International evidence-based guideline for the assessment and management of polycystic ovary syndrome 2018

Administrative report

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1. Governance and stakeholder involvement

1.1. Consumers participate in the guideline development and the processes employed to recruit, involve and support consumer participants are described.

- Extensive engagement
- International survey via consumer advocacy groups (1600 respondents worldwide to guide priorities for key questions and to inform outcomes). This work was published and informed needs, gaps, priorities and scope.
- An international consumer advisory panel convened, which includes senior members from the peak national and international consumer organisations in PCOS, including the Polycystic Ovary Syndrome Association Australia, Verity in the United Kingdom, PCOS Challenge USA and Resolve - the US National Infertility Association. The panel met three times plus additional feedback sought by electronic questionnaire at each critical time-point in guideline development, including selecting topic priorities, forming clinical questions and on proposed draft recommendations. At least one consumer representative was present in every guideline development group meeting. The peak consumer groups (nationally and internationally) played an integral role in disseminating the public consultation draft of the guideline to its organisational members to seek feedback on guideline content. All feedback provided was responded to.
- A translation advisory consumer group established to guide translation of the guideline, including resources which are all extensively co-designed with consumers. This work is supported by an NHMRC Partnership Grant.

1.2. Potential competing interests are identified, managed and documented, and a competing interest declaration is completed by each member of the guideline development group.

- The process used for declaration and management of competing interests is modelled on the process used by NHMRC. Refer appendix I: Process for disclosure of interests and form. Disclosure of interest declarations were completed by each member of the guideline development group prior to the first meeting and updated prior to subsequent meetings. Declarations of conflict of interest was a standing agenda item at each meeting.

1.3. Desirable: The amount and percentage of total funding received from each funding source is stated.

- NHMRC funded Centre for Research Excellence in Polycystic Ovary Syndrome ≈ $500,000
- European Society of Human Reproduction and Embryology ≈ $65,000 plus in kind
- American Society for Reproductive Medicine ≈ $65,000 plus in kind
- Victorian State Government(guideline translation) ≈ $250,000 (model of care and clinical service)
- NHMRC partnership grant (guideline translation) ≈ $750,000 (App, resource development and evaluation)
- Extensive in kind contribution from 32+ societies involved.

1.4. Desirable: The guideline development process includes participation by representatives of Aboriginal and Torres Strait Islander peoples and culturally and linguistically diverse communities (as appropriate to the clinical need and context), and the processes employed to recruit, involve and support these participants are described.

Aboriginal and Torres Strait Islander and culturally and linguistically diverse communities' considerations were covered by all Guideline Development Groups in each recommendation in the GRADE framework. Relevant issues were captured. In evidence review, the search terms used to identify studies addressing the population of interest (i.e. women with PCOS) were only limited to PCOS terms. Therefore, studies addressing women with PCOS in all cultural, geographical and socioeconomic backgrounds and settings would be identified by the search.

The Australian Indigenous Doctors Association was targeted to provide feedback on the guideline during the public consultation period – no response was received. Indigenous and CALD communities will be well represented to guide dissemination and implementation activities.

2. Guideline recommendations

2.1 The method used to arrive at consensus-based recommendations or practice points (Requirements D.4 and D.5) (e.g. voting or formal methods, such as Delphi) is documented.

The method used to develop consensus recommendations and clinical practice points is outlined in the guideline in Table 1 in 'Interpreting the recommendations' and in Table 10 in 'Chapter 6: Guideline development methods'. Clinical Consensus Recommendations: In the absence of evidence, a clinical consensus recommendation has been made by the guideline development group. Clinical Practice Points: Evidence not sought. A practice point has been made by the guideline development group where important issues arose from discussion of evidence-based or clinical consensus recommendations.

2.2 The guideline and recommendations have been assessed by at least two reviewers, independent of the guideline development process, using the AGREE II instrument.

The guideline and recommendations were assessed by two independent reviewers. Assessment reports are attached as Appendix II and Appendix III.

The majority of areas scored 6 -7 out of a possible score of 7. Where scores were below this, the information required was either in guideline sections not identified by the appraiser or was not in the guideline document but was available in alternative documents that will sit alongside the guidelines on the website. For example the conflict-of-interest process and public consultation details are in separate documents.

Where scores related to difficulty in finding the relevant information such as consumer engagement or the aims and objectives of the guidelines, these have been more clearly identified now.

The significant discrepancy in scores between the reviewers on the aims of the guideline and consumer engagement sections reflects the fact that one appraiser

identified this information in the document whilst the other did not. However both requirements were fully satisfied within the guideline development processes and were outlined in different sections in the document. These have now been more clearly identified.

Note: Most observations raised by reviewers occurred simultaneously with several other processes and were dealt with by the time the appraisal was returned.

3. Public consultation

3.1 The process for public consultation on the draft guideline complies with Section 14A of the Commonwealth National Health and Medical Research Council Act 19921 and accompanying regulations

Public consultation on the draft guideline commenced on 10 February 2018 and closed on 12 March 2018 (32 days). Public consultation was conducted in compliance with NHMRC requirements. A web portal, which included instructions for submitting feedback and all of the consultation documents, was developed to facilitate the guideline consultation process. The consultation web portal can be viewed at http://pcos-cre.edu.au/consultation-draft-update-expansion-2011-evidence-based-guideline-assessment-management-polycystic-ovary-syndrome/

A list of targeted stakeholders invited to participate in consultation is detailed at item 3.3 in this report.

37 societies and consumer groups were engaged to form a special interest group to provide feedback. Feedback was received from 20 societies and 3 consumer groups.

3.2 During the public consultation period, the developer has undertaken and documented consultation with:

- **the Director-General, Chief Executive or Secretary of each state, territory and Commonwealth health department**
- **relevant authority, ie, when a guideline makes any recommendation/s specifying interventions that are not available or restricted in Australia (see Requirement D.10).**

During the guideline public consultation period, we invited consultation with:

- Department of Health Victoria
- Department of Health SA
- Department of Health WA
- Department of Health Qld
- Department of Health NSW
- Department of Health TAS
- Department of Health ACT

Feedback was not received from any of the above agencies.

Additionally, we invited feedback from:

- Therapeutic Goods Administration (TGA)
- Medical Services Advisory Committee (MSAC)
- Consumer health forum info@chf.org.au sent 8/2

Feedback was not received from any of the above agencies. However, recommendations complied with TGA advice and wording from our recent guideline updates in 2014.

Following consultation with NHMRC, it was deemed unnecessary to approach the Pharmaceutical Benefits Advisory Committee as the guideline was not addressing issues relevant to PBAC.

3.3 The developer has identified and consulted with key professional organisations (such as specialty colleges) and consumer organisations that will be involved in, or affected by, the implementation of the clinical recommendations of the guideline.

Refer table 1 below for the complete list of partners/ collaborators in the guideline across 32 societies and 4 world leading consumer groups.

Table 1 Organisational partners/ collaborators in the guideline

Society/ organisation name	Financial contributor	Signed letter of agreement	Represented on International Advisory Group	Represented on Project Board	Represented on GDG	Invited to participate in public consultation
American Society for Reproductive Medicine (ASRM)	Y	Y	Y	Y	Y	Y
European Society of Human Reproduction and Embryology (ESHRE)	Y	Y	Y	Y	Y	Y
Androgen Excess and Polycystic Ovary Syndrome Society (AEPCOS)	N	Y	Y	Y	Y	Y
Asia Pacific Paediatric Endocrine Society (APPES)	N	Y	N	N	Y	Y
Asia Pacific Initiative on Reproduction (ASPIRE)	N	Y	Y	N	Y	Y
British Fertility Society (BFS)	N	Y	N	N	Y	Y
Canadian Society of Endocrinology and Metabolism (CSEM)	N	Y	N	N	N	Y
European Society of Endocrinology (ESE)	N	Y	N	N	Y	Y
European Society for Paediatric Endocrinology (ESPE)	N	Y	N	N	N	Y
International Federation of Gynecology and Obstetrics (FIGO)	N	N	N	N	Y	Y
Federation of Obstetric and Gynaecological Societies of India (FOGSI)	N	N	N	N	Y	Y
International Federation of Fertility Societies (IFFS)	N	Y	N	N	N	Y
International Society of Endocrinology (ISE)	N	Y	N	N	N	Y
The Japanese Society for Paediatric Endocrinology (JSPE)	N	Y	N	N	Y	Y
Nordic Federation of Societies of Obstetrics and Gynaecology (NFOG)	N	N	N	Y	Y	Y
PCOS Society India	N	Y	Y	N	Y	Y
Pediatric Endocrine Society (PES)	N	Y	N	N	Y	Y
Royal College of Obstetricians and Gynaecologists (RCOG)	N	Y	N	N	Y	Y
South African Society of Gynaecology and Obstetrics (SASOG)	N	Y	Y	N	Y	Y
Italian Society of Gynaecology and Obstetrics (SIGO)	N	Y	N	N	Y	Y
Latin American Society for Pediatric Endocrinology (SLEP)	N	Y	N	N	N	Y
Endocrine Society (US Endo)	N	Y	Y	N	Y	Y
Australian Diabetes Society (ADS)	N	N	N	N	Y	Y
Australasian Paediatric Endocrine Group (APEG)	N	Y	N	N	Y	Y
Endocrine Society Australia (ESA)	N	N	N	Y	Y	Y
Fertility Society Australia (FSA)	N	Y	Y	Y	y	Y
Royal Australian College of General Practitioners (RACGP).	N	Y	N	N	Y	Y
The Royal Australasian College of Physicians (RACP)	N	N	N	N	N	Y
The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)	N	Y	N	N	Y	Y
Exercise and Sports Science Australia (ESSA)	N	Y	N	Y	Y	Y
Australian Psychological Society (APS)	N	N	N	N	Y	Y

Dietitians Association Australia (DAA)	N	N	N	Y	Y	Y
Consumer groups						
Polycystic Ovary Syndrome Association Australia (POSAA)	N	N	N	Y	Y	Y
Verity	N	N	N	N	Y	Y
RESOLVE	N	N	N	N	N	Y
PCOS Challenge	N	N	N	N	Y	Y
Victorian Assisted Reproductive Technology Association (VARTA)	N	N	N	N	Y	Y

Additionally, the following organisations were invited to provide feedback on the guideline during public consultation:

- Therapeutic Goods Administration (TGA)
- Medical Services Advisory Committee (MSAC)
- Consumer health forum
- Department of Health Victoria
- Department of Health South Australia
- Department of Health WA
- Department of Health Qld
- Department of Health NSW
- Department of Health TAS
- Department of Health ACT
- Guideline development group members
- Jean Hailes for Women's Health
- Centre for Research Excellence in PCOS Chief and Associate investigators
- Australian Indigenous Doctors Association
- Australian PCOS alliance members

3.4 Desirable: **A version of the public consultation submissions summary is publicly available, with submissions de-identified.**

A website for the guideline and associated resources and reports, including the public consultation submissions summary with submissions de-identified, is currently being developed. We anticipate the website will be ready for launch prior to the release of the guideline.

Report prepared by
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Date: April 2018

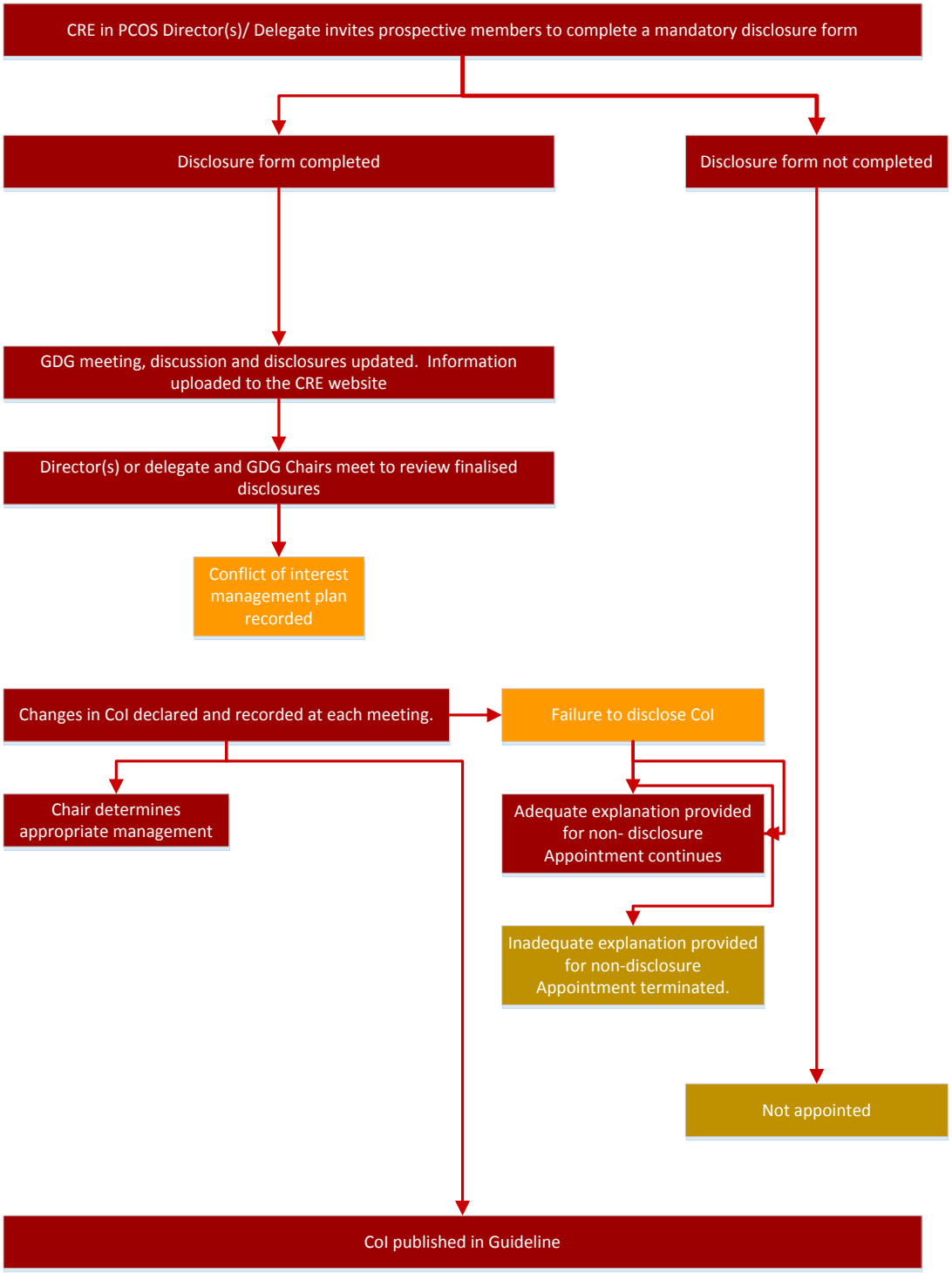
Appendix I

CRE PCOS
Centre for Research Excellence in Polycystic Ovary Syndrome

Process for disclosure of interests and form (guideline development)

Introduction

To meet international standards, all guideline participants must declare their interests to the Australian National Health and Medical Research Council, as the guideline approval body. This form should be read in conjunction with the policy *Identifying and Managing Conflicts of Interest of Prospective Members and Members of CRE Committees and Working Groups Developing Guidelines.* The process for disclosure of interests is also described in the flow chart below.



This form also confirms consent for disclosed information to be discussed with other prospective members and to be published in the final guideline and on the guideline website.

There are two parts of the form to complete:

- Part A pertains to financial relationships to entities with a direct interest in the guidelines.
- Part B pertains to other relationships or activities not covered in Part A.

Your disclosure requires **all** interests to be declared, not only those you perceive as a conflict.
Please describe the nature of the interest, relationship and commercial relevance. You may also provide any proposal you have to manage this interest (e.g. exclusion from discussions on certain topics).

The Director(s) or their Delegate will review disclosures and determine whether or not a management plan is recommended. The Chair will remind the committee of disclosures and proposed management plans at each guideline meeting and members will update their disclosures. Any concerns will be discussed.

Section 2 of this form will be completed by the CRE Director(s) or their Delegate.

Submitting this Form

Completed, signed forms may be scanned and emailed with any relevant attachments to Linda Downes, Project Manager for the International evidence-based guidelines in PCOS project, email linda.downes@monash.edu

CREPCOS
Centre for Research Excellence in Polycystic Ovary Syndrome

Form for disclosure of interests (guideline development)

Part A - Relevant financial activities

Please note: responses within the form are limited to 200 characters. If longer please include a separate attachment.

Question 1
Over the past 3 years, have you been **empolyed by an entity having a commercial or other interest** in the topic of PCOS?

◯ No (skip to question 2) ◯ Yes

Yes: Benefits to you (received or expected) - 200 character limit.

Yes: Benefits to immediate family (received or expected) - 200 character limit.

Relevant attachment number (if applicable)

Question 2
Do you, or as far as you are aware, any immediate family members have any **ownership interests* or Board membership** in any entity which has a commercial interest in the topic of PCOS (including where a stock in the entity is not publicly traded)?
* Ownership interests include stock options but exclude indirect investments through mutual funds and the like.

◯ No (skip to question 3) ◯ Yes

Yes: Benefits to you (received or expected) - 200 character limit.

Yes: Benefits to immediate family (received or expected) - 200 character limit.

Relevant attachment number (if applicable)

Question 3

Have you or, as far as you are aware, any immediate family members **been given financial support for travel or accommodation** from any entity which has a commercial interest in the topic of PCOS? Disclosure is required in relation to disbursements over the 3 years preceding and any anticipated disbursements in the twelve months following appointment to the committee or working group.

◯ No (skip to question 4) ◯ Yes

Yes: Benefits to you (received or expected) - 200 character limit.

Yes: Benefits to immediate family (received or expected) - 200 character limit.

Relevant attachment number (if applicable)

Question 4

Have you or, as far as you are aware, any immediate family members **been paid consultancy fees or honoraria or received a grant, gift, gratuity or any other form of remuneration** from any entity which has a commercial interest in the topic of PCOS? Disclosure is required in relation to disbursements over the 3 years preceding and any anticipated disbursements in the twelve months following appointment to the committee or working group.

◯ No (skip to question 5) ◯ Yes

Yes: Benefits to you (received or expected) - 200 character limit.

Yes: Benefits to immediate family (received or expected) - 200 character limit.

Relevant attachment number (if applicable)

Question 5

Have you or, as far as you are aware, any immediate family members **received any other form of support or payment not declared above** from any entity which has a commercial interest in the topic of PCOS? Disclosure is required in relation to disbursements over the 3 years preceding and any anticipated disbursements in the twelve months following appointment to the committee or working group.

◯ No ◯ Yes

Yes: Benefits to you (received or expected) - 200 character limit.

Yes: Benefits to immediate family (received or expected) - 200 character limit.

Relevant attachment number (if applicable)

Part B - Other relationships or activities

Question 6
Are you **affiliated or associated with any organisations** whose interests are either aligned with or opposed to the subject matter of the proposed guidelines? Please also list organisational membership and state if you are officially representing these organisations on the guideline work.

◯ No (skip to question 7) ◯ Yes

Yes: Please provide details of these affiliations/ associations - 200 character limit. If list exceeds the character limit please submit a separate attachment with this form.

If you are representing an organisation, do you consent to communicating with them on guideline process and advocate for feedback on guideline content during development?

◯ Yes

◯ No

Relevant attachment number (if applicable)

Question 7
Are there any other **relationships or activities** that could be perceived potentially to influence your contribution?

◯ No (skip to question 8) ◯ Yes

Yes: Please provide details of these relationships or activities - 200 character limit. If list exceeds the character limit please submit a separate attachment with this form.

Relevant attachment number (if applicable)

Section 1 - Declaration

Name

Committee/ guideline name

Declaration:
- I declare that the information provided was correct on the date entered below
- I declare that I have read the CRE in PCOS policy *Identifying and managing conflicts of interest of prospective members of the CRE in PCOS committees and working groups developing guidelines* and agree to comply with the policy.

In signing this form I hereby agree to:
- this information being provided to other prospective members for their consideration.
- update this information throughout the development of these guidelines
- comply with any interest management plan
- allow the publication of any interest I have disclosed in this form, and any interests declared after I complete this form and any management plan in the final guideline and any other publication required by NHMRC for guideline approval.

Signature of potential member

Date

Section 2 - Determination (office use only)

CRE Director(s) or delegate (tick where appropriate).
Note: *The member who has disclosed an interest in a matter must not be present when the Director(s) consider the matter or take part in any decision in relation to the matter.*

- ☐ official appointment may proceed and participation can occur without any management plan
- ☐ official appointment may proceed and interests can be managed with a management plan
- ☐ recommendation is made to move the participant to an alternative committee or panel
- ☐ an appointment is precluded

Signature of CRE Director of delegate

Date

Print name

APPRAISAL OF GUIDELINES FOR RESEARCH & EVALUATION II

AGREE II

AGREE II Clinical Practice Guideline Appraisal Report

Appraiser:

Reviewer 1
Centre for Clinical Effectiveness
Monash Health

SCOPE AND PURPOSE

1. The overall objective(s) of the guideline is (are) specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comment 1

Overall, the aim and purpose of the guideline very broad and encompasses many objectives for different populations of women. It is also described throughout different sections of the guideline Executive Summary and Introduction.

Content of a clear, succinct statement of the aims and purpose is not easy to find in the guideline. More consistent use of terms could enhance comprehension of the purpose and aims, specifying health outcomes for specific populations, and be more concise.

Stated is “timely diagnosis, accurate assessment and optimal treatment of polycystic ovary syndrome (PCOS)” [page 9], and to “promote accurate diagnosis, optimal consistent care, prevention of complications and improved patient experience and health outcomes for women worldwide with PCOS” [page 9].

Consider making aim more specific and concise, so that Page 9 and Page 29 are consistent, and emphasise the guideline purpose and aim (i.e., “screening, diagnosis, assessment and treatment of PCOS to improve psychological, metabolic and reproductive health outcomes of women with PCOS.”)

Comment 2

It is important to state the specific expected benefits or health outcomes (i.e. psychological, metabolic and reproductive health outcomes?) and to what population of women. page 29.

First paragraph on Page 29: Guideline purpose states “… treatment of PCOS…. improve health outcomes” Consider clarifying “of women worldwide with PCOS…”?

SCOPE AND PURPOSE

2. The health question(s) covered by the guideline is (are) specifically described.

1 Strongly Disagree	**2**	**3**	**4**	**5**	**6**	**7** Strongly Agree

Overall, questions are found easily in the document with clinical need below to support the question. However, improving the consistency in how questions are phrased would enhance readability and understanding. This could enhance the clarity of the clinical questions and define the applicability to different sub-groups and populations of women.

Comment 1

Improve specificity of clinical questions by including the population of women addressed; improve consistency in questions.

e.g. 1.2 evidence mentions adolescents, while question is unclear to whether this is for adult women only?

"In women with suspected PCOS, what is the most effective measure to clinically diagnose PCOS-related hyperandrogenism?" – if consistent with previous question, "to diagnose clinical hyperandrogenism"?

"When is ultrasound indicated to diagnose PCOS?" in adult women or adolescents?

"In women with PCOS…" – does this exclude adolescents? Does this include pre and post-menopausal?

"….in adolescents and adults…."

Same comment on recommendations for 2.5 (and others), where target population is not specified.

Comment 2

Are Sections 1.4 and 1.5 questions the same?

Section 1.5 -

"What are the most effective ultrasound criteria to diagnose PCOS?"

"What are the most effective ultrasound criteria to diagnose PCOM?"

There is a mismatch of evidence and questions. The clinical need for questions states that there is "significant heterogeneity and the diagnostic value of serum AMH". Firstly, the evidence and recommendations did not address what the most effective criteria were? Secondly, AMH levels and antral follicle count are mentioned, and while evidence and recommendations are against the use serum AMH; what about follicle count/and or other criteria that the question was supposed to address? Again, what is the population – in adolescents and adults?

Section 1.5. AMH questions in MASTER do not match the questions and the evidence in "Screening…" technical report page 189.

Same mismatch in evidence and questions for Section 2.3. on "what is the best tool/method?", which is not addressed in the recommendations.

Comment 3.

Specify the populations of women this refers to as per defined in the introduction (i.e., women with PCOS - adolescent (<20?), reproductive, <45 years, post-menopausal?)

In the sections 2, 3 and 4, adolescents, and women are not always considered separated in questions and evidence.

Comment 4

Section 2.6. for consistency, consider "How to access culturally and linguistically diverse appropriate care?"

Chapter 5.1a. first two questions are not easily understood. (page 91)

SCOPE AND PURPOSE

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comment 1

Overall, context is clearly described and easily found in the paragraph.

Page 29 Patient population: This guideline is “relevant to the assessment and management of adolescents, reproductive age and postmenopausal women who have PCOS, including women with PCOS who are infertile.” This is clearly mentioned in the Introduction.

However, patient population should be more clearly defined here.

Consider “adolescents (<20), two years onset of….; reproductive age (<45?)… postmenopausal… infertile...regardless of ethnicity”?

These categories of women (adolescents and adult women) are sometimes defined in questions, and sometimes not specifically addressed in certain questions. (e.g., clinical need in 1.5; 3.1; evidence in 3.2) While Section 4.2. and 4.3. onwards clearly distinguish and present the evidence for these two groups of women separately.

As defined in the patient population, there is a need to address specific groups of women, so that the correct individuals would receive appropriate action as recommended by the guidelines.

STAKEHOLDER INVOLVEMENT

4. The guideline development group includes individuals from all relevant professional groups.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

There was a diverse group of members involved in the development process (Page 116).

Appendix I-III includes the list of members, disciplines, organisations and roles for each guideline development group. The guideline development team and project group consisted of necessary evidence synthesis officer and experts.

STAKEHOLDER INVOLVEMENT

5. The views and preferences of the target population (patients, public, etc.) have been sought.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

Page 127 documents the public consultation process that occurred.

Public consultation strategy is included in a separate document which details the stakeholders involved (Aus government, international societies, national entities, consumer groups, and other entities).

The methods were in accordance with the NHMRC consultation information document. This included publishing on Health tracker, NHMRC website, media releases and newsletters.

Evidence table for extensive public consultation that occurred involving over 400 comments and responses that were made.

STAKEHOLDER INVOLVEMENT

6. The target users of the guideline are clearly defined.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comment 1

Page 30 defines the specific target users of the guideline clearly in Setting and Audience. This is clear and very specific.

Consider including a statement on how the guideline aims may be used or benefit by these targeted users. This information is found in Introduction and Executive Summary (i.e., inform decisions, Improvement in care, Inform policy). The paragraph on Page 29 captures some of the benefits, consider changing sentence to These guidelines aim to "benefit women

"These guidelines aim to ensure that women with PCOS receive optimal, evidence-based care by"

- engaging multidisciplinary international expert representation in PCOS care nominated by partner and collaborator societies;
- including international consumer and primary care representatives;
- following rigorous AGREEII-compliant evidence-based guideline processes;
- developing an international comprehensive guideline on diagnosis, assessment and management of PCOS;
- providing a single source of international evidence-based recommendations to guide clinical practice and reduce variation worldwide with the opportunity for adaptation in relevant health systems as needed;
- providing a basis for improving patient outcomes;
- identifying knowledge gaps and promoting research and translation into practice and policy
- co-developing resources to upskill health professionals and empower consumers including a mobile app and online resources
- delivering an international translation program with in-depth evaluation

Comment 2

There are research recommendations in the technical reports that do not seem to be mentioned elsewhere. In Executive Summary, it mentions the need for "promoting consistent evidence-based care and guiding and encouraging research in PCOS."

Furthermore, the Setting and Audience does not mention research professionals. There are important recommendations where this group of professionals may benefit as gaps are highlighted.

RIGOUR OF DEVELOPMENT

7. Systematic methods were used to search for evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

Page 122 states that "a broad-ranging systematic search for terms related to PCOS was developed by the evidence team. This PCOS search string was then combined with specific searches tailored for each clinical question according to the PICO developed by the guideline development group. The search terms used to identify studies addressing the population of interest (ie. women with PCOS) were only limited to PCOS terms. Therefore studies addressing women with PCOS in all cultural, geographical and socioeconomic backgrounds and settings would be identified by the search. The search strategy was limited to English language articles and limits on year of publication are specified in the PICO for each clinical question according to whether an update search was conducted or in cases where interventions were only available from a particular point in time."

A comprehensive strategy (using PICO) and methodology will be described in each technical report for clinical questions defined by the five guideline development groups. This was in accordance to using the PICO or for narrative reviews, GRADE.

Clear presentation of the strategy and methods for only some technical reports (using PICO) will allow replication of the respective searches. There were many narrative reviews performed, where GRADE framework was used and impossible to replicate the searches of evidence that were performed.

Comments on individual technical reports:

- Screening, diagnosis, assessment and life stage – good presentation of methods, PICO included
- Assessment and treatment of infertility – methods document with search string and selection missing. GRADE framework was used.
- Prevalence, screening, diagnostic and treatment of well-being – search terms, PICO included for select questions only. GRADE framework.
- Pharmacological treatment for non-fertility indications – methods document with search string, results and selection missing. GRADE framework.
- Lifestyle – PICO included, good presentation methods.

RIGOUR OF DEVELOPMENT

8. The criteria for selecting the evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

Target populations, study designs, comparators and outcomes were detailed only in some technical reports.

Comment on technical reports:

- Screening, diagnosis, assessment and life stage – clear inclusion and exclusion criteria, reasons and rationale provided. Page 15 selection process incomplete?
- Assessment and treatment of infertility – inclusion/exclusion criteria but rationale for exclusion missing.
- Prevalence, screening, diagnostic and treatment of well-being – inclusion/exclusion criteria (some select questions) but no rationale included.
- Pharmacological treatment for non-fertility indications – inclusion/exclusion criteria and rationale for including/excluding studies missing.
- Lifestyle – reasons for inclusion/exclusion included

RIGOUR OF DEVELOPMENT

9. The strengths and limitations of the body of evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

Page 123-125 state the methods of how the strengths and limitations of the data were addressed, risk of bias were assessed by appropriate methods according to study type. These were addressed more explicitly in evidence tables of the separate technical reports.

- Screening, diagnosis, assessment and life stage – tables of evidence presented clearly
- Assessment and treatment of infertility – tables of evidence presented clearly.
- Prevalence, screening, diagnostic and treatment of well-being – evidence tables presented clearly
- Pharmacological treatment for non-fertility indications – evidence tables presented clearly
- Lifestyle – evidence tables presented clearly

RIGOUR OF DEVELOPMENT

10. The methods for formulating the recommendations are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

Methods for formulating recommendations extremely clear and described extensively. These are easily found in the document.

"The methods used to develop this guideline are aligned with International best practice, AGREE II criteria and the comprehensive criteria of the Australian government NHMRC and ESHRE for approval of evidence-based guidelines" Page 31, and detailed in page 115 and 120, 125

An International survey and Delphi exercise was conducted to develop and prioritise (existing and newly developed) clinical questions to be addressed. A further prioritisation exercise was conducted within the topic specific guideline development groups and consumer advisory groups to rank the importance of clinical questions to guide the evidence team and to reach consensus on which clinical questions were to be addressed by a systematic review or by narrative review.

RIGOUR OF DEVELOPMENT

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

Desirable and undesirable effects are considered and captured in the panel discussions according to GRADE framework.

This are documented clearly in each of the five technical reports.

RIGOUR OF DEVELOPMENT

12. There is an explicit link between the recommendations and the supporting evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comment 1
There is a paragraph of evidence prior to each set of recommendations from which the recommendations are based. Full details of evidence summaries are found in each of the technical reports, according to the clinical questions.

Comment 2
No doubt that evidence to support each recommendation is included, however the links to evidence could be more explicit. It was not easy to find the links to the evidence tables and consensus due to the large size of technical reports and different numbering system.
E.g., The numbering is 1.1.1 in master copy and 1.1.a and 1.1b etc or no numbering in the technical reports.
Consider numbering recommendations in all technical reports, as per in the master copy (i.e., Page 5, 75, 88 of the Screening technical report) to provide a clearer link to the results and evidence in the technical reports.
This comment applies to the other technical reports as well.

Comment 3
It is clearly described when evidence was lacking, and how expert consensus was achieved. The discussion and outcomes of panel discussions were documented according to the GRADE framework.

RIGOUR OF DEVELOPMENT

13. The guideline has been externally reviewed by experts prior to its publication.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments
Overall, this is described well throughout the document.

Extensive health professional and patient engagement informed guideline priority areas. International Society-nominated panels included consumers, paediatrics, endocrinology, gynaecology, primary care, reproductive endocrinology, psychiatry, psychology, dietetics, exercise physiology, public health, project management, evidence synthesis and translation experts.

Statement to state that the "guideline will be reviewed …….. independently by relevant professional colleges and societies and through public consultation. "

Description on the process and methods taken were in Executive Summary and guideline development section:
"This stakeholder engagement directly informed the guideline and translation program and involved over 3000 health professionals and consumers with PCOS. Our partners and collaborators contributed members to the guideline governance, development and translation committees. They formed special interest groups with considerable expertise in PCOS to provide feedback during the public consultation process and are engaged in translation and evaluation" and "consultation process through online surveys and in providing feedback into the guideline through special interest groups formed across the partner and collaborator organisations"

Comment 2
Outcomes of the external review are captured in a peer-reviewed document available separately from the guidelines. Affiliations, the number of reviewers, their comments, and the response to their comments are included in this document.

In the formation of final recommendations. It is stated that "feedback will be reviewed by the project board and guideline development groups, blinded by the organisation providing the feedback." Do you mean they were blinded TO the organisations providing feedback…so that they did not know which organisations submitted the comments, and responses were considered in an unbiased fashion.

RIGOUR OF DEVELOPMENT

14. A procedure for updating the guideline is provided.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments
Scheduled review and update of the guideline clearly described on Page 128

The guideline development groups will be re-convened to review relevant sections of this guideline if any of the following occur within five years:

- a change in the indications registered by the Therapeutic Goods Administration for any drug included in this guideline; or
- publication of any new major randomised controlled trials or systematic reviews that potentially have a bearing on the safety of the recommendations in this guideline.

CLARITY OF PRESENTATION

15. The recommendations are specific and unambiguous.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comment 1

Consistency with presenting recommendations for the different sub groups or populations of women could be improved.

In some cases, adolescents (<20 years), some do not have year ranges, and some recommendations do not explicitly state whether it applies to adolescents or adult women, women of childbearing age, or of all ages.

Greater clarity in the presentation of evidence and recommendations for specific groups of women is required, (Section 4.2. and 4.3. onwards clearly distinguishes and presents the evidence for these two groups of women separately). Therefore as should be clearly defined in the patient population, there is a need to address specific groups of women in each recommendation, so that the correct individuals would receive appropriate action as recommended by the guidelines.

Comment 2

Other than clarifying the above, the recommendations are specific and identify intent or purpose, with caveats or qualifying statements. The also include limitations of the recommendations.

There also is clear presentation of what are practice points, what recommendations are supported by evidence, what are developed by consensus.

CLARITY OF PRESENTATION

16. The different options for management of the condition or health issue are clearly presented.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

Different options for assessment and management of the condition are clearly presented in most cases. They recommendations both cover broad scope of the management of the condition and therefore recommendations include the different options and alternatives for specific tests or interventions.

In some cases, the description of population or clinical situation most appropriate to each option is absent. 5.5.5, 5.2.3,

CLARITY OF PRESENTATION

17. Key recommendations are easily identifiable.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

Key recommendations are clearly tabled on pages 15-28 of master document.

They are very clearly presented by numerals, as well as categorized according to topics (questions) addressed by each guideline development group, as well as recommendation categories and quality of evidence.

Check Table 4. “CR” or “CRR” to be consistent with Table 2 recommendation categories.

APPLICABILITY

18. The guideline describes facilitators and barriers to its application.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

The guideline implementation document states that "guideline implementation, translation and dissemination plan directly addresses implementation barriers identified within the evidence synthesis process, such as clinician knowledge gaps and condition specific health literacy among women with PCOS".

However the evidence of this plan documenting the methods by which information regarding the facilitators and barriers to implementation recommendations were sought were not available.

Comment

Barrier to implementation were discussed briefly in 2.3 where it is mentioned "Sensitivities and cultural challenges around psychosexual dysfunction from the woman's and health professional perspectives may present barriers to implementation. However the international, multi-disciplinary guideline development group, including consumers, agreed that despite implementation challenges, the recommendation was warranted on the basis of prevalence data from a recent systematic review and on potential impact."

While 3.1 discusses the financial and resource barriers that may present. (Page 66)

Barriers are mentioned briefly in the guidelines. They are sometimes described under implementation considerations as part of the GRADE framework for specific recommendations, but this was not always consistent. The authors address may wish to barriers more adequately, and suggest specific strategies to overcome them to enhance the applicability of the guideline.

APPLICABILITY

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comment 1
The guideline generally lacks tools that would facilitate its application.
The implementation document mentions the link to tools, but the evidence of these tools are not available.

The following are some examples that were not available that may help enable users to put the guideline into practice:

- Links to the appropriate tools that are recommended for use (i.e., PCOS quality of life tool (PCOSQ) or the modified PCOSQ, Health Questionnaire (PHQ) or the Generalised Anxiety Disorder Scale (GAD7), SCOFF etc)
- Screening toolkit (as a separate document)
- Outcomes of pilot tests and lessons learned
- Barrier analysis with links to strategies or solutions
- Implementation toolkit

Comment 2
Page 129-134 Translation and Dissemination document provides a clear strategy on how to implement the guideline according to different user groups.

APPLICABILITY

20. The potential resource implications of applying the recommendations have been considered.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments
Statement that mentions that "Resource implications were extensively considered within the development process of the guideline and will result in a reduction in use of resources due to; less use of diagnostic ultrasound, less expensive treatment options such as metformin, simpler diagnostic criteria, less intensive metabolic screening and a reduction in expensive IVF treatments."

"This guideline did not include a formal analysis of cost effectiveness or economic feasibility, however the potential impact of cost on recommendations was considered in GRADE process." Furthermore, it did not appear that health economists were involved in the expert panels discussions where costs effectiveness was considered.

It is evident that resource implications and cost have been considered, as they are addressed and mentioned in recommendations and evidence.

APPLICABILITY

21. The guideline presents monitoring and/or auditing criteria.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

Page 129

It is stated that “An international collaborative data hub will collect data from PCOS services aligned with guideline recommendations. Benchmarking and feedback will occur to guide further alignment with evidence-based care with government and NHMRC funding this initiative. In addition, iatrics will monitor downloads of guideline and guideline resources. Finally, focus groups and surveys will be used to check knowledge and awareness in consumers and health professionals with results compared to large-scale data (3500 participants) collected prior to guideline release.

Also mentioned is that “the translation and dissemination plan is supported by a comprehensive evaluation framework, measuring international impacts and outcomes” Page 32

Evaluation framework was in accordance to separate document provided. This is a very large and very detailed framework where the guideline falls within, and it describes specific outcomes that will be measured, and how it will be measured.

Dissemination plan document (separate document) included the outcomes and evaluation measurements for the desired outcomes. The evaluation measures in this plan could be more specific and measureable – i.e., the uptake of guideline is difficult to quantify, consider more measureable and specific outcomes. Could consider quantifying by number of societies engaged, % of endorsements received from external societies etc.

EDITORIAL INDEPENDENCE

22. The views of the funding body have not influenced the content of the guideline.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

Editorial independence and Disclosures of interest is very well described and detailed.

This guideline is editorially independent. The primary funders, NHMRC, were not involved in the development of the guideline and have not influenced the scope. They set standards for guideline development and based on independent peer review approved the guideline process. ESHRE and ASRM nominated experts in PCOS who participated in the project board and guideline development groups. ESHRE and ASRM formed special interest groups to provide feedback on the guideline during public consultation and all feedback will be reviewed by the project board and guideline development groups, blinded by the organisation providing the feedback. All members of committees and GDGs publically disclosed all relevant interests and these were reviewed at each meeting and considered when making recommendations. (Page 31)

Also noted that guideline development groups were formed based on skills (clinical and academic interests), expertise, geographical spread and were nominated by partner or collaborator organisations.

EDITORIAL INDEPENDENCE

23. Competing interests of guideline development group members have been recorded and addressed.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

The name of funding source is stated.

Statement that "the primary funders, NHMRC, were not involved in the development of the guideline and have not influenced the scope."

Consumer panel, technical team and all five guideline development groups have registered and recorded any competing or conflicts of interests. This has been provided in a separate document.

OVERALL GUIDELINE ASSESSMENT

For each question, please choose the response which best characterizes the guideline assessed:

1. Rate the overall quality of this guideline.

1 Lowest possible quality	2	3	4	5	6	7 Highest possible quality

2. I would recommend this guideline for use.

Yes, with modifications	1) Scope and purpose – consider specifying health outcomes, and populations concisely 2) Recommendations – recommendations should clearly define which population it applies to avoid any ambiguity 3) Questions – potential errors in questions for Section 1.5; consider rephrasing questions 5.1a; need to be very specific in target populations 4) Consider barrier analysis and strategies to overcome 5) Consider toolkit or links to tools referenced by the guideline recommendations 6) Consider more explicit linkage to the full evidence in Technical reports (consistent numbering that applies to guideline document, questions and evidence in the technical reports) 7) Completing all blanks and empty spaces throughout technical reports. See notes for some examples.

NOTES

Section 2.6. Change to question.
Check whether recommendation categories should be “CR” or “CRR”
Incomplete pages 332, 379, 15, 187 in “Screening…” technical report, and few others along the way.

Appendix III: Agree II, reviewer 2 appraisal

AGREE II Clinical Practice Guideline Appraisal Report

Appraiser: Reviewer 2, Centre for Clinical Effectiveness, Monash Health

Title: International Evidence-based Guideline for the Assessment and Management of Polycystic Ovary Syndrome 2018

OVERALL GUIDELINE ASSESSMENT

Overall quality: 5 (7 is the Highest possible quality)

Recommend this guideline for use: Yes, with modifications

Overall comments: This guideline covers and extensive body of work and a tremendous effort has been made in incorporating international experts in the development of this work. The authors and individuals that have provided expertise to this guideline should be commended for their work. Overall, the guideline is well written and contains only a small number of typographical or grammatical errors. There are some areas that may require attention, however. These are outlined below.

It is difficult to find sections of this guideline because the information is housed in separate documents that are not cited in the main guideline. Consideration should be given to how each piece of information that has been used to inform this guideline be incorporated in to the main document so that the reader can easily find items. For example, there is important information provided in the 'CRE POCS Evaluation Framework' document but it is not referred to in the main document.

The formatting of the technical reports do not seem consistent in terms of structure or formatting. As a result, it is difficult to navigate through them and ascertain why they are different from each other.

The recommendations table there is a column outlining the category of the recommendation. In this category, 'CR' has not been defined. Do you mean 'CCR'?

Page 10: Is this really a recommendation? *"Ultrasound criteria have been modified, given advancing ultrasound technology and anti-Müllerian hormone levels were deemed not yet adequate for PCOS diagnosis.."*

Page 10: Spelling of apnea.

Page 10: It is suggested that language such as "*In PCOS"* be altered to be more appropriate to the patient i.e. "…in patients with PCOS…"

Page 10: Perhaps change . "*The guideline is…*" to "This guideline is…"

Page 29: The first dot point under Key principles should not be a dot point.

1. The overall objective(s) of the guideline is (are) specifically described.

Score 2

Although the issues of target population and health intent are clearly stated, the expected benefit of the guideline is not explicit. There are no details of the specific health impact the guideline would have on society and populations of patients or individuals relevant to the guideline. It was deemed that this aspect of the domain was a critical area to be described upfront in the guideline. It is for this reason that the score for this item is low.

As indicated earlier, the target population is clearly stated with specific explanation of those who will benefit from the use of the guideline (e.g. consumers, health professionals, policy makers).

Health intent is covered. There is specific mention of the areas in which the guideline will provide improvement (e.g. diagnosis, assessment, treatment, etc.).

This item is well written and clear.

2. The health question(s) covered by the guideline is (are) specifically described.

Score 7

The health question covered by the guideline is provided.

The target population is provided in its own heading.

The setting and audience provided in its own heading.

Information easy to find.

Very clear as to the key principles, guideline development group, methods of development, funding, conflict of interests, and translation.

Items provided in Introduction are clear and concise.

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

Score 6

Target population well defined, easy to find and clear.

Severity/stage of disease is not stated but this may not be relevant.

Comorbidities not stated but may not be relevant.

Excluded populations not stated but may not be relevant.

The population information seems specific enough so that the correct and eligible individuals would receive the action recommended in the guideline.

4. The guideline development group includes individuals from all relevant professional groups.

Score 6

Working groups were formed for the 5 clinical areas.

Consumers were included, as well as some consideration for ethnicity (indigenous reps).

Conflict of interest was considered and recorded. However, it is not clear exactly what the process of solving conflicts were.

Training of working groups in guideline development was conducted.

Members of project board, advisory panel and working groups clearly stated. Name, title discipline, organisation, country and role stated clearly.

Members are easy to find, seem to represent the appropriate scope of the guideline, and include a fair representation of professional streams.

5. The views and preferences of the target population (patients, public, etc.) have been sought.

Score 5

There was an international survey of 1800 women and focus groups used to inform gaps in care, guideline priority questions, prioritised outcomes for each intervention and to inform guideline translation, education and support needs and preferred methods of delivery. However, there is no clear strategy outlined of how these consumers were recruited, or how information was gathered.

It appears that there has not been any consultation with patients with PCOS. Or, if there has, this has not been explicitly outlined.

This point did not impact the scoring of this criterion but, I am not convinced the consumers are true consumers. For example, the consumer representatives are either from organisations with an interest in PCOS or are members of MCHRI.

6. The target users of the guideline are clearly defined.

Score 5

There is a clear description of the target users of this guideline provided in the Introduction.

Target users seem appropriate.

This criterion could be improved by a more explicit, and specific statements regarding the beneficiaries of the guideline, rather than very broad, general statements such, such as ‘health professionals’.

7. Systematic methods were used to search for evidence.

Score 6

Chapter 6 outlines clearly the methods. Databases, time period searched, search terms, and full search strategy were clearly outlined.

The searching seems to be relevant enough to answer each question. In general, there is enough information to be able to replicate the search.

How many people extracted data for each review? This is not clear and therefore potential biases cannot be evaluated.

Appraisal of quality/risk of bias not clearly explained in terms of how many people did this. Also, the appraisal was not outlined in Chapter 6 as it has been mentioned that it would be.

8. The criteria for selecting the evidence are clearly described.

Score 5

Inclusion/exclusion were clearly established and explained. These criteria were based on a clearly defined PICO for each review.

It seems that all relevant literature was searched and there are no reasons to believe the other literature should be considered.

There was no explicit explanation or rationale as to why particular variables outlined in the PICO were excluded.

9. The strengths and limitations of the body of evidence are clearly described.

Score 7

There is a clear description of how the evidence was assessed for bias and quality. The GRADE tool was adequately used.

Tables are clearly provided to outline quality (GRADE) of evidence, in particular the quality of each recommendation.

All recommendations were worded in a manner that considered benefits and harms.

Study limitations were mentioned and put in context of how that would impact the findings.

Language is neural and unbiased.

10. The methods for formulating the recommendations are clearly described.

Score 7

There is clear explanation of how recommendations were formed.

Recommendation category is either evidence-based or consensus based. When sufficient evidence was available in PCOS, an evidence based recommendation was made, where there was insufficient evidence in PCOS, evidence in general or other relevant populations was considered and if

appropriate and there was consensus, clinical consensus recommendations were made. Clinical practice points were included for implementation issues such as safety, side effects and risks.

The Evidence to Decision framework is used.

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

Score 7

For recommendations, clinical practice points were included for implementation issues such as safety, side effects and risks. Therefore, recommendations reflect risk.

Questions that informed the recommendations ask specifically of the literature things around risk.

Consideration of risk seems to be part of the recommendation formulating process and not an add-on.

12. There is an explicit link between the recommendations and the supporting evidence.

Score 4

Table in Recommendations section does not refer to any work informing these recommendations including, reviews, tables, references.

There are sections in the Technical Reports that explicitly outline the justifications for recommendations however, this is not consistent throughout all comparable sections of each Technical Report.

Overall, there is no congruency between the evidence and the recommendations. It is not possible by looking at the Recommendations to find the supporting evidence for each recommendations. It is not clearly stated that if the recommendation was not able to be made purely based on evidence then it was informed by consensus. For example, Table 4 illustrated the GRADE and quality of the evidence and there are a number of '-' in the table. What do these represent?

13. The guideline has been externally reviewed by experts prior to its publication.

Score 3

There is some evidence and explanation of the external review and public consultation process. However, it has not been clearly, explicitly, and specifically explained in detail.

Some of the processes in the documents submitted are describe the process prospectively and there lacks detail regarding precisely what took place. For example, there is no clear description of those involved in the review process i.e. who, how many, professions, affiliation, etc.

There is no description of the purpose or intent of the review process, only reference to NHMRC requirement.

There is no explanation of how the information was gathered and fed into current version of guideline.

14. A procedure for updating the guideline is provided

Score 4

There is a statement provided outlining that the necessary individuals will reconvene to respond to any changes in recommendations that may be informed by TGA approval, RCT or systematic reviews within the next 5 years.

There is no explanation of procedure, timescale, method to determine updating, panel selection, lit review, criteria for review, etc.

There is no explicit statement outlining that the guideline will be updated after a certain time period.

15. The recommendations are specific and unambiguous

Score 7

All recommendations seem specific and unambiguous. When necessary, there is a clear reference to intent, purpose, action, population, and caveats.

Recommendations are also reflected against GRADE and quality to give an understanding of certainty.

16. The different options for management of the condition or health issue and clearly presented.

Score 5

Sections of the Recommendations are presented in appropriate categories and subcategories. However, they are not further clarified by presenting the recommendations in more specific areas such as; diagnosis, treatment, screening, etc. These are currently all put under one single heading.

17. Key recommendations are easily identifiable

Score 7

Recommendations are clearly tabulated and easy to find. Recommendations are presented in a manner so that relevant sections are grouped together.

Summary of recommendations in Executive Summary seems to contain a small amount of text that is not any form of recommendation.

Recommendations reflect the objectives of the guideline.

18. The guideline described facilitators and barriers to its application?

Score 5

Each recommendation justification provides comment on implementation challenges as necessary. Implementation considerations are also provided as a point to comment on regarding Clinical Practice Points in the GRADE process.

There is a specific section assigned to translation and implementation in the guidelines. The implementation and dissemination plan outlines clear guiding principles and aims.

There is a clear statement outlining facilitator organisations and engagement what will enable international implementation. Furthermore, there is a table that clearly and articulately maps translation across the spectrum of end users of the guideline.

However, there is no clear explanation as to how facilitators and barriers were ascertained or how this information was sought. There is also no description of how the information around barriers and facilitators were incorporated in to, or influenced the recommendations.

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

Score 4

The guideline includes a table that covers the translation strategy, which is clear and measurable. There is also a document (implementation guideline) that refers to the tools required for implementation of the recommendations.

It seems as though most of the tools for implementation are yet to be developed (e.g. apps, education, models of care, etc.). Further, it would be useful if these tools were provided in the documentation or hot-linked for the reader to access. There has been no explanation of any implementation barriers identified and how these are anticipated to be overcome (barrier analysis). These are all areas that have impacted the scoring of this section.

20. The potential resource implications of applying the recommendations have been considered.

Score 5

There is consideration of resources in the GRADE framework assessment which covers the size of the resource requirement, certainty of evidence of required resources.

There is a statement about the resource implications in the 'Implementation guideline' document. However, there is no explanation as to how these were ascertained.

There is comment included on relevant Justification sections around resource implications.

There is no comment about education, app development, evaluation, etc.

21. The guideline presents monitoring and/or auditing criteria.

Score 7

There is sufficient detail regarding outcome monitoring, auditing, and evaluation.

Some comment about timing or regularity monitoring, auditing, and evaluation would be of benefit.

22. The views of the funding body have not influenced the content of the guideline.

Score 6

The name of the funding body has been stated but there is no explicit statement regarding the influence of the funding on the recommendations.

Funding section was easy to find.

23. Competing interests of guideline development group members have been recorded and addressed.

Score 5

There is sufficient information provided in the various items of documentation for this guideline outlining the process for identifying conflicts of interest.

In the main guideline document, there is no explicit statement that there were, or were not, any conflicts of interests for any members, and how these might influence recommendation development, if at all. Nor is there a statement of what was undertaken to ensure conflict did not influence recommendations other than reference to an NHMRC process. There is also no information regarding the outcome of any issues relating to conflicts of interest. As a result, this section has been down-graded. It may be useful to refer to these in the main document as supplementary information.