

## **Australian National Polycystic Ovary Syndrome evidence based guidelines: draft scope**

### **Introduction:**

Polycystic Ovary Syndrome (PCOS) has been identified as an area of clinical need by the Federal Government and by key stakeholder groups. PCOS is a clinical priority based on the following:

- it is a common condition affecting up to 10% of women
- high prevalence in indigenous women of 21%
- diagnosis can be challenging
- complications are serious yet are largely preventable
- there is a lack of awareness of PCOS in both consumers and health professionals
- there is considerable inconsistency in care
- there is a substantial gap between evidence-based best practice and current practice in Australia
- the burden and cost of PCOS complications, including infertility, diabetes and cardiovascular disease, are significant
- currently there are no Australian systematic evidence-based guidelines for PCOS management

### **Aims:**

These guidelines are being developed to ensure women with PCOS receive optimal, evidence based treatment, with a focus on prevention of complications. The guidelines will integrate clinical expertise and consumer preferences and aim to provide health professionals with recommendations for the management of women with PCOS and to promote consistency of care of PCOS in primary care and specialist settings.

The guidelines also aim to form the foundation of a separate translation/ education project to raise awareness, promote early diagnosis and to provide information and support for health professionals and women with PCOS and their families as well as to inform policy makers. Once developed, the guidelines will be supported by a range of evidence based translation tools and resources, to be developed by the Jean Hailes Foundation in liaison with the PCOS Alliance and Evidence Based Guidelines Project Strategic Advisory Group. These groups will facilitate the implementation of the recommendations of the guidelines into practice, targeting both health professionals and women with PCOS.

Guidelines are a tool to improve patient care. They will not replace the central role of the health professional who should apply these guidelines in the context of the individual patient. The key recommendations of these guidelines are intended to provide guidance to the clinician as to the most appropriate management of patients based on the best evidence available from the literature.

Recommendations will also be based on a multidisciplinary consensus opinion to provide guidance in clinically important areas where evidence is lacking. The guidelines will be transparent about which recommendations are evidence based and which are based on consensus opinion. The recommendations in these guidelines will be based on the best evidence available up to 2010, and should be interpreted in that context.

### **Definition of PCOS**

The Alliance has agreed to base all decisions on PCOS using the so-called Rotterdam definition (also called the ESHRE/ASRM consensus). This has received wide acceptance across Europe, Asia and Australia and is now the most accepted definition. It is acknowledged that the so-called NIH criteria have a strong support base among American clinicians and among some medical endocrinologists. It is generally accepted that the NIH criteria define a more serious form of the syndrome, but exclude approximately 30% of those meeting Rotterdam criteria. Rotterdam determined PCOS is inclusive of NIH defined PCOS.

### **Criteria for diagnosis:**

The 2003 Rotterdam consensus workshop concluded that PCOS is a syndrome of ovarian dysfunction along with the cardinal features hyperandrogenism and polycystic ovary (PCO) morphology. PCOS remains a syndrome, and as such no single diagnostic criterion (such as hyperandrogenism or PCO) is sufficient for clinical diagnosis. Its clinical manifestations may include menstrual irregularities, signs of androgen excess, and obesity. Insulin resistance and elevated serum LH levels are also common features in PCOS. PCOS is associated with an increased risk of type 2 diabetes and cardiovascular risk factors. (Fertil Steril\_ 2004;81:19 –25).

Revised 2003 criteria (2 out of 3):

1. Oligo- or anovulation,
  2. Clinical and/or biochemical signs of hyperandrogenism,
  3. Polycystic ovaries
- and exclusion of other aetiologies (congenital adrenal hyperplasia, androgen-secreting tumours, Cushing's syndrome)

### **Key principles that underpin the development and interpretation of all Alliance evidence based guidelines**

1. The need for consumers and health professionals to recognise the lifecourse implications of PCOS
2. Health professionals (to be defined in guideline – glossary of terms) and women need to partner together in managing PCOS and preventing the complications of the condition
3. Consideration should be given to the modulating or exacerbating factors of PCOS
4. When considering therapies, the impact on metabolic, reproductive and psychological features of PCOS should be considered
5. Education, optimal lifestyle and emotional wellbeing are critical to therapy at all life stages and with the management of all PCOS features and complications
6. The indigenous population will be considered in developing the guidelines.

**Context and focus areas for the Alliance guidelines:**

The PCOS Alliance evidence based guidelines (EBG's) address key areas of clinical need. They are not designed to be an inclusive guide to all aspects of PCOS care, with some areas outside the scope of the current Alliance guidelines. These gaps are either filled by existing guidelines which will require adaptation by the Australian Alliance or will be areas for future EBG initiatives.

1. Assessment and investigation of PCOS (Alliance EBG)
2. Promoting optimal emotional wellbeing in PCOS through ongoing assessment and management (Alliance EBG)
3. Promoting optimal lifestyle for treatment of clinical features and prevention of complications in PCOS (Alliance EBG)
4. Promoting optimal therapy for infertility (Alliance EBG)
5. Promoting optimal preconception health (future guideline)
6. Promoting optimal medical therapy for the non fertility related clinical features of PCOS (future guideline)

Note: *A guideline is not required for diagnosis as Rotterdam criteria has been accepted by the PCOS Alliance.*

**The 4 key clinical areas selected by the Alliance representing the key stakeholders in PCOS in Australia were selected at the initial Alliance meeting and confirmed at the most recent annual Alliance meeting, (where all stakeholders were present) and confirmed by the Project Board and Strategic Advisory Group . They are based on:**

1. highest clinical priority
2. greatest knowledge gaps
3. commissioning by the Federal government
4. expertise of Alliance members

**It is acknowledged that consumers also prioritise medical treatment of non fertility related complications. As there are existing EBGs in those areas, it is intended that the Alliance may adapt these for use in Australia.**

**Primary target audience:**

These guidelines will target

- Community care
- General Practice
- Nurses
- Endocrinology
- Obstetrics and Gynaecology
- Allied Health - Psychologists, Dieticians, Exercise Physiologists, Physiotherapists
- Students
- Consumers
- Policy makers

- Indigenous health care workers
- The therapy for infertility guideline will primarily target obstetricians, gynaecologists and endocrinologists

**Settings:**

These guidelines will apply in primary and secondary health settings, in community and hospital settings and to health practitioners who work with women with PCOS.

**Objectives:**

- To develop evidence-based guidelines to optimise evaluation, complication prevention and management in key clinical priority areas in PCOS
- To promote consistent, evidence based care in PCOS
- To inform a national translation/ education program on PCOS targeting consumers and health professionals
- To inform policy makers on evidence based care for women with PCOS
- To improve both the physical and emotional wellbeing of women with PCOS
- To inform the aligned education project to facilitate increased awareness

**Primary target population:**

The guidelines will target all women who have PCOS, with the exception of the fertility guideline, which targets those women with PCOS who are also infertile.

**Major outcomes considered:**

- Improved evaluation, prevention and optimal management of complications of PCOS (diabetes, heart disease, infertility, anxiety and depression)Consistent, evidence based care in PCOS
- Greater recognition and management of psychological features of PCOS
- Greater focus on lifestyle management in PCOS
- Improved preconception care in PCOS
- Improved fertility outcomes in PCOS
- Prioritisation of PCOS in the national policy setting
- Improved quality of life, physical and emotional wellbeing of women with PCOS
- Optimal allocation of resources and identification of the need for additional resources
- Increased investment in research and further evaluation of PCOS
- Identified knowledge gaps
- Promote advocacy in PCOS.

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Refined by the PCOS Alliance and Evidence Based Guidelines Project Board 3/12/09

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