline in the Register of disclosures of interest. Of named authors, Dr Costello has declared shares in Virtus Health and past sponsorship from Merck Serono for conference presentations. Prof. Laven declared grants from Ferring, Euroscreen and personal fees from Ferring, Euroscreen, Danone and Titus Healthcare. Prof. Norman has declared a minor shareholder interest in an IVF unit. The remaining authors have no conflicts of interest to declare. The guideline was peer reviewed by special interest groups across our partner and collaborating societies and consumer organizations, was independently assessed against AGREEII criteria and underwent methodological review. This guideline was approved by all members of the guideline development groups and was submitted for final approval by the NHMRC. (Fertil Steril® 2018; 2018; 2018; 2018 The Authors. Published by Elsevier Inc. on behalf of the American Society for Reproductive Medicine. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).)

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INTRODUCTION

Polycystic ovary syndrome (PCOS) is the most common endocrinopathy affecting reproductive aged women, with a prevalence of between 8% and 13% depending on the population studied and definitions used (1, 2). PCOS is complex with reproductive, metabolic and psychological features (1, 2). Clinical practice in the assessment and management of PCOS is inconsistent, with key evidence practice gaps, whilst women internationally have highlighted delayed diagnosis and dissatisfaction with care (3-5). Current guidelines either are limited in breadth, do not follow rigorous best practice in development, have not involved consumers, or are outdated (6-10), resulting in inconsistent guidance for clinicians and women alike. To address these identified gaps, here we summarize the development process and recommendations from the first international evidence-based guideline for the assessment and management of PCOS, bringing together extensive consumer engagement and international collaboration with leading societies and organizations, multidisciplinary experts, and primary care representatives. In this process, the guideline development groups unanimously supported the Rotterdam diagnostic criteria for adult women.

This comprehensive evidence-based guideline builds on prior high quality guidelines and culminates from a rigorous, Appraisal of Guidelines for Research and Evaluation-II (AGREEII)-compliant, evidence-based guideline development process. It provides a single source of international evidence-based recommendations to guide clinical practice with the opportunity for adaptation in relevant health systems. Together with an extensive translation program, the aim is to reduce

worldwide variation in care and promote high quality service provision to improve health outcomes and quality of life in women with PCOS. The guidelines are supported by a multifaceted international translation program with co-designed resources to enhance the skills of health professionals and empower women with PCOS, with an integrated comprehensive evaluation program.

WHAT DOES THIS MEAN FOR ADOLESCENTS AND WOMEN WITH PCOS?

This guideline aims to optimize evidence-based, consistent care that meets the needs and improves the quality of life of women with PCOS. The guideline and translation program were developed with full consumer participation at all stages, targeting areas and outcomes of priority for women with PCOS. The aim is to support women and their health care providers to optimize diagnosis, assessment and management of PCOS. There is an emphasis on partnership in care and empowerment of women with PCOS. Personal characteristics, preferences, culture and values are considered. With effective translation, the guideline and health professional and consumer resources will address gaps and priorities identified by women with PCOS and will promote vital future research.

MATERIALS AND METHODS

Best practice evidence-based guideline development methods were applied and are detailed in the full guideline and the technical reports and outlined in Figure 1 and available at https://www.monash.edu/medicine/sphpm/mchri/pcos (11).

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