Translation and implementation of the Australian-led PCOS guideline: clinical summary and translation resources from the International Evidence-based Guideline for the Assessment and Management of Polycystic Ovary Syndrome

Helena J Teede[1,2], Marie L Misso[1,2], Jacqueline A Boyle[1,2], Rhonda M Garad[1,2], Veryan McAllister[1,3], Linda Downes[1,2], Melanie Gibson-Helm[1,2], Roger J Hart[1,4], Luk Rombauts[5], Lisa Moran[1,2], Anuja Dokras[6], Joop Laven[7], Terhi Piltonen[8], Raymond J Rodgers[1,9], Mala Thondan[10], Michael F Costello[1,11], Robert J Norman[1,9], on behalf of the International PCOS Network

Polycystic ovary syndrome (PCOS) affects 8–13% of reproductive age women, with around 21% of Indigenous women affected.[1,2] Clinically, reproductive features are prominent and underpin PCOS diagnosis.[3] The Rotterdam diagnostic criteria are based on two of three features: oligo- or anovulation, hyperandrogenism (clinical or biochemical) and polycystic ovaries on ultrasound, after exclusion of other causes (Box 1).[3] Aetiology includes genetic causes, in utero hormone exposure and lifestyle factors (Box 2).[4,5] PCOS is an endocrine disorder underpinned by insulin resistance and hyperandrogenism.[5,6] It is associated with significant metabolic features including increased rates of gestational diabetes and type 2 diabetes mellitus as well as an increase in cardiovascular risk factors (Box 2).[7] PCOS has significant psychological impact with increased depression and anxiety and impaired quality of life (Box 2).[8,9] There is also an increased rate of weight gain and prevalence of obesity in PCOS, increasing severity of the condition, causing considerable concern for those affected and mandating attention to healthy lifestyle.[10]

Obtaining a timely PCOS diagnosis is challenging for women, with many experiencing delays with multiple different doctors involved.[11-13] Inadequate information provision and lack of satisfaction with care has been reported, especially in areas such as psychological features, lifestyle and prevention. Doctors often focus on individual features of PCOS such as infertility, rather than taking a broader approach to care.[13] There is also potential for overdiagnosis, including when isolated polycystic ovarian morphology on ultrasound is incorrectly equated with PCOS. Access to timely, accurate diagnosis and information provision needs significant improvement.

1 Diagnosis of polycystic ovary syndrome

Adult women	Rotterdam diagnostic criteria require two of: 1. Oligo- or anovulation; 2. Clinical and/or biochemical hyperandrogenism; 3. Polycystic ovaries; ***after*** exclusion of other aetiologies
Adolescents	Diagnostic criteria require: 1. Oligo- or anovulation: and, 2. Clinical and/or biochemical hyperandrogenism; ***after*** exclusion of other aetiologies Ultrasound is not recommended in diagnosis <8 years post menarche

Adapted from Teede et al.[9]

Abstract

Introduction: We have developed the first international evidence-based guideline for the diagnosis and management of polycystic ovary syndrome (PCOS), with an integrated translation program incorporating resources for health professionals and consumers. The development process involved an extensive Australian-led international and multidisciplinary collaboration of health professionals and consumers over 2 years. The guideline is approved by the National Health and Medical Research Council and aims to support both health professionals and women with PCOS in improving care, health outcomes and quality of life. A robust evaluation process will enable practice benchmarking and feedback to further inform evidence-based practice. We propose that this methodology could be used in developing and implementing guidelines for other women's health conditions and beyond.

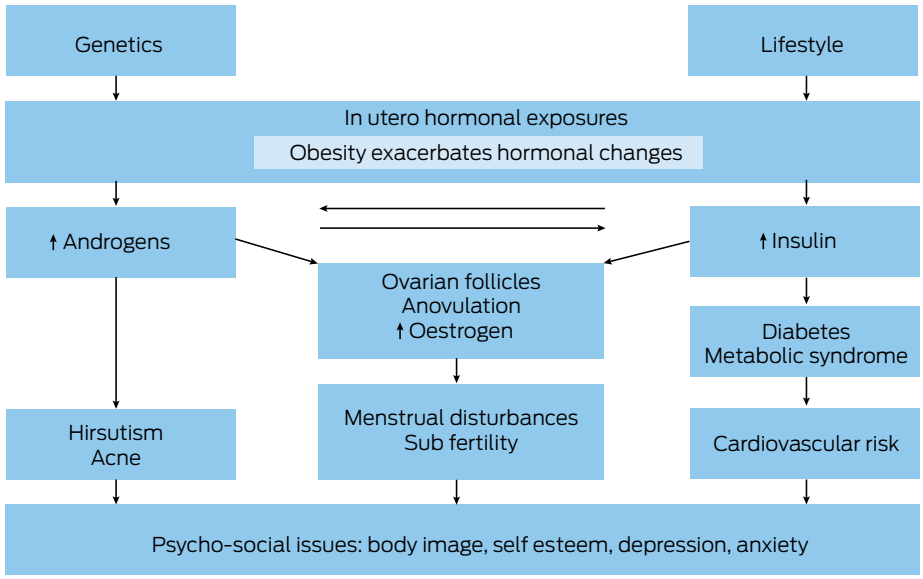
Main recommendations: The recommendations cover the following broad areas: diagnosis, screening and risk assessment depending on life stage; emotional wellbeing; healthy lifestyle; pharmacological treatment for non-fertility indications; and assessment and treatment of infertility.

Changes in management as a result of this guideline:

- Diagnosis:
  - when the combination of hyperandrogenism and ovulatory dysfunction is present, ultrasound examination of the ovaries is not necessary for diagnosis of PCOS in adult women;
  - requires the combination of hyperandrogenism and ovulatory dysfunction in young women within 8 years of menarche, with ultrasound examination of the ovaries not recommended, owing to the overlap with normal ovarian physiology; and
  - adolescents with some clinical features of PCOS, but without a clear diagnosis, should be regarded as "at risk" and receive follow-up assessment.
- Screening for metabolic complications has been refined and incorporates both PCOS status and additional metabolic risk factors.
- Treatment of infertility: letrozole is now first line treatment for infertility as it improves live birth rates while reducing multiple pregnancies compared with clomiphene citrate.

[1] National Health and Medical Research Council Centre for Research Excellence in PCOS, Monash and Adelaide Universities, Melbourne, VIC. [2] Monash Centre for Health Research and Implementation, Monash Public Health and Preventive Medicine, Monash University and Monash Health, Melbourne, VIC. [3] Polycystic Ovary Syndrome Association of Australia, Sydney, NSW. [4] University of Western Australia, Perth, WA. [5] Department of Obstetrics and Gynaecology, Monash University, Melbourne, VIC. [6] Obstetrics and Gynecology, University of Pennsylvania, Philadelphia, PA, USA. [7] Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynaecology, Erasmus Medical Centre, Rotterdam, Netherlands. [8] Obstetrics and Gynecology, PEDEGO Research Unit, Medical Research Centre, Oulu University Hospital, Oulu, Finland. [9] Robinson Research Institute, University of Adelaide and Fertility SA, Adelaide, SA. [10] Harp Family Medical Centre, Melbourne, VIC. [11] UNSW Sydney, Sydney, NSW. ✉ helena.teedee@monash.edu · doi: 10.5694/mja18.00656

2 Aetiology and clinical manifestations of polycystic ovary syndrome



Adapted from Teede et al.[9]

Clinically, there is considerable variation in care and evidence of confusion around diagnostic criteria.[11,14] Researchers are frustrated with inadequate priority and funding in PCOS, especially given the prevalence, disease and economic burden.[15] These challenges are exacerbated by inconsistent guideline quality and recommendations. Past guidelines have not followed recommended rigorous development processes, have not involved diverse health professionals including primary care providers, have not engaged women affected by PCOS, are country specific or, as in the case of the 2011 Australian PCOS guidelines,[9] are now out of date. In this context, PCOS is a clear priority area for updated, consistent rigorously co-developed guidelines, translation resources and health professional and consumer support.[16]

The National Health and Medical Research Council (NHMRC) funded a Centre of Research Excellence to address current gaps. Through a multidisciplinary national alliance and international network, including primary care providers and women with PCOS, we have developed the *International evidence-based guideline for the assessment and management of polycystic ovary syndrome 2018* and co-designed an extensive range of translation resources (Box 3).[16]

The guideline addresses:

- screening, diagnostic assessment, risk assessment and life stage (Algorithm 1);
- prevalence, screening, diagnostic assessment and treatment of emotional wellbeing (Algorithm 2);
- lifestyle (Algorithm 3);
- pharmacological treatment for non-fertility indications (Algorithm 4); and
- assessment and treatment of infertility (Algorithm 5).

Diverse PCOS features are considered, including reproductive (hyperandrogenism, anovulation, infertility), metabolic (insulin resistance, impaired glucose tolerance, gestational and type 2 diabetes, adverse cardiovascular risk profiles) and psychological features (increased anxiety and depression and worsened quality of life).[17] The guideline recognises variable presentation across the lifespan; ethnicity, which has an impact on dermatological and metabolic features; and cultural factors affecting experiences of women with PCOS.

The guideline abstract is provided in Box 4 and the full guideline is available at https://www.monash.edu/medicine/sphpm/mchri/pcos.

Guideline development process and methods

The guideline and translation program were developed through the integration of clinical perspectives, the preferences of women and the best available evidence. International society-nominated panels included consumers and experts in the fields of paediatrics, endocrinology, gynaecology, primary care, reproductive endocrinology, psychiatry, psychology, dietetics, exercise physiology, public health, project management and evidence synthesis translation. Governance included an international advisory and a project board, five guideline development groups, and consumer and translation committees. The NHMRC Australian Centre for Research Excellence in PCOS co-funded the guideline in partnership with the European Society of Human Reproduction and Embryology and the American Society for Reproductive Medicine. Thirty-seven organisations across 71 countries collaborated to address 60 prioritised clinical questions based on 40 systematic and 20 narrative reviews, generating 166 recommendations. Methods met NHMRC standards and procedures for externally developed guidelines[18] and are outlined in the full guideline and Box 5.[19] These involved rigorous systematic review, training, online communication and face-to-face meetings to discuss the evidence and apply the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework. Evidence quality, feasibility, acceptability, cost, implementation and ultimately recommendation strength were agreed across the panel. Convened committees from partner and collaborating organisations provided peer review and the guideline was approved by the NHMRC.[20-22]

Women with PCOS and health professionals as the end users played a fundamental role in developing the guideline and resources. Stakeholder engagement and processes for guideline and translation resource development are outlined in Box 5.[19] A summary of the recommendations is published elsewhere.[20-22] The *MJA* has also published an editorial accompanying this supplement.[23]

In this supplement, we aim to optimise translation and implementation of the guideline (Box 4) by providing a brief clinical summary in the Australian context, noting key changes in practice, and by supporting health care providers, especially those in primary care, with co-designed, practical information, tools and consumer resources to improve outcomes and quality of life for women with PCOS (Box 3). We also highlight implications for Aboriginal and Torres Strait Islander women who are at high risk of PCOS.

The guideline is underpinned by a robust evaluation process which will enable practice benchmarking and feedback data to be collected to guide further alignment with evidence-based care. Downloads of the guideline and its resources will be monitored; focus groups and surveys will measure awareness in consumers and knowledge and practice change by health professionals. This

3 Resources for women and health professionals to support evidence-based care in polycystic ovary syndrome (PCOS)

Resources for health professionals	
Algorithm 1	Screening, diagnostic assessment, risk assessment and life stage https://www.monash.edu/__data/assets/pdf_file/0018/1411641/Algorithm-1-20180615.pdf
Algorithm 2	Prevalence, screening, diagnostic assessment and treatment of emotional wellbeing https://www.monash.edu/__data/assets/pdf_file/0004/1411645/Algorithm-2.pdf
Algorithm 3	Lifestyle https://www.monash.edu/__data/assets/pdf_file/0008/1411649/Algorithm-3.pdf
Algorithm 4	Pharmacological treatment for non-fertility indications https://www.monash.edu/__data/assets/pdf_file/0019/1411651/Algorithm-4-20180801.pdf
Algorithm 5	Fertility treatment https://www.monash.edu/__data/assets/pdf_file/0003/1411653/Algorithm-5-20180619.pdf
Online programs	Webinars, interviews with experts and women with PCOS
Certificate programs	Online (fee-paying education programs)
GP Tool and care plan	Outline of PCOS for GPs to be used during the consultation https://www.monash.edu/__data/assets/pdf_file/0003/1411662/PCOS-GP-Tool-20180622.pdf; https://www.monash.edu/medicine/sphpm/mchri/pcos/resources/practice-tools-for-health-practitioners
Resources for women	
Infographic 1	What is PCOS and do I have it? https://www.monash.edu/__data/assets/pdf_file/0009/1410858/PCOS-Quiz.pdf
Infographic 2	Lifestyle and PCOS https://www.monash.edu/__data/assets/pdf_file/0006/1410855/PCOS-and-Lifestyle-Management.pdf
Infographic 3	Emotional wellbeing and PCOS https://www.monash.edu/__data/assets/pdf_file/0004/1410853/PCOS-and-Emotional-Well-being.pdf
Infographic 4	PCOS medical treatment https://www.monash.edu/__data/assets/pdf_file/0020/1410860/PCOS-Treatment.pdf
Infographic 5	Fertility and PCOS https://www.monash.edu/__data/assets/pdf_file/0005/1410854/PCOS-and-Fertility.pdf
Video series	A series of videos delivered by experts on all aspects of PCOS
Mobile app	Available on Apple iTunes and Google platforms — multilingual options in development
Written resources	Fact sheets, e-resources, booklets and tools available online
Online programs	Webinars and online resources and presentations
Question prompt list	Question list embedded in the app or available stand-alone to improve interaction between women with PCOS and their health professionals

All resources are available at https://www.monash.edu/medicine/sphpm/mchri/pcos

information will then be compared with data that were collected before the guideline release, to measure change.

This strategic international approach involved strong partnership between consumers, multidisciplinary health professionals, academics and professional societies and we propose that this is transferable to other women's health conditions and beyond. Such an approach can reduce duplication of effort and promote consistency of care and focus on provision of useful, accessible and meaningful resources to support both health professionals and people affected by a variety of conditions.[24]

Screening, diagnostic assessment, risk assessment and life stage (Algorithm 1)

We aim to improve accuracy and to simplify and facilitate timely diagnosis, while avoiding overdiagnosis, especially in adolescents. The guideline endorses the consensus-based Rotterdam diagnostic criteria[3,20] for adult women and supports them with best available evidence. Algorithm 1 (https://www.monash.edu/__data/assets/pdf_file/0018/1411641/Algorithm-1-20180618.pdf) highlights the refined diagnostic criteria in adolescents, which require both hyperandrogenism and irregular cycles, with ultrasound now not recommended for diagnosis within 8 years of menarche, owing to overlap with normal reproductive physiology. Adolescents with clinical features but not a clear diagnosis are deemed "at risk", with follow-up assessment recommended. Diagnostic features are refined, including irregular cycles, clinical and biochemical hyperandrogenism, and polycystic ovarian morphology. Exclusion of thyroid disease (thyroid-stimulating hormone), hyperprolactinemia (prolactin) and non-classic congenital adrenal hyperplasia (17-hydroxyprogesterone) is recommended, with further evaluation in patients with amenorrhea and more severe clinical features including consideration of hypogonadotropic hypogonadism, Cushing disease or androgen-producing tumours. The guideline recognises that PCOS is an insulin-resistant and metabolic disorder; tests for insulin resistance, however, lack accuracy and should not be incorporated into the diagnostic criteria for PCOS at this time. Anti-Müllerian hormone is likewise not recommended for diagnosis at this time.

Complication screening is recommended in PCOS. Cardiovascular risk factor screening is updated and simplified, including monitoring weight and weight change, assessing body mass index, family history, ethnicity, smoking status, blood pressure and glycaemic status in all patients with PCOS, and waist circumference and lipid profiles in those with additional risk factors. Frequency and type of testing are guided by presence of both PCOS and other risk factors. Obstructive sleep apnoea and endometrial cancer risk are also addressed.

Prevalence, screening, diagnostic assessment and treatment of emotional wellbeing (Algorithm 2)

Algorithm 2 (https://www.monash.edu/__data/assets/pdf_file/0004/1411645/Algorithm-2.pdf) highlights the increased prevalence of psychological features in PCOS, including anxiety and depressive symptoms, psycho-sexual dysfunction, eating disorders and disordered eating, and adverse impact on body image. The importance of these issues for women is recognised, along with the resulting significant impairment of quality of life. It is vital to ascertain and focus on the individual areas of most importance to women with PCOS. Appropriate screening is recommended based on risk, along with consideration of PCOS features that may have an impact on treatment.

In models of care, identification of priority areas for the individual with PCOS is paramount to enable targeted treatment that improves quality of life. Primary care providers are well positioned to assess, provide care and coordination and, if needed, refer to ensure that care is targeted to need and priority.

4 Abstract from the *International evidence-based guideline for the assessment and management of polycystic ovary syndrome 2018*

Objective: To develop and translate rigorous, comprehensive evidence-based diagnosis, assessment and treatment guidelines, to improve the lives of women with polycystic ovary syndrome (PCOS) worldwide.

Participants: 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.

Evidence: Best practice evidence-based guideline development involved extensive evidence synthesis and the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework covered evidence quality, feasibility, acceptability, cost, implementation and ultimately recommendation strength.

Process: Governance included an international advisory board from six continents, a project board, five guideline development groups with 63 members, consumer and translation committees. The Australian Centre for Research Excellence in PCOS, funded by the National Health and Medical Research Council (NHMRC), partnered with European Society of Human Reproduction and Embryology and the American Society for Reproductive Medicine. Thirty seven organisations across 71 countries collaborated with 23 face to face international meetings over 15 months. Sixty prioritised clinical questions involved 40 systematic and 20 narrative reviews, generating 166 recommendations and practice points. Convened Committees from partner and collaborating organisations provided peer review and the guideline was approved by the NHMRC.

Conclusions: We endorse the Rotterdam PCOS diagnostic criteria in adults (two of clinical or biochemical hyperandrogenism, ovulatory dysfunction, or polycystic ovaries on ultrasound) and where irregular menstrual cycles and hyperandrogenism are present, highlight that ultrasound is not necessary in diagnosis. Within eight years of menarche, both hyperandrogenism and ovulatory dysfunction are required, with ultrasound not recommended. Ultrasound criteria are tightened with advancing technology. Anti-Müllerian hormone levels are not yet adequate for diagnosis. Once diagnosed, assessment and management includes reproductive, metabolic and psychological features. Education, self-empowerment, multidisciplinary care and lifestyle intervention for prevention or management of excess weight are important. Depressive and anxiety symptoms should be screened, assessed and managed with the need for awareness of other impacts on emotional wellbeing. Combined oral contraceptive pills are firstline pharmacological management for menstrual irregularity and hyperandrogenism, with no specific recommended preparations and general preference for lower dose preparations. Metformin is recommended in addition or alone, primarily for metabolic features. Letrozole is first-line pharmacological infertility therapy; with clomiphene and metformin having a role alone and in combination. In women with PCOS and anovulatory infertility, gonadotrophins are second line. In the absence of an absolute indication for IVF, women with PCOS and anovulatory infertility, could be offered IVF third line where other ovulation induction therapies have failed. Overall evidence is low to moderate quality, requiring significant research expansion in this neglected, yet common condition. Guideline translation will be extensive including a multilingual patient mobile application and health professional training.

Ethnic and cultural difference and life stage need consideration. Care should address short and long term psychological features and be mindful of how reproductive and metabolic features may affect psychological wellbeing.

Lifestyle (Algorithm 3)

Algorithm 3 (https://www.monash.edu/__data/assets/pdf_file/0008/1411649/Algorithm-3.pdf) highlights that healthy lifestyle and prevention of excess weight gain are critical for all women with PCOS from adolescence. Lifestyle interventions are similarly effective in women with and without PCOS, and are first line treatment in the majority of women with PCOS who are overweight. Modest weight loss of 5–10% of body weight is recommended to improve PCOS features, primarily through caloric restriction. No specific diet offers greater benefit in PCOS. Exercise recommendations are made for weight maintenance, health and weight loss. Incorporating behavioural strategies such as goal setting, self-monitoring, stimulus control, problem solving, assertiveness training, slower eating, reinforcing changes and relapse prevention are recommended to improve adherence and efficacy.

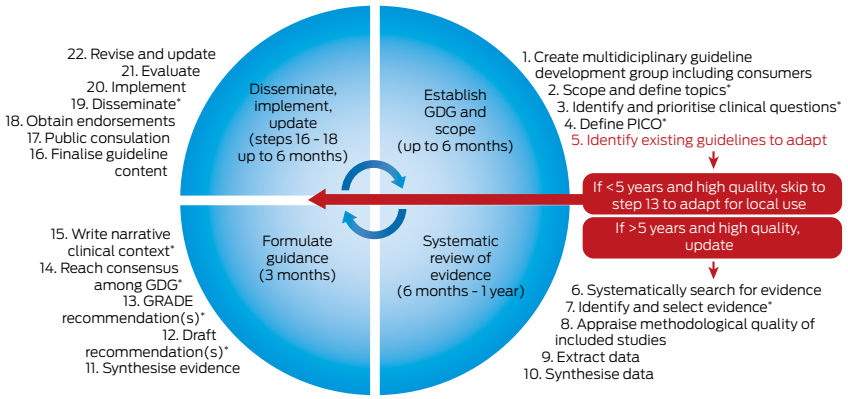
Pharmacological treatment for non-fertility indications (Algorithm 4)

Algorithm 4 (https://www.monash.edu/__data/assets/pdf_file/0019/1411651/Algorithm-4-20180801.pdf) outlines recommendations regarding pharmacological treatment for non-fertility indications. Combined oral contraceptive pills (COCPs) continue to be recommended as first line medical treatment for hyperandrogenism and regulation of menstrual cycles in PCOS. COCP efficacy is largely related to hepatic-mediated oestrogenic effects on sex hormone-binding globulin, which in turn decrease free testosterone levels. Other forms of hormonal contraception are less effective in this regard. COCP use for 6–12 months reduces androgens and hirsutism. Mood impacts have not been shown in PCOS; however, general population studies have noted COCP impact on libido and mood. No one preparation has been shown to be superior in PCOS, with all COCP agents increasing sex hormone-binding globulin and improving clinical outcomes. Based on general population data, COCPs are recommended at the lowest effective oestrogen dose balancing efficacy, metabolic risk profile, side effects, costs and availability, and 35 mg ethinyl estradiol preparations are not recommended first line treatment. Where COCPs and lifestyle changes fail in meeting treatment goals, metformin, as an insulin sensitiser, may assist in prevention of weight gain and improvement in metabolic features. Metformin improves body mass index, cyclicity, androgen levels and metabolic features, has demonstrated efficacy in combination with lifestyle modification, and is recommended in addition to lifestyle intervention, not as a substitute. Low dose therapy is recommended initially, with subsequent titration to reduce the mild and self-limiting gastrointestinal side effects. Anti-androgens in PCOS have limited evidence and are only recommended for hirsutism when at least 6 months of COCPs with cosmetic therapy have failed. Bariatric surgery can improve clinical features; however, registry studies demonstrate concerns around pregnancy outcomes and should only be considered in PCOS after lifestyle therapy fails.

Assessment and treatment of infertility (Algorithm 5)

Algorithm 5 (https://www.monash.edu/__data/assets/pdf_file/0003/1411653/Algorithm-5-20180619.pdf) outlines recommendations on pre-conception care and infertility management. While infertility assessment and management require specialist care, optimisation of psychological health, lifestyle intervention and provision of evidence-based resources to inform women on infertility treatment recommendations are well placed in primary care. The key change recommended in the guideline is the use of letrozole as first line pharmacological treatment in PCOS-associated and anovulatory infertility. Compared with clomiphene citrate, letrozole improves live birth rate, with a reduced rate of multiple pregnancy. However, in Australia, this involves off-label prescription and requires explanation and consent from the patient. Clomiphene citrate is recommended alone or combined with metformin. Metformin can be used alone, recognising lower success rates than other agents. When first line therapy has failed, exogenous gonadotrophins in women with clomiphene citrate-resistant PCOS are generally recommended second line, as is laparoscopic ovarian drilling.

5 Guideline development process



GDG = guideline development group. *Time points and tasks where prioritisation of engagement from GDG is required.

Reproduced with permission from Misso and Teede.[19]

Importantly, in vitro fertilisation is indicated for women with PCOS and anovulation, after failure to respond to first and second line ovulation induction, or if there are other factors contributing to infertility. Algorithm 5 provides a detailed explanation regarding drug choice, based on clinical and other factors.

General practice tool, care plan and consumer resources to support care

Tools and resources have been developed with and for general practitioners, including a GP tool and care plan template to support decision making and evidence-based care in clinical practice (https://www.monash.edu/medicine/sphpm/mchri/pcos/resources/practice-tools-for-health-practitioners). A key component of the range of consumer tools, developed in partnership with consumers, is the PCOS app (AskPCOS). This is the first evidence-based PCOS app that has a range of unique features (eg, a comprehensive repository of information, question prompt list) to increase PCOS-related health literacy. GPs and other health professionals are the preferred source of consumer information, yet there is a clear need for complementary, additional, high quality, evidence-based resources for affected women. Such resources are accessible by searching "Monash PCOS" in your Web browser, or see Box 3 for direct links to the guideline resources for women and health professionals. These resources address demonstrated gaps, including inadequate and generally poor quality existing information, to support clinical care and improve knowledge, consumer engagement and health outcomes.

Considerations for Aboriginal and Torres Strait Islander women

Given the higher prevalence and more severe clinical features of PCOS in Aboriginal and Torres Strait Islander women,[2,25] early diagnosis and management are vital to prevent and manage the reproductive, metabolic and psychological features of PCOS. This must be undertaken in a culturally appropriate and respectful manner.

In diagnosis, high quality ultrasound access may be challenging, as Aboriginal and Torres Strait Islander women are more likely to live in remote locations.[26] The reduced guideline focus on ultrasound in PCOS diagnosis may assist here. Regarding screening for features of PCOS, Aboriginal and Torres Strait Islander women have increased risks of obesity, type 2 diabetes, dyslipidaemia and mental health disorders, independent of PCOS.[27] They are more likely to be overweight or obese at all ages, with obesity contributing around 16% of the disparity in health burden.[28] Diabetes is a key cause of mortality and disability-adjusted life-years in Aboriginal and Torres Strait Islander women,[28] and PCOS amplifies these risks, making screening more critical.

Lifestyle management is the first line treatment for PCOS and associated complications. However, access to culturally appropriate care, services and lifestyle programs is suboptimal, because socio-economic factors, as well as lack of access to healthy food for those living in remote locations, create barriers to modifying lifestyle. Improving this situation is likely to require broader community and government action. There is little information about exercise among Aboriginal and Torres Strait Islander women. However, low participation rates in sports, less in women than men, have been noted.[28] Facilitators of engagement include having a group, family, community or team focus, choice of activities and realistic goal attainment.[29,30] Overall, we anticipate that the lifestyle recommendations in the guideline will be broadly applicable to Aboriginal and Torres Strait Islander women, but we acknowledge the socio-economic and geographical barriers and the need for adaptation to engage this population, especially in rural and remote locations.

Although the data are unclear, it is likely that infertility rates among Aboriginal and Torres Strait Islander women are at least similar to the national prevalence (the limited reports suggest they are actually higher) despite the younger age of first birth and increased total fertility rate.[31,32] This emphasises the need for early diagnosis and for prevention. Socio-economic and geographic barriers may also affect uptake of medication recommendations (eg, letrozole) or procedures (eg, laparoscopic surgery). See also http://www.naccho.org.au/wp-content/uploads/1.National-guide-to-a-preventive-health-assessment-for-Aboriginal-and-Torres-Strait-Islander-people-2.pdf.

Resources are currently in the co-development phase with Aboriginal and Torres Strait Islander women.

Conclusion

The *International evidence-based guideline on the assessment and management of polycystic ovary syndrome 2018* has been rigorously developed and informed by consumers, multidisciplinary health professionals and leading PCOS experts from six continents. The guideline is designed to address the needs of health professionals in providing better, timely care and improved outcomes for women with PCOS, as well as enabling women to be more informed and involved in their treatment.

The PCOS guideline and translation resources aim to accelerate the delivery of consistent, evidence-based care across Australia. GPs are well supported in the implementation of the recommendations from the PCOS guideline by the provision of the range of freely available practice tools, tailored to the Australian context. GPs can also augment the PCOS-related health literacy of consumers by directing them to the range of consumer resources.

Collaborating authors: Estifanos Baye, Monash Centre for Health Research and Implementation, Melbourne; Leah Brennan, Australian Catholic University, Melbourne; Cheryce Harrison, Monash Centre for Health Research and Implementation, Melbourne; Samantha Hutchison, Monash Health Centre for Research Implementation, Melbourne;

Anju Joham, Monash Centre for Health Research and Implementation, Melbourne; Louise Johnson, Victorian Assisted Reproductive Treatment Authority, Melbourne; Cailin Jordan, Genea Hollywood Fertility, Perth; Jayashri Kulkarni, Monash Alfred Psychiatry Research Centre, Melbourne; Darren Mansfield, Monash Health, Melbourne; Kate Marsh, Northside Nutrition and Dietetics, Sydney; Ben W Mol, Monash University, Melbourne; Alexia Peña, Robinson Research Institute, University of Adelaide, Adelaide; Raymond Rodgers, Robinson Research Institute, University of Adelaide, Adelaide; Jane Speight, Deakin University, Geelong; Nigel Stepto, Victoria University, Melbourne; Eliza C Tassone, Monash Centre for Health Research and Implementation, Melbourne; Angela Wan, Monash University, Melbourne; Jane Woolcock, Women's and Children's Hospital, Adelaide.

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Algorithm 1:
Screening, diagnostic assessment, risk assessment and life-stage

Step 1: Irregular cycles + clinical hyperandrogenism

(exclude other causes)* = diagnosis

↓

Step 2: If no clinical hyperandrogenism

Test for biochemical hyperandrogenism (exclude other causes)* = diagnosis

↓

Step 3: If ONLY irregular cycles OR hyperandrogenism

Adolescents ultrasound is not indicated = consider at risk of PCOS and reassess later

Adults - request ultrasound for PCOM, if positive (exclude other causes)* = diagnosis

*** Exclusion of other causes requires TSH, Prolactin levels, FSH and if clinical status indicates other causes need to be excluded**

(e.g. CAH, Cushings, adrenal tumours etc)

Hypogonadotrophic hypogonadism, generally due to low body fat or intensive exercise, should also be excluded clinically and with LH and FSH levels.

Diagnostic Criteria

Irregular menstrual cycles

- normal in the first year post menarche = pubertal transition.
- > 1 to < 3 years post menarche: < 21 or > 45 days.
- > 3 years post menarche to perimenopause: < 21 or > 35 days or < 8 cycles per year.
- > 1 year post menarche > 90 days for any one cycle.
- Primary amenorrhea by age 15 or > 3 years post thelarche (breast development).

With irregular cycles, PCOS should be considered and assessed according to the guidelines.

Ovulatory dysfunction can still occur with regular cycles. If anovulation suspected test progesterone levels.

Clinical hyperandrogenism

Comprehensive history and physical examination for clinical hyperandrogenism. Adults: acne, alopecia and hirsutism and in adolescents severe acne and hirsutism.

Be aware of potential negative psychosocial impact of clinical hyperandrogenism. Perception of unwanted face and body hair and/or alopecia are important, regardless of apparent clinical severity.

Standardised visual scales are preferred when assessing hirsutism such as the modified Ferriman Gallway score (mFG). A cut-off score of ≥ 4-6 indicates hirsutism, depending on ethnicity. It is acknowledged that self-treatment is common and can limit clinical assessment.

The Ludwig visual score is preferred for assessing the degree and distribution of alopecia.

Hirsutism prevalence is same across ethnicities. mFG cut-offs for hirsutism and severity, vary by ethnicity.

Only terminal hairs relevant in pathological hirsutism (untreated > 5 mm long, variable shape and pigmented).

Biochemical hyperandrogenism

Use calculated free testosterone, free androgen index or calculated bioavailable testosterone in diagnosis.

Androstenedione and dehydroepiandrosterone sulfate (DHEAS) have limited role in PCOS diagnosis.

High quality assays needed for most accurate assessment. Direct free testosterone assays not preferred. Interpretation of androgen levels should be guided by the reference ranges of the laboratory used.

Reliable assessment of biochemical hyperandrogenism not possible on hormonal contraception. Consider withdrawal for ≥ 3 months before testing, advising non-hormonal contraception during this time.

In diagnosis, biochemical hyperandrogenism most useful when clinical hyperandrogenism is unclear.

Where levels are well above laboratory reference ranges, other causes should be considered. History of symptom onset and progression is critical in assessing for neoplasia, however, some androgen-secreting neoplasms may only induce mild to moderate increases in biochemical hyperandrogenism.

Ultrasound and polycystic ovarian morphology (PCOM)

Ultrasound should not be used for the diagnosis of PCOS in those with a gynaecological age of < 8 years (< 8 years after menarche), due to the high incidence of multi-follicular ovaries in this life stage.

The transvaginal ultrasound approach is preferred in the diagnosis of PCOS, if sexually active and if acceptable to the individual being assessed.

Using endovaginal ultrasound transducers with a frequency bandwidth that includes 8MHz, the threshold for PCOM should be a follicle number per ovary of ≥ 20 and/or an ovarian volume ≥ 10ml on either ovary, ensuring no corpora lutea, cysts or dominant follicles are present.

If using older technology, the threshold for PCOM could be an ovarian volume ≥ 10ml on either ovary.

In patients with irregular menstrual cycles and hyperandrogenism, an ovarian ultrasound is not necessary for PCOS diagnosis; however ultrasound will identify the complete PCOS phenotype.

Transabdominal ultrasound should primarily report ovarian volume with a threshold of ≥ 10ml, given the difficulty of reliably assessing follicle number with this approach.

Ethnic variation

Consider ethnic variation in PCOS including:

- relatively mild phenotypes in Caucasians.
- higher BMI in Caucasians, especially North America and Australia.
- more severe hirsutism in Middle Eastern, Hispanic and Mediterranean women.
- increased central adiposity, insulin resistance, diabetes, metabolic risks and acanthosis nigricans in South East Asians and Indigenous Australians.
- lower BMI and milder hirsutism in East Asians.
- higher BMI and metabolic features in Africans.

Anti-müllerian hormone (AMH)

Serum AMH levels should not yet be used as an alternative for the detection of PCOM or to diagnose PCOS.

Cardiovascular disease risk and weight management

All with PCOS should be offered regular monitoring for weight change and excess weight, in consultation with and where acceptable to the individual. Monitoring could be at each visit or at a minimum 6-12 monthly, with frequency planned and agreed between the health professional and the individual.

Weight, height and ideally waist circumference should be measured and BMI calculated.

- BMI categories and waist circumference should follow World Health Organisation guidelines also noting ethnic and adolescent ranges.
- Consideration for Asian and high risk ethnic groups including monitoring waist circumference.

All with PCOS should be assessed for individual cardiovascular risk factors and global CVD risk.

If screening reveals CVD risk factors including obesity, cigarette smoking, dyslipidemia, hypertension, impaired glucose tolerance and lack of physical activity, women with PCOS should be considered at increased risk of CVD.

Overweight and obese women with PCOS, regardless of age, should have a fasting lipid profile (total cholesterol, low density lipoprotein cholesterol, high density lipoprotein cholesterol and triglyceride level at diagnosis). Thereafter, measurement should be guided by the results and the global CVD risk.

All women with PCOS should have blood pressure measured annually.

CVD risk in women with PCOS remains unclear pending high quality studies, however prevalence of CVD risk factors is increased, warranting awareness and consideration of screening.

Gestational diabetes, impaired glucose tolerance and type 2 diabetes

Regardless of age, gestational diabetes, impaired glucose tolerance and type 2 diabetes (5 fold in Asia, 4 fold in the Americas and 3 fold in Europe) are increased in PCOS, with risk independent of, yet exacerbated by obesity.

Glycaemic status should be assessed at baseline in all with PCOS and thereafter, every one to three years, based on presence of other diabetes risk factors.

In high risk women with PCOS (including a BMI > 25kg/m^2 or in Asians > 23kg/m^2, history of abnormal glucose tolerance or family history of diabetes, hypertension or high risk ethnicity) an oral glucose tolerance test (OGTT) is recommended. Otherwise a fasting glucose or HbA1c should be performed.

An OGTT should be offered in all with PCOS when planning pregnancy or seeking fertility treatment, given increased hyperglycaemia and comorbidities in pregnancy.

If not performed preconception, an OGTT should be offered at < 20 weeks gestation, and all women with PCOS should be offered the test at 24-28 weeks gestation

Obstructive sleep apnea (OSA)

Screening should only be considered for OSA in PCOS to identify and alleviate related symptoms, such as snoring, waking unrefreshed from sleep, daytime sleepiness, and the potential for fatigue to contribute to mood disorders. Screening should not be considered with the intention of improving cardiometabolic risk, with inadequate evidence for metabolic benefits of OSA treatment in PCOS and in general populations.

A simple screening questionnaire, preferably the Berlin tool, could be applied and if positive, referral.

A positive screen raises the likelihood of OSA, however it does not quantify symptom burden and alone does not justify treatment. If women with PCOS have OSA symptoms and a positive screen, they should ideally be referred to a specialist centre for further evaluation.

Endometrial cancer

Health professionals and women with PCOS should be aware of a two to six fold increased risk of endometrial cancer, which often presents before menopause; however absolute risk remains relatively low.

Health professionals should have a low threshold for investigation of endometrial cancer in PCOS, with transvaginal ultrasound and/or endometrial biopsy recommended with persistent thickened endometrium and/or risk factors including prolonged amenorrhea, abnormal vaginal bleeding or excess weight. Routine ultrasound screening of endometrial thickness in PCOS is not recommended.

Optimal prevention for endometrial hyperplasia and endometrial cancer is not known. A pragmatic approach could include COCP or progestin therapy in those with cycles longer than 90 days.

For more information on PCOS, see the **International evidence-based guideline for the assessment and management of polycystic ovary syndrome 2018** available at: www.monash.edu/medicine/sphpm/mchri/pcos

Algorithm 2: Prevalence, screening, diagnostic assessment and treatment of emotional wellbeing

Psychological domains	Screening protocol / tools	Intervention
Quality of life (QoL)	Lower QoL scores in general and PCOS specific tools such as the modified PCOSQ tool.	Capture and consider women's perceptions of their symptoms, impact on their QoL and priorities. Target treatment to areas of greatest concern to those with PCOS.
Anxiety and depressive symptoms	High prevalence of moderate to severe anxiety and depressive symptoms in adults; and a likely increased prevalence in adolescents. Routine screening for all at diagnosis and subsequently based on clinical judgement, considering risk factors, comorbidities and life events. Suggested screening based on regional guidelines OR initial questions could include: Over the last 2 weeks, how often have you been bothered by the following problems: • Feeling down, depressed or hopeless? • Little interest or pleasure in doing things? • Feeling nervous, anxious or on edge? • Not being able to stop or control worrying? * Factors including obesity, infertility, hirsutism need consideration along with use of hormonal medications in PCOS, which may independently exacerbate depressive and anxiety symptoms and other aspects of emotional wellbeing.	**If responses to initial screening questions positive:** Assess risk factors and symptoms using age, culturally and regionally appropriate tools, such as the Patient Health Questionnaire (PHQ) or the Generalised Anxiety Disorder Scale (GAD7) and/or refer to an appropriate professional for further assessment. • If treatment is warranted, psychological therapy and/or pharmacological treatment should be offered to women with PCOS, informed by regional clinical practice guidelines. **Pharmacological treatment:** Avoid inappropriate treatment with antidepressants or anxiolytics and consider impact on weight. Where mental health disorders are clearly documented and persistent, or if suicidal symptoms are present, treatment of depression or anxiety should be informed by clinical regional practice guidelines.
Psychosexual dysfunction	Decreased scores on sexual function screen. If concerns identified, screen adult women with PCOS. **Note:** Obesity and infertility are common in PCOS and also impact sexual function.	If psychosexual dysfunction is suspected, further assessment, referral or treatment should follow as appropriate.
Body Image	Negative body image has been described in PCOS and can be screened based on regional guidelines or by a stepped approach. Initial questions could include: • Do you worry a lot about the way you look and wish you could think about it less? • On a typical day, do you spend more than 1 hour per day worrying about your appearance? • What specific concerns do you have about your appearance? • What effect does it have on your life? • Does it make it hard to do your work or be with your friends and family?	Consider the impact of PCOS features such as hirsutism, acne, and weight gain in assessing and addressing body image in PCOS.
Eating disorders and disordered eating	High prevalence of eating disorders and disordered eating has been described and can be screened based on regional guidelines or by using the following stepped approach. Initial screening questions can include: • Does your weight affect the way you feel about yourself? • Are you satisfied with your eating patterns? Or the SCOFF tool can be used.	If concerns are identified, further screening should involve: • Assessment of risk factors and symptoms using age, culturally and regionally appropriate tools. • Referral to an appropriate health professional for further mental health assessment and diagnostic interview. If this is not the patient's usual healthcare provider, inform.

For more information on PCOS, see the **International evidence-based guideline for the assessment and management of polycystic ovary syndrome 2018** available at: www.monash.edu/medicine/sphpm/mchri/pcos

Algorithm 3: Lifestyle

Lifestyle

Effectiveness of lifestyle interventions

Healthy lifestyle behaviours (healthy eating and regular physical activity) should be recommended in all women with PCOS including those with excess weight, to achieve and/or maintain healthy weight and to optimise health, and quality of life across the life course. Ethnic groups at high cardiometabolic risk require more consideration.

Achievable goals such as 5% to 10% weight loss in those with excess weight yields significant clinical improvements and is considered successful weight reduction within six months. Ongoing monitoring is important in weight loss and maintenance. Consider referral to a professional to assist with healthy lifestyle.

SMART (Specific, Measurable, Achievable, Realistic and Timely) goal setting and self-monitoring can enable achievement of realistic lifestyle goals.

Psychological factors such as anxiety and depressive symptoms, body image concerns and disordered eating need consideration to optimise healthy lifestyle engagement.

All patient interactions should be patient-centred and value women's individualised healthy lifestyle preferences and cultural, socioeconomic and ethnic differences.

Adolescent and ethnic-specific body mass index and waist circumference categories should be considered when optimising lifestyle and weight.

Behavioural strategies

Lifestyle interventions (may also include cognitive behavioural interventions) could include goal-setting, self-monitoring, stimulus control, problem solving, assertiveness training, slower eating, reinforcing changes and relapse prevention, to optimise weight management, healthy lifestyle and emotional wellbeing in women with PCOS.

Dietary intervention

General healthy eating principles should be followed for all women with PCOS across the life course, with no one dietary type recommended in PCOS.

To achieve weight loss in those with excess weight, an energy deficit of 30% or 500 - 750 kcal/day (1,200 - 1,500 kcal/day) could be prescribed for women, also considering individual energy requirements, body weight, food preferences and physical activity levels and an individualised approach.

Exercise intervention

Health professionals should encourage and advise the following for prevention of weight gain and maintenance of health:

- in adults from 18-64 years, a minimum of 150 min/week of moderate intensity physical activity or 75 min/week of vigorous intensities or an equivalent combination of both including muscle strengthening activities on 2 non-consecutive days/week.
- in adolescents, at least 60 minutes of moderate to vigorous intensity physical activity/day including those that strengthen muscle and bone at least 3 times weekly.
- activity be performed in at least 10 minute bouts or around 1000 steps, aiming to achieve at least 30 minutes daily on most days.

Health professionals should encourage and advise the following for modest weight-loss, prevention of weight-regain and greater health benefits including:

- a minimum of 250 min/week of moderate intensity activities or 150 min/week of vigorous intensity or an equivalent combination of both, and
- muscle strengthening activities involving major muscle groups on 2 non-consecutive days/week and minimised sedentary, screen or sitting time.

Physical activity can be incidental or structured. Self-monitoring, including with fitness tracking devices and technologies, could support and promote active lifestyles.

Obesity and weight assessment

Women with PCOS have higher weight gain and obesity which can impact health and emotional wellbeing. In addressing this, consider related stigma, negative body image and/or low self-esteem by use of a respectful and considerate approach, considering personal sensitivities, marginalisation and potential weight-related stigma.

Prevention of weight gain, monitoring of weight and encouraging evidence-based and socio-culturally appropriate healthy lifestyle is important in PCOS from adolescence.

For more information on PCOS, see the **International evidence-based guideline for the assessment and management of polycystic ovary syndrome 2018** available at: www.monash.edu/medicine/sphpm/mchri/pcos

Algorithm 4: Pharmacological treatment for non-fertility indications

Off label prescribing: COCPs, metformin and other pharmacological treatments are generally off label in PCOS, as pharmaceutical companies have not applied for approval in PCOS. However, off label use is predominantly evidence-based and is allowed in many countries. Where it is allowed, health professionals should inform women and discuss the evidence, possible concerns and side effects of treatment.

In those with a clear PCOS diagnosis or in adolescents at risk of PCOS (with symptoms)

Education + lifestyle + first line pharmacological therapy for hyperandrogenism and irregular cycles

COCP First line

- Use lowest effective oestrogen dose (20-30 micrograms ethinyl oestradiol or equivalent)
- Consider natural oestrogen preparations balancing efficacy, metabolic risk profile, side effects, cost and availability
- Follow WHO COCP general population guidelines for relative and absolute contraindications and risks
- 35 micrograms ethinyloestradiol plus cyproterone acetate not first line in PCOS due to increased adverse effects
- Hirsutism requires COCP and additional cosmetic therapy for at least 6 months
- Consider additional PCOS related risk factors such as high BMI, hyperlipidemia and hypertension

Note:
Other contraceptives don't increase hepatic SHBG production with limited efficacy for hyperandrogenism

Second line pharmacological therapies

COCP + lifestyle + metformin

No COCP preparation is superior in PCOS.

Should be considered in women with PCOS for management of metabolic features, where COCP + lifestyle does not achieve goals.

Could be considered in adolescents with PCOS and BMI ≥ 25kg/m^2 where COCP and lifestyle changes do not achieve desired goals.

Most beneficial in high metabolic risk groups including those with diabetes risk factors, impaired glucose tolerance or high-risk ethnic groups.

COCP + anti-androgens

Evidence in PCOS relatively limited.

Anti-androgens must be used with contraception to prevent male fetal virilisation.

Can be considered after 6/12 cosmetic treatment + COCP if they fail to reach hirsutism goals.

Can be considered with androgenic alopecia.

Metformin + lifestyle

With lifestyle, in adults should be considered for weight, hormonal and metabolic outcomes and could be considered in adolescents.

Most useful with BMI ≥ 25kg/m^2 and in high risk ethnic groups.

Side-effects, including GI effects, are dose related and self-limiting.

Consider starting low dose, with 500mg increments 1-2 weekly.

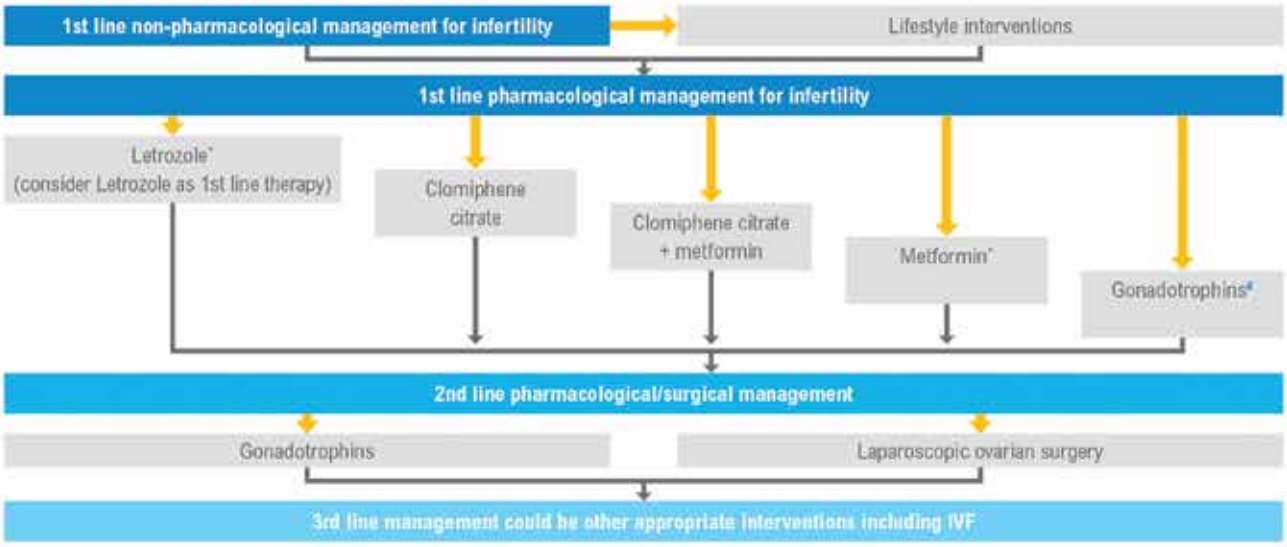
Metformin appears safe long-term. Ongoing monitoring required and has been associated with low vitamin B12.

Anti-obesity medications can be considered with lifestyle as per general population guidelines, considering cost, contraindications, side effects, availability and regulatory status and avoiding pregnancy when on therapy.

Inositol (in any form) should currently be considered experimental in PCOS, with emerging evidence of efficacy highlighting the need for further research.

For more information on PCOS, see the **International evidence-based guideline for the assessment and management of polycystic ovary syndrome 2018** available at: www.monash.edu/medicine/sphpm/mchri/pcos

Algorithm 5: Assessment and treatment of infertility



* **Off label prescribing:** Letrozole, COCPs, metformin and other pharmacological treatments are generally off label in PCOS, as pharmaceutical companies have not applied for approval in PCOS. However, off label use is predominantly evidence-based and is allowed in many countries. Where it is allowed, health professionals should inform women and discuss the evidence, possible concerns and side effects of treatment.

Assessment and treatment of infertility
Assessment of factors that may affect fertility, treatment response or pregnancy outcomes
Factors such as blood glucose, weight, blood pressure, smoking, alcohol, diet, exercise, sleep and mental, emotional and sexual health should be optimised in women with PCOS, to improve reproductive and obstetric outcomes, aligned with recommendations in the general population.
Refer to the International evidence-based guideline for the assessment and management of polycystic ovary syndrome 2018 available at: www.monash.edu/medicine/sphpm/mchri/pcos
Monitoring during pregnancy is important for women with PCOS, given increased risk of adverse maternal and offspring outcomes.
For women with PCOS and infertility due to anovulation alone with normal semen analysis, the risks, benefits, costs and timing of tubal patency testing should be discussed on an individual basis.
Tubal patency testing should be considered prior to ovulation induction for women with PCOS where there is suspected tubal infertility.
Ovulation induction principles
The use of ovulation induction agents, including letrozole, metformin and clomiphene citrate is off label in many countries*.
Pregnancy should be excluded prior to ovulation induction.
Unsuccessful, prolonged use of ovulation induction agents should be avoided, due to poor success rates.
Letrozole
Letrozole should be considered first line pharmacological treatment for ovulation induction in women with PCOS with anovulatory infertility and no other infertility factors to improve ovulation, pregnancy and live birth rates.
Where letrozole is not available or use is not permitted or cost is prohibitive, health professionals should use other ovulation induction agents.
Health professionals and women should be aware that the risk of multiple pregnancy appears to be less with letrozole, compared to clomiphene citrate.
Clomiphene citrate and metformin
Clomiphene citrate could be used alone in women with PCOS with anovulatory infertility and no other infertility factors to improve ovulation and pregnancy rates.
Metformin could be used alone in women with PCOS, with anovulatory infertility and no other infertility factors, to improve ovulation, pregnancy and live birth rates, although women should be informed that there are more effective ovulation induction agents.
Clomiphene citrate could be used in preference, when considering clomiphene citrate or metformin for ovulation induction in women with PCOS who are obese (BMI is ≥ 30 kg/m^2) with anovulatory infertility and no other infertility factors.
If metformin is being used for ovulation induction in women with PCOS who are obese (BMI ≥ 30kg/m^2) with anovulatory infertility and no other infertility factors, clomiphene citrate could be added to improve ovulation, pregnancy and live birth rates.
Clomiphene citrate could be combined with metformin, rather than persisting with clomiphene citrate alone, in women with PCOS who are clomiphene citrate-resistant, with anovulatory infertility and no other infertility factors, to improve ovulation and pregnancy rates.
The risk of multiple pregnancy is increased with clomiphene citrate use and therefore monitoring needs to be considered.

PCOS GP Tool

Refer to the PCOS care plan and PCOS guideline translation tools, available at the below link.

This PCOS GP Tool is based on the best available evidence and was co-designed with health professionals, and aims to assist in the delivery of evidence-based care.

For more information on PCOS, see the International PCOS evidence-based guideline for the assessment and management of polycystic ovary syndrome available at:

www.monash.edu/medicine/sphpm/mchri/pcos

CRE PCOS
Centre for Research Excellence in Polycystic Ovary Syndrome

MONASH University

asrm

shre

Step 1: Irregular cycles + clinical hyperandrogenism

(exclude other causes)* = diagnosis

Step 2: If no clinical hyperandrogenism

Test for biochemical hyperandrogenism
(exclude other causes)* = diagnosis

Step 3: If ONLY irregular cycles OR hyperandrogenism

Adolescents ultrasound is not indicated = consider at risk of PCOS and reassess later

Adults - request ultrasound for PCOM, if positive
(exclude other causes)* = diagnosis

* Exclusion of other causes requires TSH, Prolactin levels, FSH and if clinical status indicates other causes need to be excluded (e.g. CAH, Cushings, adrenal tumours etc). Hypogonadotrophic hypogonadism, generally due to low body fat or intensive exercise, should also be excluded clinically and with LH and FSH levels.

Rotterdam diagnostic criteria requires two of:

1. Oligo – or anovulation
2. Clinical and/or biochemical hyperandrogenism (calculated bioavailable, calculated free testosterone, SHBG, FAI)
3. Polycystic ovaries on ultrasound* (and exclusion of other aetiologies such as: thyroid disease, hyperproplactinemia, FSH (if pre-mature menopause is suspected) and non-classic congenital adrenal hyperplasia)

* Vaginal ultrasound is not needed if 1 and 2 are present and not recommended for < 20yrs due to the high incidence of PCOM (Polycystic ovary morphology)

Irregular periods

Irregular menstrual cycles are defined as:

- normal in the first year post menarche as part of the pubertal transition
- > 1 to < 3 years post menarche: < 21 or > 45 days
- > 3 years post menarche to perimenopause: < 21 or > 35 days or < 8 cycles per year
- > 1 year post menarche > 90 days for any one cycle
- Primary amenorrhea by age 15 or > 3 years post thelarche (breast development)

When irregular menstrual cycles are present a diagnosis of PCOS should be considered.

Ethnic variation

Consider ethnic variation in the presentation and manifestations of PCOS, including differences in hirsutism and acanthosis nigricans and in metabolic sequelae including obesity and insulin resistance.

Clinical hyperandrogenism

Hirsuitism / Alopecia / Acne

Goals

Symptom reduction

Hirsutism

- Be aware of the potentially negative psychosocial impact of clinical hyperandrogensim. Unwanted excess hair growth or female pattern hair loss should be considered important in assessment and management, regardless of apparent clinical severity
- Use standardised visual scales such as the modified Ferriman Gallwey score (mFG) with a level ≥ 4 - 6 indicating hirsutism, noting that self-treatment is common and can limit clinical assessment
- The mFG cut-off scores for defining hirsutism are the same across ethnicities – however prevalence and degree of hirsutism severity varies by ethnicity
- Only terminal hairs should be considered in pathological hirsutism, with terminal hairs clinically growing > 5mm in length if untreated, varying in shape and texture and generally being pigmented

Acne No universally accepted visual tool for assessment

Alopecia Use Ludwig visual score

Management

Hirsutism - mGF scale

Note that terminal hair growth has considerable ethnic variability

- Cosmetic options: laser hair removal, depilatory creams, threading, plucking, waxing and electrolysis
- Pharmacological therapy options (6 -12 months to see benefit)
- Combination therapy – if ≥ 6 months of OCP is ineffective, consider adding anti-androgen to OCP (Contraception is vital to prevent pregnancy while on anti-androgen medication)

Reproductive

Irregular Periods

Goals

- Regular menstrual cycles
- Reduction of risk of endometrial cancer (2 – 6 fold increased risk before menopause, however absolute risk low overall)
- Routine ultrasound screening of endometrial thickness in PCOS is not recommended

Management

- Consider commencing the COCP (In young women make a plan 8 years post menarche to fully assess hormone levels Will need to cease COCP for 3 months prior to assessment)
- If cycles < 4 per year - Medrozyprogesterone acetate to induce a withdrawal bleed if pt does not want to commence COCP

Referrals

GP monitor

Fertility

Goals

Family planning | Conception if desired | Optimise fertility

Management

- Encourage pt to consider conceiving prior to 35 yrs to allow time for fertility interventions, if needed
- Prevention of weight gain, lifestyle changes, weight loss of 5-10% of total body weight, if needed.

Referrals

Refer fertility specialist if unable to conceive after lifestyle changes at 12/12 if < 35 years or at 6/12 if > 35 years

Psychological

Emotional Wellbeing

Goals

Assess, monitor and manage depression, anxiety, body image and low self esteem

Management

Assessment of anxiety and or depressive symptoms involves assessment of risk factors, symptoms and severity. Symptoms can be screened using the following stepped approach:

Step 1: Initial questions could include:

Over the last 2 weeks, how often have you been bothered by the following problems:

- feeling down, depressed, or hopeless?
- little interest or pleasure in doing things?
- feeling nervous, anxious or on edge?
- not being able to stop or control worrying?

Step 2: If any of the responses are positive, further screening should involve:

Assessment of risk factors and symptoms using age, culturally and regionally appropriate tools, such as the Patient Health Questionnaire (PHQ) or the Generalised Anxiety Disorder Scale (GAD7), and/or refer to an appropriate professional if positive to any of the screening questions.

Referrals

Consider referral to a psychologist, counselor

Metabolic features

Cardiovascular Risk Factors

Lipids

Goals

Reduce cardiovascular risk factors

Management

Lipid profile: baseline, if BMI > 25

Referrals

GP to monitor

Cardiovascular Risk Factors

BP

Goals

Target < 85/130

Management

Baseline - every 12 months

Referrals

GP to monitor

Diabetes Risk

Goals

Awareness of high prevalence of gestational diabetes, IGT and type 2 diabetes in PCOS at a young age with risk independent of, yet exacerbated by obesity

Screening

Glycaemic status should be assessed in ALL women with PCOS at baseline, then every one to three years based on presence of other diabetes risk factors

An oral glucose tolerance test (OGTT), fasting plasma glucose or HbA1c can be used but in high risk women with PCOS (BMI >25 or in Asians > 23kg/m2, history of IGT or gestational diabetes, family history of DM2, or high risk ethnicity) an OGTT is recommended.

An OGTT is recommended pre-pregnancy and pre-fertility treatment, and at 25-28 weeks gestation given high risks of hyperglycaemia and high risks in pregnancy.

Lifestyle

Refer to Algorithm 3 and provide pt with PCOS Lifestyle and PCOS infographic.

Lifestyle interventions are as effective in women with PCOS as in women without PCOS.

Diet

Goals

Maintain healthy diet

Management

Key messages

- No one diet is more effective in weight reduction
- Healthy, balanced diet
- Reduce overall caloric intake if an unhealthy weight

Referrals

Consider referral to dietitian

Physical Activity

Goals

Target exercise – See PCOS lifestyle infographic for age specific information.

Management

Exercise routine established

Referrals

GP to monitor

Consider referral to exercise physiologist, trainer

Weight

Goals

Prevention of excess weight gain

Target 5-10% weight loss

Management

Weigh and monitor women regularly, vital to:

- Targeting prevention
- Key message: 5-10% weight loss will greatly assist in symptom control
- Encourage simple behaviour change – prioritisation of healthy lifestyle, family support, lifestyle and exercise planning, setting of small achievable goals
- If unhealthy weight pt unable to lose weight 6/12 with lifestyle changes consider metformin (titrate dose, starting 500mgs up to 2mg)

Referrals

Consider referral via team care arrangement if appropriate:

- Dietitian for tailored dietary advice, education and behavioural change
- Exercise physiologist for tailored exercise program, motivation and support
- Group support, diet and exercise programme

Other

Obstructive Sleep Apnea

Goals

Use Berlin questionnaire
sleepapnea.org/assets/files/pdf/berlin-questionnaire.pdf

Management

Screening should only be considered for OSA in PCOS to identify and alleviate related symptoms, such as snoring, waking unrefreshed from sleep, daytime sleepiness, and the potential for fatigue to contribute to mood disorders. Screening should not be considered with the intention of improving cardiometabolic risk, with inadequate evidence for metabolic benefits of OSA treatment in PCOS and in general populations

Referrals

Consider referral to sleep clinic

Additional GP Tools

GP tools available at:

www.monash.edu/medicine/sphpm/mchri/pcos

Algorithms

Algorithm 1	Screening, diagnostic assessment, risk assessment and life-stage
Algorithm 2	Prevalence, screening, diagnostic assessment and treatment of emotional wellbeing
Algorithm 3	Lifestyle
Algorithm 4	Pharmacological treatment for non-fertility indications
Algorithm 5	Assessment and treatment of infertility

Patient infographics

- What is PCOS and do I have it?
- Lifestyle and PCOS
- Emotional wellbeing and PCOS
- Fertility and PCOS
- PCOS treatment

For more information on PCOS, see the **International evidence-based guideline for the assessment and management of polycystic ovary syndrome 2018** available at: www.monash.edu/medicine/sphpm/mchri/pcos

Patient's name:

PCOS PRIMARY CARE PLAN			
Patient and GP identified problem list			
Patient problems / needs / relevant conditions	Goals - changes to be achieved	Required treatments and services including patient actions	Arrangements for treatments/services (when, who, contact details)
1. Priorities and education		Education - PCOS resources: https://www.monash.edu/medicine/sphpm/mchri/pcos and AskPCOS app	
Patient identified priorities Other identified priorities			
Patient's understanding of their condition	Clear understanding of PCOS and patient's role in self- management	Education - PCOS resources	
2. Lifestyle		Education - PCOS resources	
Nutrition	Maintain general healthy diet	Set joint agreed SMART goals for small achievable changes	Patient to implement GP to refer to dietician as required
Weight - prevention of excess weight gain and management of weight loss as needed	Weight Height BMI Target prevention of weight gain or 5-10% weight loss through caloric restriction	Education - PCOS resources Review 12 monthly for prevention and 1-2 monthly for weight loss	Patient to monitor GP to monitor GP to refer to dietician if needed
Physical activity	Current exercise Patient prioritised/agreed goals	Education - PCOS resources	Patient to implement/ monitor GP to monitor Refer as needed
Smoking	Cessation	Smoking cessation strategy: Consider: Quit, Medication	Patient to manage GP to support
Alcohol intake	Current Target ▪≤ 1 standard drink per day	Patient education	Patient to implement GP to monitor/support
3. Metabolic features		Education - PCOS resources	
BP	Target <130/80	Every 12 months	GP to monitor
Lipids – Check in PCOS with BMI >25kg/m2	Under laboratory recommended range	Fasting lipids at diagnosis and recheck based on global CVD risk	GP to monitor
Glucose routinely and around pregnancy	Target prevention, regular screening, early detection and treatment	Assessed in all at baseline, then every 1-3 years, based on additional diabetes risk factors Fasting plasma glucose or HbA1c ok in PCOS alone, OGTT with additional risk factors. OGTT for all with PCOS before and during pregnancy	GP to monitor

4. Reproductive		Education - PCOS resources	
Menstrual regulation and endometrial protection	≥4 cycles per year (if not on COCP/IUD)	Lifestyle + Medical treatment	Patient and GP to monitor
Hirsutism Alopecia Acne	Assess impact on QoL, meet patients expectations and reduce adverse patient impact	Cosmetic and/or treatment with COCP alone for at least 6-12/12 first line	Patient and GP to monitor
Fertility	Target optimal fertility Reassurance - Vast majority with PCOS will have a family if desired and no other infertility factors, but many may need oral medication support to do so. Rarely need IVF	Discuss early family initiation where possible Prevent weight gain/manage excess weight Preconception care Further resources at https://www.varta.org.au/	GP to reassure, educate, support lifestyle change and refer for management where needed
5. Psychological		Education and PCOS resources	
Identify, support and minimise psychological impact	Screen clinically or use brief psychological tool at https://www.monash.edu/medicine/sphpm/mchri/pcos	If positive on routine questions further assess, treat PCOS features and manage psychological issues	GP to refer psychologist and or additional treatment as needed
6. Other			
7. Medication current	**Medication changes**		
List:	Correct use of medication Minimise side effects	Education and PCOS resources	GP to review compliance/side effects

What is PCOS & do I have it?

Polycystic ovary syndrome (PCOS) is a common condition but with good support, it is very manageable.

Answer the following quiz:

- Has a close female family member been diagnosed with polycystic ovary syndrome (mother, sister, aunt) or have irregular cycles (periods, menstruation) or, a family history of irregular cycles or infertility?
- Do you have irregular or no periods (and are not on hormonal contraceptives)?
- Do you have acne that may be severe?
- Do you feel you have more body hair than your family members such as on your face or stomach?

YES

If you answered yes to one or more of these questions, see your doctor

Symptoms

The symptoms of PCOS vary between women. The range of symptoms you may experience are:

- Irregular periods that are more or less than monthly or no periods
- Delays in getting pregnant
- Excess hair growth on face, stomach, back and loss of hair on the top of the scalp
- Acne, darkened skin patches
- Weight gain (that needs monitoring) and increased metabolic and diabetes risk
- Impact on emotional wellbeing, self-esteem and body image

Diagnosis

There is some variation in what symptoms or signs for a PCOS diagnosis.
We require **only two** of the following three signs to diagnose a woman with PCOS:

#1

Periods less regular – more or less often than monthly

#2

Higher levels of androgen hormones found from a blood test or symptoms such as excess body hair

#3

If needed in adults – if 1 or 2 above are present then the appearance of partly formed eggs (fluid filled sacs called follicles) will be observed on ultrasound (greater than or equal to 20 follicles per ovary)

*Ultrasound is only needed if 1) and 2) are not found and is not recommended in younger women

The **AskPCOS App** provides comprehensive, high quality PCOS information and support tools that are based on the latest evidence.

Lifestyle and PCOS

Move at every opportunity

Take advantage of opportunistic activity

- Take the stairs
- Park further away
- Walk to the shops instead of driving
- Sit less, move more

Preventing excess weight gain is important in managing PCOS

How much activity is ideal?

Weight maintenance for adult women	Weight loss for adult women	Adolescents
150+ mins / week Moderate activity **OR** **75+ mins** / week Vigorous activity	**300+ mins** / week Moderate activity **OR** **150+ mins** / week Vigorous activity	**60+ mins** / day Moderate to Vigorous activity
OR a combination of both	**OR** a combination of both	
Include weight training **2x** per week	Include weight training **2x** per week	Include weight training **3x** per week

Healthy/prevention of weight gain

- 5%–10% Weight loss for women who are at an unhealthy weight
- Monitor weight and waist circumference
- Eat a balanced, healthy diet
- Pay attention to portion control
- Reduce soft drink,fruit juice and sugar sweetened drinks

Healthy lifestyle helps to:

- Maintain or reduce weight
- Improve how you feel about your body
- Make insulin work better and prevent diabetes
- Make your periods more regular
- Improve energy levels
- Improve your fertility
- Improve fitness
- Improve emotional wellbeing

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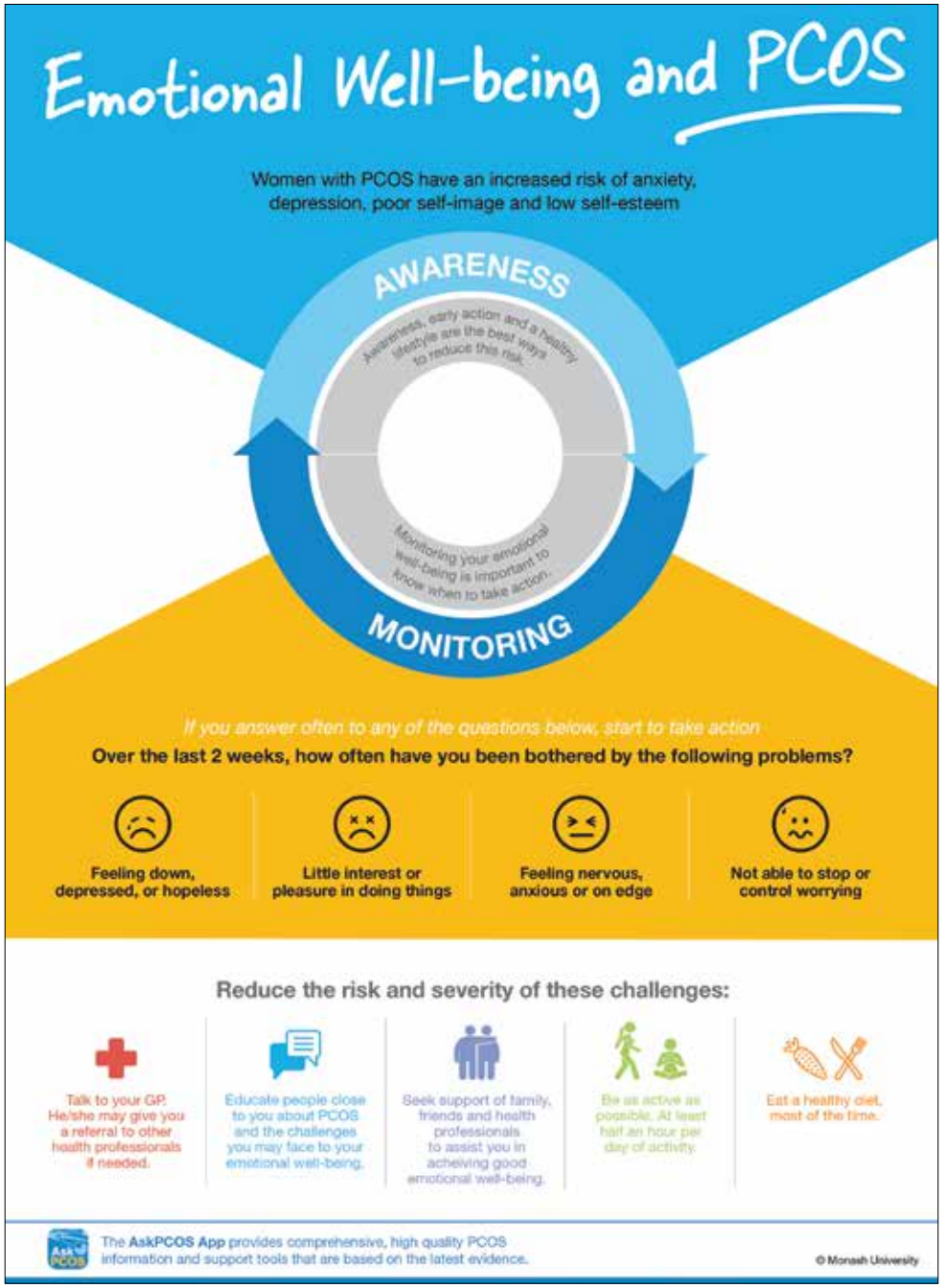
Emotional Well-being and PCOS
Women with PCOS have an increased risk of anxiety, depression, poor self-image and low self-esteem
AWARENESS
Awareness, early action and a healthy lifestyle are the best ways to reduce this risk.
Monitoring your emotional well-being is important to know when to take action.
MONITORING
If you answer often to any of the questions below, start to take action
Over the last 2 weeks, how often have you been bothered by the following problems?
Feeling down, depressed, or hopeless
Little interest or pleasure in doing things
Feeling nervous, anxious or on edge
Not able to stop or control worrying
Reduce the risk and severity of these challenges:
Talk to your GP. He/she may give you a referral to other health professionals if needed.
Educate people close to you about PCOS and the challenges you may face to your emotional well-being.
Seek support of family, friends and health professionals to assist you in acheiving good emotional well-being.
Be as active as possible. At least half an hour per day of activity.
Eat a healthy diet, most of the time.
The AskPCOS App provides comprehensive, high quality PCOS information and support tools that are based on the latest evidence.
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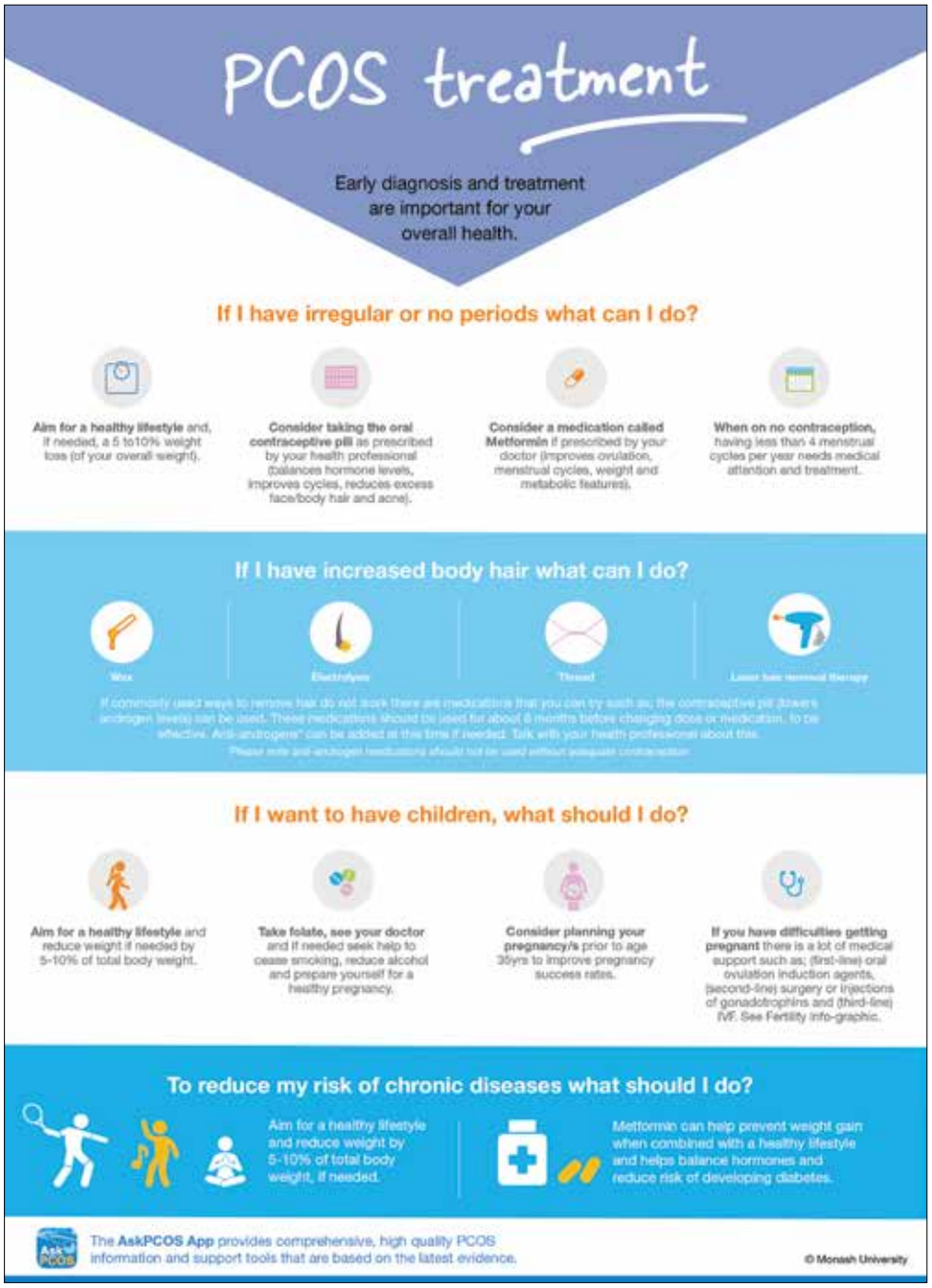
PCOS treatment
Early diagnosis and treatment are important for your overall health.
If I have irregular or no periods what can I do?
Aim for a healthy lifestyle and, if needed, a 5 to10% weight loss (of your overall weight).
Consider taking the oral contraceptive pill as prescribed by your health professional (balances hormone levels, improves cycles, reduces excess face/body hair and acne).
Consider a medication called Metformin if prescribed by your doctor (improves ovulation, menstrual cycles, weight and metabolic features).
When on no contraception, having less than 4 menstrual cycles per year needs medical attention and treatment.
If I have increased body hair what can I do?
Wax
Electrolysis
Thread
Laser hair removal therapy
If I want to have children, what should I do?
Aim for a healthy lifestyle and reduce weight if needed by 5-10% of total body weight.
Take folate, see your doctor and if needed seek help to cease smoking, reduce alcohol and prepare yourself for a healthy pregnancy.
Consider planning your pregnancy/s prior to age 35yrs to improve pregnancy success rates.
If you have difficulties getting pregnant there is a lot of medical support such as; (first-line) oral ovulation induction agents, (second-line) surgery or injections of gonadotrophins and (third-line) IVF. See Fertility info-graphic.
To reduce my risk of chronic diseases what should I do?
Aim for a healthy lifestyle and reduce weight by 5-10% of total body weight, if needed.
Metformin can help prevent weight gain when combined with a healthy lifestyle and helps balance hormones and reduce risk of developing diabetes.
The AskPCOS App provides comprehensive, high quality PCOS information and support tools that are based on the latest evidence.
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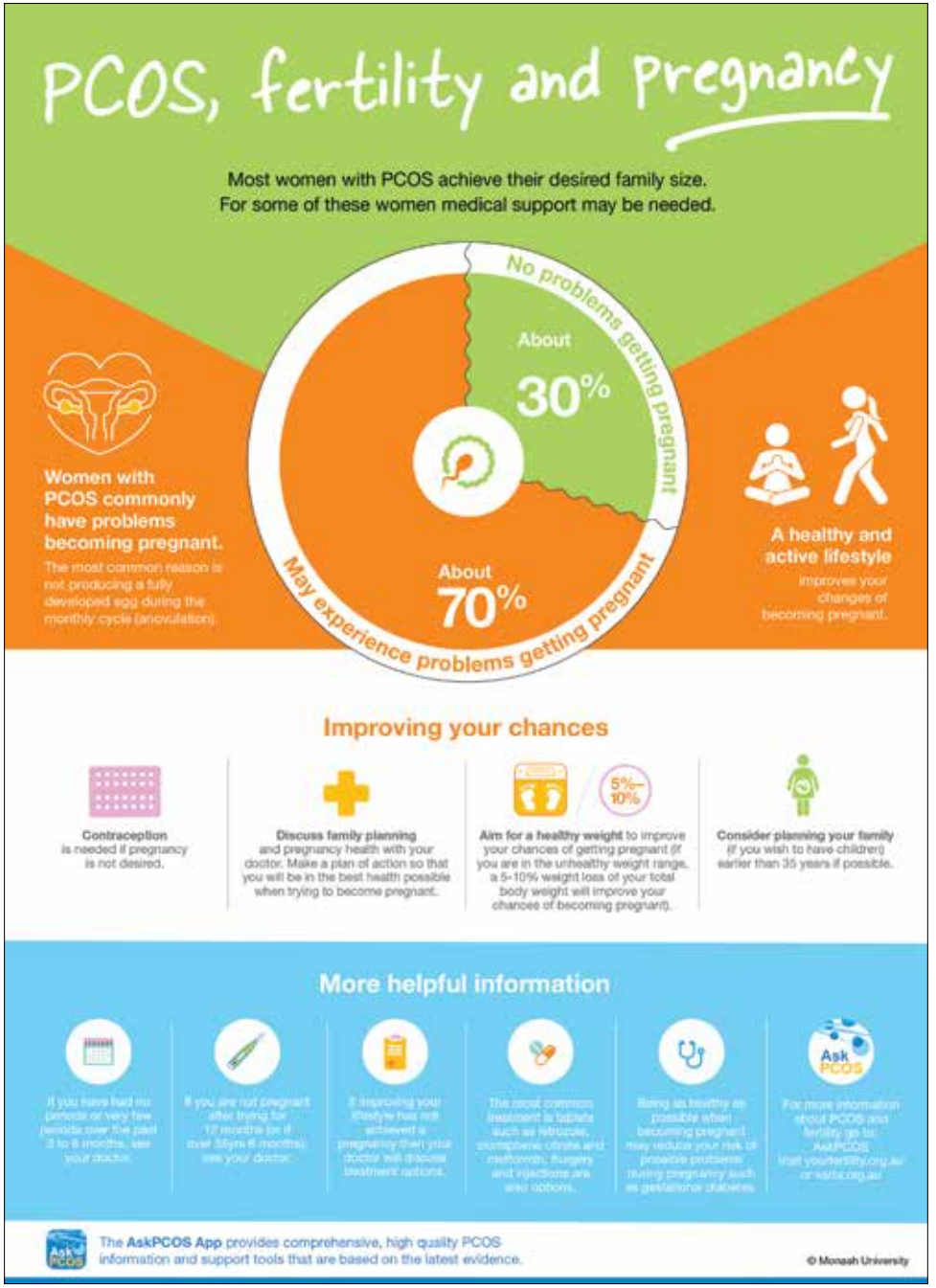
PCOS, fertility and pregnancy
Most women with PCOS achieve their desired family size.
For some of these women medical support may be needed.
No problems getting pregnant
About
30%
About
70%
May experience problems getting pregnant
Women with PCOS commonly have problems becoming pregnant.
The most common reason is not producing a fully developed egg during the monthly cycle (anovulation).
A healthy and active lifestyle
improves your changes of becoming pregnant.
Improving your chances
Contraception
is needed if pregnancy is not desired.
Discuss family planning
and pregnancy health with your doctor. Make a plan of action so that you will be in the best health possible when trying to become pregnant.
Aim for a healthy weight to improve your chances of getting pregnant (if you are in the unhealthy weight range, a 5-10% weight loss of your total body weight will improve your chances of becoming pregnant).
5%–10%
Consider planning your family
(if you wish to have children) earlier than 35 years if possible.
More helpful information
If you have had no periods or very few periods over the past 3 to 6 months, see your doctor.
If you are not pregnant after trying for 12 months (or if over 35yrs 6 months) see your doctor.
If improving your lifestyle has not achieved a pregnancy then your doctor will discuss treatment options.
The most common treatment is tablets such as letrozole, clomiphene citrate and metformin; surgery and injections are also options.
Being as healthy as possible when becoming pregnant may reduce your risk of possible problems during pregnancy such as gestational diabetes.
Ask PCOS
For more information about PCOS and fertility go to: AskPCOS, Visit yourfertility.org.au or eahp.org.au
The AskPCOS App provides comprehensive, high quality PCOS information and support tools that are based on the latest evidence.
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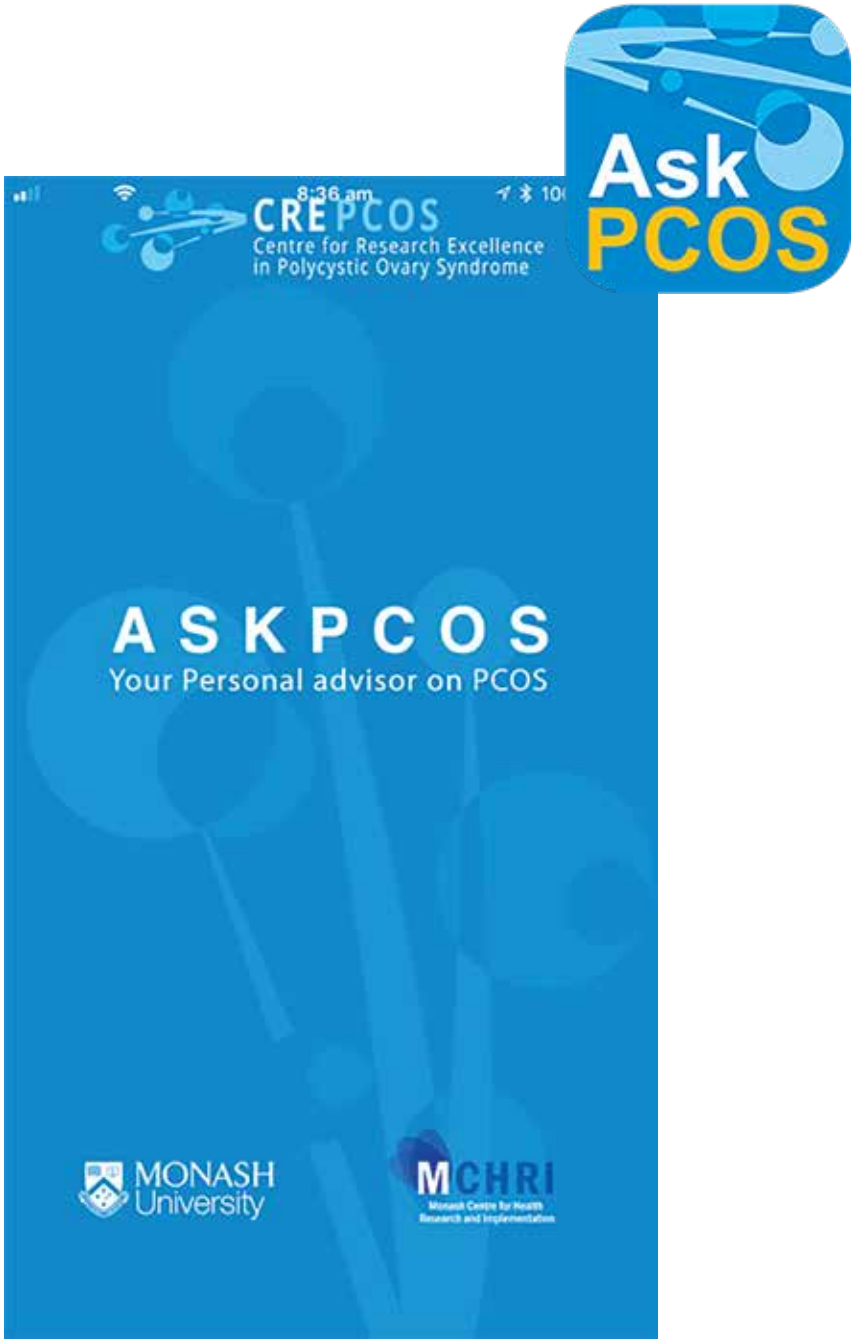
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