Australian evidence-based guidelines for unexplained infertility: ADAPTE process from ESHRE International Guideline 2023.

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.

- Consumer engagement in topic priority, governance in both ESHRE and Australia, GDG groups at meetings and feedback at ESHRE and in Australia. These organisational representatives were involved in selecting topic priorities, forming clinical questions and on proposed draft and finalised recommendations.
- Aboriginal and Torres Strait Islander and culturally and linguistically diverse representatives have been involved, including diverse international partnerships and in Australia, they have been engaged in all phases of guideline development.
- At least one consumer representative was present in every guideline development group meeting. The peak consumer group representative will play an integral role in disseminating the public consultation draft of the guideline to its organisational members to seek feedback on guideline content.
- A translation advisory consumer group will be established to guide translation of the guideline, including resources which are all extensively co-designed with consumers. This will include additional senior members from peak national consumer organisations including Aboriginal and Torres Strait Islander and culturally and linguistically representatives. An Aboriginal and Torres Strait advisor has been engaged throughout in the Australian process and will be actively involved with other broader indigenous stakeholders in the national implementation and dissemination plan.

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 an example provided by NHMRC. Refer appendix I: Identifying and managing conflicts of interest of prospective members of CRE WHiRL committees and working groups developing guidelines.

  Disclosure of interest declarations were completed by guideline development group members prior to the first meeting and updated at subsequent meetings. Disclosure of interest declarations were also completed by governance committee members and the technical team. Declarations of interest was a standing agenda item at each meeting. A register of interests can be viewed at https://whirlcre.edu.au/new-knowledge/infertility/guideline-public-consultation

1.3. 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 the Guideline Development Group in each recommendation in the GRADE framework. Relevant issues were captured. In evidence reviews, the search terms used to identify studies addressing broad popualtions but a dedicated search was doen on evidence in Indigenous populations. Therefore, studies were captured for all cultural, geographical and socioeconomic backgrounds and settings were identified by the search.

Dr Marlene Kong was appointed as Indigenous Cultural Advisor on the Guideline Development Group (GDG). The GDG had oversight of guideline recommendations for relevance to Indigenous and CALD communities. The Australian Indigenous Doctors Association will be targeted to provide feedback on the guideline during the public consultation period. Aboriginal and Torres Strait Islander and culturally and linguistically diverse communities will be well represented to guide dissemination and implementation activities. A comprehensive implementation, translation and dissemination program has been developed to amplify the impact of the guideline and prioritise Indigenous and Torres Strait Islander populations.

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

- NHMRC funded Centre for Research Excellence in Women's Health in Reproductive Life (CRE WHiRL) $50,000 (30%)
- European Society of Human Reproduction and Embryology (ESHRE) $102,690 (70%) plus in kind
- Medical Research Future Fund, Australian Federal Government Translation Grant $3M for three key areas of women's health/ CREWHiRL Guidelines including UI.
- Additional in-kind, Fertility Society of Australia

2. Guideline recommendations

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

Where there were recommendations that were contentious, consensus was activity sought. Voting to arrive at consensus-based recommendations, was used if needed. Compromise and consensus were reached in 100% of all recommendations or practice points.

The method used to develop consensus recommendations and clinical practice points is outlined in the guideline in the introduction and Annex 1 'Interpreting the recommendations' in the 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. Research recommendations alone were made where there was no evidence that met integrity requirements.

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

The guideline and recommendations will be assessed by two independent reviewers in December 2023/ January 2024, using the AGREE II instrument. Assessment reports, once completed, will be made available to NHMRC and nominated reviewers.

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

The guideline, originally developed by ESHRE, was subjected to public consultation in January 2023, at which time Australian guideline development group representatives provided extensive feedback and coordinated feedback from key stakeholders including Fertility Society of Australia and members of the CRE WHiRL.

Public consultation on the Australian adaptation of the draft guideline will commence on 20 October 2023 and close on 19 November 2023 (31 days). Public consultation is conducted in compliance with NHMRC requirements. A web portal, which includes instructions for submitting feedback and all of the consultation documents, will be developed to facilitate the guideline consultation process. The consultation web portal can be viewed at https://whirlcre.edu.au/new-knowledge/infertility/guideline-public-consultation

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

3.2 During the public consultation period, the developer will undertake and document consultation with:

- the Director-General, Chief Executive or Secretary of each state, territory and Commonwealth health department
- other relevant government departments as appropriate to your guideline topic
- relevant authority/ies, when a guideline makes any recommendation/s specifying interventions that are not available or restricted in Australia.

During the guideline public consultation period, we will invite 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
- Department of Health NT
- Australian Government Department of Health and Aged Care
- Consumer health forum

There are no other relevant government departments appropriate to unexplained infertility and the guideline does not make any recommendations specifying interventions that are not available or restricted in Australia.

3.3 The developer has identified and will consult 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.

The following organisations will be invited to provide feedback on the guideline during public consultation:

- Fertility Society of Australia and New Zealand (FSANZ)
- Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)
- Royal Australian College of General Practitioners (RACGP)
- Guideline development group members
- CRE WHiRL Chief and Associate Investigators
- Australian Indigenous Doctors Association
- European Society for Human Reproduction and Embryology (ESHRE)

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, will be developed. The website will be ready for launch prior to the release of the guideline.

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Appendix 1: Identifying and managing conflicts of interest of prospective members of CRE WHiRL committees and working groups developing guidelines

This policy applies to the Centre for Research Excellence in Women's Health in Reproductive Life (CRE WHiRL) committees and groups developing guidelines.

The NHMRC Act 1992 defines a conflict of interest as 'any direct or indirect pecuniary or non-pecuniary interest'. A conflict of interest does not preclude an individual's involvement within a particular group; however, to ensure the independence and integrity of decision-making processes and for transparency, all relevant interests must be declared and managed appropriately.

For further information on conflicts of interest, please visit the NHMRC 'Guidelines for Guidelines website at

https://www.nhmrc.gov.au/guidelinesforguidelines/plan/identifying-and-managing-conflicts-interest

1. Scope of COI policy

The Conflicts of Interest policy applies to all individuals who participate in the decision-making process as it relates to the development of guidelines within the CRE WHiRL guidelines projects. This includes but is not limited to members of the:

- CRE WHiRL Steering Committee
- Guideline Reference Group
- Guideline Development Group
- Guideline technical team, including project manager, methodologist, integrity team

2. The process of disclosing COIs

Any individual who participates in decision making processes relating to work undertaken within the project is required to complete a 'Declarations of Interest' form and return it to the project manager of the project prior to attending their first meeting. Members need to disclose all relevant interests within the previous three (3) years.

3. Identifying conflicts of interest

The intent of this policy is to have the participants in guideline development disclose any interests relevant to any of the guidelines that are under consideration in order that:

a) such interests can be assessed and managed appropriately

b) the maximum pertinent expertise can be retained

c) each participant can form their own judgement about the issue on which they are offering advice, while taking the interests of other group members into consideration.

Overall, this document seeks to provide guidance on (i) what might constitute conflicts of interests and the disclosure of such interests, (ii) the process by which a determination is made as to whether or not there is a conflict of interest and (iii) the kinds of procedures that need to be put in place in order to address or manage any conflicts of interest.

Typical circumstances in which conflicts of interest arise

There are two general circumstances under which conflicts of interest may arise, and there may be others:

a) **Financial interests**: an interest must be declared as a potential conflict when benefits or losses either in

money or in-kind have occurred or may occur at a level that might reasonably be perceived to affect a person's judgement in relation to fair decisions about evidence and their participation in group decision-making.

b) **Other relationships**: an interest must be declared as a potential conflict when a strong position or prejudice or familial connection or other relationship held by a person could reasonably, or be perceived to, affect a person's judgement in relation to fair decisions about evidence and their participation in group decision-making including making an effort to arrive at a consensus.

In particular, conflicts of interest may involve but are not limited to:

a) financial interests such as receipt by the prospective member or 'immediate family members' (partner and dependent children) of payments, gratuities, consultancies, honoraria, employment, grants, support for travel or accommodation, payment for meals and beverages or entertainment or educational event attendance (including registration fees) or gifts from an entity having a commercial interest in the guidelines

b) any other direct or pecuniary interest considered relevant (for instance, having provided expert testimony on behalf of an entity with a commercial or other interest in the guidelines to be developed)

c) relationships, including board membership, employment, stock ownership or consultancies between the prospective member or 'immediate family members' (partner and dependent children) and corporations whose products or services are related to the guideline topics or that have a commercial or other interest in the guidelines to be developed

d) affiliations to or associations with any organisations or activities which could reasonably be perceived to be an influence due to a competing interest either for or against the issue for which a guideline is being developed

e) institutional interests (that is, interests arising from an affiliation or association of an individual to an institution) – for example, when parties with an interest in the topic of the guideline have made gifts to the member's institution to endow chairs or fund the construction of research facilities or donate equipment to support a project in which the member is involved; or when research conducted within an institution could affect the value of equity that the institution holds in a company or the value of a patent that the institution licenses to a company

f) a prospective member having been involved in the development of related guidelines, standards, educational materials or fact sheets, writing of publications, delivering speeches, or engagement in public debate on the topic related to the guidelines to be developed

g) receipt of research funding by the prospective member or immediate family members from any entity that has a commercial interest in the prospective guidelines

h) any other influences which might reasonably be considered likely to affect the expert judgement of the individual, or lead to the perception by others that the judgement of the individual is compromised.

4. The appointment of members: guidance for the Directors of the CRE or their delegate on assessment and management of interests

The following serves as a guide to the circumstances in which a prospective committee or working group member may be appointed on condition of a suitable conflict of interest management strategy being put in place. The final decision will be a matter of judgement by the Director(s) or their Delegate. This judgement will take into account the information declared in a written disclosure of interests and will:

a) consider whether or not there are factors that could, or could be perceived to, affect a person's expert judgement in relation to fair decisions about evidence and their participation in group decision-making

b) consider whether there could exist real, perceived or potential competing interests that could influence a person's expert judgement or erode the integrity of a group decision

c) determine whether or not the disclosed interests will be managed by a range of measures (e.g. exclusion from certain discussions[1]; divestment of financial interests; resignation from membership of entities whose interests could be affected by any recommendations; a peer review or public consultation process)

d) ensure the committee or working group is chaired by someone who has no conflicts of interest that could, or could be perceived to, erode the integrity of a group decision.

Disclosures are required of all financial interests and prior to a determination on whether or not the disclosure constitutes a low or high level of conflict of interest. Disclosure is required in relation to disbursements over the three years preceding, and any anticipated disbursements in the twelve months following appointment to the committee or working group.

The Director or their Delegate will determine whether or not, on the basis of the declaration of interests:

a) an appointment may proceed and participation can occur without any constraint

b) an appointment may proceed and interests can be managed with constraints – in other words, how a management plan will be put in place which may include measures to mitigate the conflict

In addition to the disclosure of interests both prior to and at the time of appointment, members are required, during their term on the committee or working group, to declare any relevant interests to the Chair if they arise or become evident.

If members are found to have breached this interest policy, the Director must terminate the appointment if the committee member fails to comply, without reasonable excuse, with an obligation to disclose an interest.

As part of the oversight of decisions taken on disclosures of interests, there may be a report included in the guideline on the decisions taken in relation to conflicts of interest.

5. Key elements of the process of disclosing and managing interests

Completion of the disclosure is a prerequisite for consideration of an appointment to a committee or working group developing guidelines.

Appointment to a committee or working group developing guidelines is subject to approval by the Director(s) or Delegate. The Director(s) or Delegate will invite prospective members to complete a form for disclosure of information in relation to interests which may impact on development of the guideline. This form will also record the prospective

[1] A conflict of interest may only apply to a specific task within a committee's mandate. For example, an individual may contribute their expertise to a discussion or be able to answer questions from other members but not vote on a final outcome or the crafting of a final recommendation.

members' willingness to accept the CRE's decisions on means to manage any conflicts of interest and will confirm their consent for this information to be published in the final guideline or as required by NHMRC for guideline approval[2].

Disclosures of interest will be a standing agenda item at each meeting. Meetings will be presided by the Chair of the committee or working group. Members, including the Chair, will be afforded the opportunity to bring up-to-date their disclosures and voice any concerns about interests relating to other prospective committee members.

The Director(s) or Delegate will be required to create a record of all decisions in relation to appointments to a committee or working group. The record of these decisions will be held in a central CRE repository and on the CRE website.

Prospective members should be advised by letter or email of the details of any conflict of interest management plan.

6. The role of the Chair

- Professor Helena Teede chaired the Australian Adaptation and only has disclosures related to competitive government funding and had no conflicts of interest to declare in relation to infertility.
- The final decision to determine whether or not the member of a committee or working group can participate in discussion, as new disclosures of interest arise, must be made by the Chair of the committee or working group[3]
- In order to ensure consistency in decision-making, the CRE must ensure that Chairs, as well members of committees or working groups receive advice and guidance on the principles contained in this document and on whether or not disclosures of interests may trigger the need for action to manage a conflict of interest throughout the life of a committee or working group.
- If the Chair declares an interest, the Director(s) or Delegate will determine the actions needed for action to manage a conflict of interest throughout the life of a committee or working group.
- The Chair (or, when appropriate, the Director(s) or Delegate) must ensure that a record be kept of the actions taken to manage conflict of interest throughout the life of the committee or working group. The record must include the updating of declarations of interest before each meeting and any actions taken (e.g. a member was asked to leave the meeting while a recommendation was made, or a member was present during discussions but did not take part). If no action was necessary this must also be noted in the record of the meeting.
- Members must also be advised that, at the beginning of every meeting, they will be asked to declare any changes not already stated in their disclosure of interests. Any changes will also be recorded and updated in a register of interests, which will be uploaded to the CRE website

[2] It may also be necessary in some circumstances to obtain a family member's direct consent to the disclosure in a manner that is consistent with the requirements of the Information Privacy Principles contained in the Privacy Act 1988.

[3] Where a member has disclosed an interest, the Chair and guideline development group members determine whether the disclosure represents no conflict, a low or high conflict. Where there is high conflict, the member must abstain from voting or decision on relevant recommendations. Where there is low conflict, the Chair and Committee are reminded of the nature of the conflict at the commencement of each meeting.