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Clinicians' perspectives on diagnosing polycystic ovary syndrome in Australia:

A qualitative study

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Running title: Clinicians' views of polycystic ovary syndrome

Abstract

Study question: What are clinicians' views about the diagnosis of polycystic ovary syndrome (PCOS), and how do they handle any complexities and uncertainties in practice?

Summary answer: Clinicians have to navigate many areas of complexity and uncertainty regarding the diagnosis of PCOS, related to the diagnostic criteria, limitations in current evidence and misconceptions surrounding diagnosis, and expressed concern about the risk and consequences of both under- and overdiagnosis.

What is known already: PCOS is a complex, heterogeneous condition with many areas of uncertainty, raising concerns about both underdiagnosis and overdiagnosis. Quantitative studies with clinicians have found considerable variation in diagnostic criteria used and care provided, as well as lack of awareness around the breadth of PCOS features and poor uptake of recommended screening for metabolic complications. Clinicians' views about the uncertainties and complexities of diagnosing PCOS have not been explored.

Study design, size, duration: Semi-structured telephone interviews were conducted with clinicians from September 2017 to July 2018 to explore their perceptions about the diagnosis of PCOS, including how they handle any complexities and uncertainties in practice.

Participants, materials, setting, methods: 36 clinicians (15 general practitioners, 10 gynaecologists and 11 endocrinologists) currently practicing in Australia, recruited through advertising via professional organisations, contacting a random sample of endocrine and gynaecology teams across Australia and snowballing. Transcribed audio-recordings were analysed thematically using Framework analysis.

Main results and the role of chance: Clinicians expressed a range of uncertainties and complexities regarding the diagnosis of PCOS, which were organised into three areas: 1) establishing diagnosis (e.g. lack of standardisation regarding diagnostic cut-offs, risk of

misdiagnosis), 2) factors influencing the diagnostic process (e.g. awareness of limitations in evidence and consideration of the benefits and harms), and 3) strategies for handling challenges and uncertainties (e.g. using caution and communication of uncertainties).

Clinicians also varied in their concerns regarding under- and overdiagnosis. Overall, most felt the diagnosis was beneficial for women provided that it was the correct diagnosis and time was taken to assess patient expectations and dispel misconceptions, particularly concerning fertility.

Limitations, reasons for caution: There is possible selection bias, as clinicians who are more knowledgeable about PCOS may have been more likely to participate. Clinicians' views may also differ in other countries.

Wider implications of the findings: These findings underscore the vital need to first consider PCOS a diagnosis of exclusion and use caution before giving a diagnosis in order to reduce misdiagnosis, as suggested by clinicians in our study. Until there is greater standardisation of diagnostic criteria, more transparent conversations with women may help them understand the uncertainties surrounding the criteria and limitations in the evidence. Additionally, clinicians emphasised the importance of education and reassurance to minimise the potential harmful impact of the diagnosis and improve patient-centred outcomes.

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Introduction

Polycystic ovary syndrome (PCOS) is a complex endocrine disorder affecting reproductive-aged women, with prevalence estimates ranging from 4%-22.5% depending on the population studied and diagnostic criteria used (Skiba *et al.*, 2018). PCOS is associated with a number of adverse reproductive, metabolic and psychological outcomes (Dumesic *et al.*, 2015). The aetiology is still unclear and appears to include a combination of environmental factors, genetic causes and in utero exposure (Diamanti-Kandarakis & Dunaif, 2012; Tata *et al.*, 2018). There is currently no cure for PCOS, with treatment targeted at reducing symptoms and emphasis on a healthy lifestyle to reduce the risk of associated comorbidities (Teede *et al.*, 2018). Although the Rotterdam criteria are recommended in Australian and international guidelines (National Institute of Health, 2012; Teede *et al.*, 2018; Teede *et al.*, 2011), two other sets of diagnostic criteria are in use (Table I).

Along with multiple diagnostic criteria, there are clinical uncertainties and complexities regarding diagnosis. Symptoms are on a broad spectrum of severity, and it can be difficult to differentiate normal variability from the abnormality of PCOS (Skiba *et al.*, 2018). PCOS is also a diagnosis of exclusion, as many conditions mimic symptoms of PCOS (Azziz *et al.*, 2006). Women can see a range of different healthcare providers (e.g. general practitioners, endocrinologists, gynaecologists) depending on their primary symptoms, which also vary by age, weight and ethnicity (Dokras & Witchel, 2014). Additionally, diagnostic criteria have been mostly based on expert consensus rather than clinical evidence, and have led to substantial debate (Azziz, 2006; Skiba *et al.*, 2018; Wang & Mol, 2017). These complexities

have contributed to inconsistent approaches to diagnosis (Conway *et al.*, 2014; Dokras *et al.*, 2017), with many women reporting significant dissatisfaction with the diagnostic experience and information provided, including delays in receiving a diagnosis (Gibson-Helm *et al.*, 2017). This has raised concerns about underdiagnosis, as a timely diagnosis is thought to enable early treatment of symptoms, fertility counselling and early engagement in lifestyle management to prevent weight gain and related metabolic complications (Gibson-Helm *et al.*, 2017).

Adding to the complexity, diagnostic criteria for PCOS expanded to include polycystic ovaries, increasing the number of women diagnosed and raising concerns about overdiagnosis (Copp *et al.*, 2017). In addition, some phenotypes introduced by the expanded Rotterdam criteria (i.e. those with normal androgen levels) do not seem to have the same increased health risks as the original National Institute of Health phenotype (Daan *et al.*, 2014; Lizneva *et al.*, 2016). Furthermore, current evidence is limited by referral bias, with most studies recruiting from specialist clinics and PCOS support groups, where women with more severe symptoms are more likely to be (Azziz *et al.*, 2016; Lizneva *et al.*, 2016). It is uncertain how the existing evidence applies to the different phenotypes and women with milder symptoms.

Little is known about how clinicians handle the uncertainty surrounding PCOS diagnosis. A limited number of studies have found marked differences between general practitioners, endocrinologists and gynaecologists regarding diagnostic tests used and medication prescribed for PCOS (Cussons *et al.*, 2005; Powers *et al.*, 2015). Online surveys in various countries have also found considerable variation in care, lack of awareness around the

breadth of PCOS features, as well as poor uptake of regular screening for metabolic complications as recommended in guidelines (Dhesi *et al.*, 2016; Gibson-Helm *et al.*, 2018). Additionally, many clinicians reported not using the Rotterdam criteria or were unaware of which criteria they used (Asante *et al.*, 2015; Dokras *et al.*, 2017), despite these criteria being recommended in several guidelines since 2011 (National Institute of Health, 2012; Teede *et al.*, 2018; Teede *et al.*, 2011). In light of these findings, this study aimed to understand clinicians' views about the diagnosis of PCOS, and explore how they manage any complexities and uncertainties in clinical practice.

Materials and Methods

Design

This qualitative study used semi-structured interviews to explore clinicians' experiences and views about the challenges and complexities of diagnosing PCOS (Supplementary Table S1).

Ethics approval

Study methods were approved by The University of Sydney Human Research Ethics Committee (2017/243). All participants provided written informed consent.

Participants and recruitment

Participants were clinicians from the key disciplines directly involved in the diagnosis of PCOS. A multifaceted strategy was utilised to ensure a diverse sample of Australian clinicians were recruited. This included advertising via newsletters or social media accounts of relevant professional organisations, contacting a random sample of endocrine and

gynaecology teams across Australia using publicly available contact details, and through active and passive snowballing with the help of collaborators and participants.

Data collection

The semi-structured interview guide was developed by the whole research team, piloted with a clinician from each specialty and reviewed by the team's PCOS consumer panel (consisting of three women who identify across the spectrum of PCOS symptom severity). Topics included thoughts about the diagnosis and diagnostic criteria, any challenges and uncertainties, communication with patients, and perceived benefits and harms of the diagnosis (Supplementary Data B). Interviews were conducted by phone between September 2017 and July 2018, lasted 20-60 minutes and were audio-recorded and transcribed verbatim.

Analysis

Data were analysed thematically using Framework analysis to understand clinicians' experiences and perspectives (Ritchie, 2003). Framework analysis uses a matrix-based approach with columns depicting themes and rows listing the cases, enabling the relationships between themes and cases to be explored (Ritchie & Spencer, 1994). The first step involved familiarisation with the data, where one researcher reviewed the transcripts and developed a list of emerging topics and salient themes. These initial impressions, along with the interview guide and field notes, formed the basis of the coding framework. An additional four researchers independently read a subset of transcripts and reviewed the framework, which was then further revised with continuous discussion. One researcher coded all the interviews into the final framework, with a random subset (10%) double-coded

by an additional researcher to ensure rigour. Similarities or differences were discussed and re-assessed. Prominent themes arising from the framework were identified and discussed in-depth with the research team.

Results

Participant characteristics

The 36 participants varied in years of experience and included 15 general practitioners (GPs), 10 gynaecologists (3 of whom were also reproductive endocrinologists) and 11 endocrinologists (including 1 paediatric endocrinologist), working in a mix of both public and private practice (Table II). Most participants mentioned using the Rotterdam diagnostic criteria. The most common symptoms women presented with differed according to clinical specialty (e.g. GPs-irregular menstrual cycles, endocrinologists-weight gain and androgen excess, and gynaecologists-irregular menstrual cycles and infertility).

Thematic analysis

Findings were organised into three overarching areas: 1) establishing diagnosis, 2) factors influencing the diagnostic process, and 3) strategies for handling challenges and uncertainties.

Establishing diagnosis

Uncertainties surrounding the diagnosis of PCOS

The majority of clinicians reported using the Rotterdam criteria in adult women, and discussed how they are “*useful*” in capturing the broad syndrome, facilitating research and are easy to apply.

"It's handy for us as GPs because you've got something to follow." (ID5, GP, practicing 5 years)

At the same time, many also discussed how the Rotterdam criteria are not *"perfect"* and that for many women the diagnosis is borderline or unclear.

"Sometimes it's very hard to say when the normal finishes and the abnormal begins." (ID26, Endo, practicing 25 years)

Many discussed how polycystic ovaries are very common and almost *"a normal variant"*, and that *"people can flop in and out of being diagnosed"* as biochemical profiles and ultrasound findings can change over time, causing *"a lot of confusion and distress for patients"* (ID20, Gyn, practicing 16 years). Some clinicians, particularly GPs, described how interpreting blood results can be *"challenging"* due to lack of standardised cut-offs. A few also commented that the guidelines don't acknowledge the role of insulin resistance, which they viewed as central to PCOS. Most GPs reported always ordering ultrasounds, even if other criteria had been met for diagnosis.

"I think sometimes I may be guilty of I've already got enough information to make the diagnosis and I still order the ultrasound anyway." (ID11, GP, practicing 3 years)

However, many specialists and a few GPs commented on how ultrasounds are unhelpful, variable in quality and a *"waste of time"* (ID23, Gyn, practicing 29 years) as they don't alter management.

Problems with misdiagnosis

Many clinicians stressed the importance of considering PCOS a diagnosis of exclusion, using clinical insight and taking a thorough history, as *"misdiagnosis is a big issue"* (ID18, Gyn, practicing 17 years). They described how it can be *"difficult to untangle what really is the*

problem" (ID20, Gyn, practicing 16 years) because many other factors can mimic PCOS symptoms, such as stress, contraceptive use, Cushing's syndrome, obesity, hypothalamic amenorrhea or disordered eating.

"Often I do get women coming saying oh yes, I've got polycystic ovarian syndrome, I've been diagnosed by a GP. And the only syndrome they have is obesity." (ID34, Endo, practicing 15 years)

Some discussed how emphasis on ultrasounds can result in misdiagnosis, as *"people tend to believe the ultrasound and often don't do blood tests, and often they turn out to have something else."* (ID23, Gyn, practicing 29 years). For some specialists, misdiagnosis is their biggest concern as it stops patients from receiving appropriate and timely treatment for their actual condition.

"You don't treat the condition that they actually have. I've just recently diagnosed someone with an unresolved eating disorder who came to me with PCOS. But she doesn't [have PCOS]. She's actually anorexic. So you have to be quite careful in how you treat people." (ID21, Gyn, practicing 22 years)

The majority of clinicians also discussed how diagnosing PCOS in adolescents is *"fraught with danger"* as symptoms overlap with normal signs of pubertal development, so it is *"reasonable to tread carefully with adolescents and delay making a diagnosis"* (ID25, Gyn, practicing 3 years).

Factors influencing the diagnostic process

Prioritising avoidance of underdiagnosis or overdiagnosis

Clinicians varied widely regarding the factors that influence their decision making. Some GPs perceived underdiagnosis as the main risk and timely diagnosis the biggest challenge.

"We don't necessarily sort of screen for it [PCOS] and some people think that irregular periods are normal. So I think we have to be quite proactive." (ID7, GP, practicing 5 years)

For many clinicians, particularly GPs, a diagnosis is important because it starts discussions about optimal health and facilitates a holistic, collective approach to symptom management. A few clinicians discussed how they would rather overdiagnose than underdiagnose PCOS, as healthy lifestyle recommendations are beneficial for everyone and any medical treatment is justified by bothersome symptoms.

"I think it's actually better if anything to slightly overdiagnose than underdiagnose. Because if you can get women into these healthy lifestyle changes and stuff, this is good for everybody." (ID7, GP, practicing 5 years)

On the other hand, some clinicians expressed that overdiagnosis was their "*biggest concern*" and that the condition was being "*overplayed*" (ID30, Endo, practicing 30 years). Some using the Rotterdam criteria reported feeling they easily capture a lot of women, and "*if you look hard enough*" you can diagnose women who are not concerned about symptoms or seeking a diagnosis, causing unnecessary worry (ID5, GP, practicing 5 years). Others reported using alternative diagnostic criteria or clinical expertise, as they believe "*excess of androgens should be a mandatory element*" (ID15, GP, practicing 10 years) to avoid both misdiagnosis and overdiagnosis.

"I use the AES criteria for diagnosis. I think the Rotterdam criteria are completely outdated and lead to an almost, over- and misdiagnosis with significant consequences. There are lots of women who are overdiagnosed or misdiagnosed with

PCOS on the basis of irregular cycles and polycystic appearance of the ovaries on ultrasound.” (ID24, Gyn, practicing 21 years)

Many endocrinologists discussed how PCOS is *“a condition that has evolved with our social environment”* (ID30, Endo, practicing 30 years) due to increasing rates of obesity, expressing concerns that the diagnosis is medicalising a societal phenomenon. Some discussed the challenge of determining whether it is obesity causing symptoms suggestive of PCOS or whether obesity is a manifestation of the condition.

“I think the label of PCOS is just bandied about so often, I probably actually spend more time telling women I don’t think they have true PCOS.” (ID31, Endo, practicing 18 years)

These clinicians perceived that *“over-medicalising”* and labelling weight issues as PCOS undermines patients' sense of *“agency”* and control over their weight, while recognising patients' preference for a medical explanation of their obesity (ID35, Endo, practicing 28 years).

“I’m not sure that we do people any favours by giving them a label. You might be also setting them up for failure by giving them a label to something that they may not necessarily have and then the treatments probably won’t necessarily help their situation.” (D34, Endo, practicing 15 years)

Distinct from these attitudes, gynaecologists who worked in private fertility clinics often viewed that giving the diagnosis was not relevant as it made no difference to fertility treatment.

“It doesn’t really matter to me [whether PCOS is diagnosed or not]. It’s more a case of whether they’re ovulating or not.” (ID22, Gyn, practicing 18 years)

Perceived benefits and harms for women diagnosed

When considering the impact of the diagnosis, a number of perceived benefits and harms were discussed (see Table III for illustrative quotes). Many clinicians considered a range of benefits, such as providing an explanation for symptoms and enabling early intervention to maintain optimal metabolic health and fertility. A few also discussed how the diagnosis enables lifestyle to be addressed in a non-stigmatising way. Regarding harms, some clinicians discussed how the diagnosis can have a negative psychological impact, as *"there's a lot of anxiety about PCOS, especially among young women"* (ID25, Gyn, practicing 3 years). Several clinicians discussed the negative impact of labelling young women with a chronic disease, as *"labels stick like glue"* (ID30, Endo, practicing 30 years), cause ongoing concerns about their health and impact how they view themselves. This was particularly significant for adolescents, as the label makes no difference to management and adolescents have *"all the anxiety around the diagnosis but potentially not the resources or the maturity to manage it"* (ID26, Endo, practicing 25 years).

Clinicians varied in weighing the benefits and harms. A few thought the diagnosis could cause more harm than benefit, particularly for those with mild symptoms. Some felt that although the diagnosis carried some stigma, it was still important to know as it gave women *"a clear way forward"*. Others described feeling *"in two minds"*, as it can help women plan ahead but the long-term benefits are unclear and it may cause more grief than required. Overall, most viewed the label as helpful *"as long as she has it in perspective that she doesn't necessarily have to get all of the disaster consequences of the label"* (ID20, Gyn, practicing 16 years).

Strategies for handling challenges and uncertainties

Caution with labelling when there is uncertainty

Many clinicians across specialties discussed challenges with managing women for whom the diagnosis is unclear. Approaches for communicating with these patients varied and were influenced by the patient's age and expectations (e.g. whether they had already self-diagnosed PCOS). Some clinicians discussed how they communicate the possibility of PCOS, and explain that time is needed to confirm the diagnosis.

"I say it may be PCOS, but I'm uncertain and I don't want to make that diagnosis now."

(ID21, Gyn, practicing 22 years)

Other clinicians, particularly those concerned about the negative impact of disease labelling, described avoiding the label entirely and focusing on treating bothersome symptoms and encouraging a healthy lifestyle. This strategy, however, is not always successful if patients (or their parents in the case of adolescents) insist on a diagnosis.

"We just have to be very cautious in labelling them with conditions that are going to

stay with them for a long time if there's any level of uncertainty." (ID30, Endo,

practicing 30 years)

A few endocrinologists described the challenge in managing patient expectations of receiving a diagnosis, given that *"most people have Googled their symptoms"* (ID31, Endo, practicing 18 years). They suggested that the use of incorrect or premature diagnostic labels may be driven by a desire for certainty on the part of both clinicians and patients.

"I think some medical people don't like to be uncertain. And patients sometimes want to have some sort of certainty too. But I don't think we should just necessarily

pretend that it's certain when it's not." (ID34, Endo, practicing 15 years)

Tailoring care and communication

Although some clinicians reported communicating all of the associated long-term risks to all diagnosed patients, many emphasised the need for patient-centred communication and how the clinical context and patient goals should determine the information provided.

"The challenge that faces us as clinicians is we're not just labelling people within a criteria, we also have to address the human element and communicate in a way that's appropriate to that patient, to give that patient the best outcome." (ID25, Gyn, practicing 3 years)

Many clinicians discussed explaining to patients that PCOS varies on a spectrum of presentations and severity, and how they felt that this minimises the fear of associated adverse consequences.

"I talk about it to women as a concept and a group of issues, rather than a discrete disease or diagnosis...I think the diagnosis is too difficult and flawed to apply rigidly. So I kind of see it as a spectrum." (ID32, Endo, practicing 15 years)

Education and reassurance vital in minimising harm

Misinformation surrounding PCOS was a key issue raised by the majority of clinicians.

Infertility was the most common misconception, with most clinicians reporting that women read online or are told by a doctor that they will not be able to conceive naturally.

"They're often being told they can't get pregnant. That's one of the most disturbing things I hear many times a day." (ID23, Gyn, practicing 29 years)

Many clinicians, particularly specialists, discussed how providing accurate information and reassurance was crucial to dispel myths, manage expectations and minimise the potential for harm. In particular around reduced fertility, some discussed the importance of

communicating that *"lots of women with PCOS manage to fall pregnant naturally without any intervention"* and that *"if they don't want to fall pregnant then they need to use some form of contraception. They can't just rely on being sub-fertile"* (ID7, GP, practicing 5 years).

Clinicians expressed that sensitively communicating the possibility of fertility problems and dispelling these myths was challenging and time consuming as *"it doesn't take very much for women to doubt their fertility"* (ID2, GP, practicing 7 years) and women needed a lot of reassurance.

"I have an hour's discussion with the patient, getting rid of all the information she's been given by other people. But undoing that is a tremendous amount of work."

(ID23, Gyn, practicing 29 years)

Other clinicians' narratives, however, suggested that they overtly discussed the associated risks at the time of diagnosis, noting that *"knowledge is always power"*. This included statements about cardiovascular disease, despite uncertainties around likelihood.

"Even in the skinny ones I'll talk about cardiovascular risk, 'cause I know that they've still got the cardiovascular risks associated with the insulin resistance, even if they're not actually overweight" (ID6, GP, practicing 3 years)

Overall, most discussed how it is vital to deliver the diagnosis in a positive and encouraging way so the patient is *"empowered to try and take control of her long-term metabolic health"*, rather than walk away with a defeatist, despairing outlook *"thinking that they're going to end up needing to shave and wear a wig because of alopecia, be infertile and then end up with diabetes."* (ID35, Endo, practicing 28 years).

Discussion

Clinicians described experiencing a range of uncertainties and challenges regarding PCOS diagnosis. These related to diagnostic criteria (e.g. lack of standardised cut-offs, risk of misdiagnosis, unclear utility of ultrasounds) and their perception of the diagnosis overall (e.g. limitations in evidence, possible benefits and harms for patients). Clinicians also varied in their concerns regarding PCOS, influenced by their awareness of the uncertainty surrounding diagnosis and considerations of benefits and harms. They either favoured early diagnosis to maximise timely engagement and prevent weight gain and related metabolic complications, had a more critical stance towards limitations in evidence and raised concerns about premature or unnecessary labelling, or were in two minds, still weighing up the benefits and harms. Overall, most felt the diagnosis was beneficial for women provided it was the correct diagnosis and time was taken to assess patient expectations and dispel misconceptions (e.g., women thinking they will never be able to conceive naturally).

This work builds on findings from quantitative research (Dokras *et al.*, 2017) showing that whilst the majority of clinicians use the Rotterdam criteria to diagnose PCOS, many use and interpret these criteria in different ways. This variation is due to the uncertainties and complexities that exist when trying to apply the criteria to a heterogeneous condition with substantial phenotypical variation and overlap with other conditions. These uncertainties are exacerbated by the substantial debate surrounding the diagnostic criteria (Azziz, 2006; Lizneva *et al.*, 2016; Wang & Mol, 2017), the unclear benefits and harms of the diagnosis in the long-term (Copp *et al.*, 2017), and the still limited understanding of the aetiology of PCOS (Azziz *et al.*, 2016). In light of this, many clinicians in this study cautioned to take time when establishing the diagnosis to avoid labelling prematurely or inaccurately, particularly

for adolescents. Indeed, new international guidelines now recommend that adolescents with an unclear diagnosis should be regarded 'at risk' and reassessed later to reduce the risk of overdiagnosis (Teede *et al.*, 2018). These diagnostic complexities could also explain why some women report long delays and seeing multiple doctors before receiving a diagnosis (Gibson-Helm *et al.*, 2017). Expanding quantitative findings (Dokras *et al.*, 2017), clinicians who had been practicing longer seemed more cautious with diagnosing and less likely to use the Rotterdam criteria, expressing a view that these criteria increase misdiagnosis and overdiagnosis. Although there was variation within specialties, key diagnostic concerns also seemed to differ across specialties, with more GPs concerned about underdiagnosis, gynaecologists about misperceptions and endocrinologists about overdiagnosis.

As well as recognising the complexities associated with diagnosing PCOS, participants acknowledged both benefits and harms of a PCOS diagnosis for patients, although considerations of harms varied widely. Participants' perceived benefits and harms are consistent with previous research on disease labelling, which suggests that labels can provide validation and increase patients' understanding and ability to cope (Copp *et al.*, 2019), but can also induce feelings of anxiety and hopelessness (Haynes, 1978; Scherer *et al.*, 2013; Shaffer & Scherer, 2018). There were particularly varying views regarding lifestyle changes. Whilst some clinicians thought the diagnosis could cause harm by undermining women's sense of control over their weight and result in disengagement with healthy lifestyle changes, many believed the diagnosis enabled early engagement in lifestyle management to prevent weight gain and related metabolic complications. This presumed benefit contrasts with mounting evidence showing that personalised risk information does not change behaviour (French *et al.*, 2017; Hollands *et al.*, 2016; Marteau, 2018), suggesting

clinicians may be overestimating this potential benefit. Views also differed in how helpful the diagnosis was in guiding management.

Importantly, these findings underscore the crucial need to consider PCOS a diagnosis of exclusion and complete the recommended work-up to reduce misdiagnosis. The new international guidelines attempt to address some of these uncertainties raised by clinicians by clarifying the diagnostic criteria. For example, the definition of oligomenorrhea has been more clearly defined and the antral follicle count for polycystic ovary morphology has been increased to >20 to account for increasing sensitivity of imaging technology (Teede *et al.*, 2018). A diagnosis of PCOS should not be assigned lightly, as it implies an increased risk of a myriad of adverse reproductive, metabolic and psychological consequences, may mandate chronic treatments and regular screening for comorbidities, and could potentially affect health insurance premiums (Azziz *et al.*, 2006). An incorrect PCOS diagnosis also means women miss out on correct treatment. For example, untreated hypothalamic amenorrhea, which was reported to be frequently misdiagnosed as PCOS, can have significant implications such as bone loss (Shufelt *et al.*, 2017).

Notably, many specialists spent additional time educating the patient regarding her fertility potential and undoing misinformation, sometimes perpetuated by other clinicians.

Appropriate education of clinicians and counselling of patients regarding the chances of spontaneous ovulation, need for contraception and fertility over the reproductive span is urgently needed. Additionally, physicians need appropriate education regarding the associated comorbidities as these risks differ amongst women with different symptoms, enabling tailored risk counselling. For uncertain cases, more transparent conversations with

women may help them understand the uncertainties surrounding the criteria, explaining why clinicians may be hesitant to give a diagnosis. This may reduce dissatisfaction associated with delayed diagnosis whilst still providing rapid and appropriate treatment of bothersome symptoms. Communicating uncertainty however is challenging, and more research in this area is needed.

Strengths of this study include the varied recruitment method to ensure a diverse sample of physicians from the key disciplines involved in PCOS healthcare in Australia; general practitioners, gynaecologists and endocrinologists. Additionally, the interview guide was developed by a multidisciplinary team to ensure relevance, including researchers experienced in qualitative methodology, PCOS experts and PCOS consumers, and rigorous qualitative analysis was undertaken to reach final themes. A possible limitation is potential selection bias, as physicians more knowledgeable or experienced with PCOS may have been more likely to participate. However, given the variation in perspectives reported and range in years of experience, strong selection bias is unlikely. These views may also differ from those of clinicians in other countries. Further research on clinicians' views in different locations and different healthcare systems is warranted.

In conclusion, these findings provide valuable insight into clinicians' experiences with the PCOS diagnostic criteria and the complexities regarding diagnosis in Australia, highlighting concerns about the risk and consequences of both underdiagnosis and overdiagnosis. Additionally, misdiagnosis was raised as a key issue, underscoring the crucial need to first exclude mimicking conditions. These findings also suggest some clinicians are concerned about giving a diagnosis when there is uncertainty because disease labels and their attached

implications are hard to remove once given. Effective communication and tailored care may be a way to minimise the potential harmful impact of the diagnosis, dispel misconceptions and improve patient-centred outcomes.

Authors' roles: TC, KM and JJ conceived the study. TC, JJ, KM, JH, JD, AD and BWM were involved in designing the study and developing the methods. TC conducted the interviews. TC, JJ, DM, JD and KM read transcripts, developed the analytical framework and contributed to the analysis. TC coded all the interviews, with a subset double-coded by DM. TC drafted the manuscript. All authors critically revised the manuscript. TC and JJ are guarantors.

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Reference list

- Asante A, Omurtag K, Stewart EA, Coddington CC. Screening for insulin resistance in polycystic ovary syndrome: Views of physician members of the American society for reproductive medicine. *J Reprod Med* 2015;**60**: 371-377.
- Azziz R. Controversy in clinical endocrinology: diagnosis of polycystic ovarian syndrome: the Rotterdam criteria are premature. *J Clin Endocrinol Metab* 2006;**91**: 781-785.
- Azziz R, Carmina E, Chen Z, Dunaif A, Laven JS, Legro RS, Lizneva D, Natterson-Horowitz B, Teede HJ, Yildiz BO. Polycystic ovary syndrome. *Nat Rev Dis Primers* 2016;**2**: 16057.
- Azziz R, Carmina E, Dewailly D, Diamanti-Kandarakis E, Escobar-Morreale HF, Futterweit W, Janssen OE, Legro RS, Norman RJ, Taylor AE *et al*. Positions statement: criteria for defining polycystic ovary syndrome as a predominantly hyperandrogenic syndrome: an Androgen Excess Society guideline. *J Clin Endocrinol Metab* 2006;**91**: 4237-4245.
- Conway G, Dewailly D, Diamanti-Kandarakis E, Escobar-Morreale HF, Franks S, Gambineri A, Kelestimur F, Macut D, Micic D, Pasquali R *et al*. European survey of diagnosis and management of the polycystic ovary syndrome: results of the ESE PCOS Special Interest Group's Questionnaire. *Eur J Endocrinol* 2014;**171**: 489-498.
- Copp T, Hersch J, Muscat DM, McCaffery KJ, Doust J, Dokras A, Mol BW, Jansen J. The benefits and harms of receiving a polycystic ovary syndrome diagnosis: a qualitative study of women's experiences. *Hum Reprod Open* 2019: hoz026.
- Copp T, Jansen J, Doust J, Mol BW, Dokras A, McCaffery K. Are expanding disease definitions unnecessarily labelling women with polycystic ovary syndrome? *BMJ* 2017;**358**: j3694.
- Cussons AJ, Stuckey BG, Walsh JP, Burke V, Norman RJ. Polycystic ovarian syndrome: marked differences between endocrinologists and gynaecologists in diagnosis and management. *Clin Endocrinol* 2005;**62**: 289-295.
- Daan NM, Louwers YV, Koster MP, Eijkemans MJ, de Rijke YB, Lentjes EW, Fauser BC, Laven JS. Cardiovascular and metabolic profiles amongst different polycystic ovary syndrome phenotypes: who is really at risk? *Fertil Steril* 2014;**102**: 1444-1451.
- Dhesi AS, Murtough KL, Lim JK, Schulkin J, McGovern PG, Power ML, Morelli SS. Metabolic screening in patients with polycystic ovary syndrome is largely underutilized among obstetrician-gynecologists. *Am J Obstet Gynecol* 2016;**215**: 579.
- Diamanti-Kandarakis E, Dunaif A. Insulin resistance and the polycystic ovary syndrome revisited: an update on mechanisms and implications. *Endocr Rev* 2012;**33**: 981-1030.
- Dokras A, Saini S, Gibson-Helm M, Schulkin J, Cooney L, Teede H. Gaps in knowledge among physicians regarding diagnostic criteria and management of polycystic ovary syndrome. *Fertil Steril* 2017;**107**: 1380-1386.
- Dokras A, Witchel SF. Are young adult women with polycystic ovary syndrome slipping through the healthcare cracks? *J Clin Endocrinol Metab* 2014;**99**: 1583-1585.
- Dumesic DA, Oberfield SE, Stener-Victorin E, Marshall JC, Laven JS, Legro RS. Scientific statement on the diagnostic criteria, epidemiology, pathophysiology, and molecular genetics of polycystic ovary syndrome. *Endocr Rev* 2015;**36**: 487-525.
- French DP, Cameron E, Benton JS, Deaton C, Harvie M. Can communicating personalised disease risk promote healthy behaviour change? A systematic review of systematic reviews. *Ann Behav Med* 2017;**51**: 718-729.

- Gibson-Helm M, Dokras A, Karro H, Piltonen T, Teede HJ. Knowledge and practices regarding polycystic ovary syndrome among physicians in Europe, North America, and internationally: An online questionnaire-based study. *Semin Reprod Med* 2018;**36**: 19-27.
- Gibson-Helm M, Teede H, Dunaif A, Dokras A. Delayed diagnosis and a lack of information associated with dissatisfaction in women with polycystic ovary syndrome. *J Clin Endocrinol Metab* 2017;**102**: 604-612.
- Haynes RB, Sackett DL, Taylor DW, Gibson ES, Johnson AL. Increased absenteeism from work after detection and labeling of hypertensive patients. *N Engl J Med* 1978;**299**: 741-744.
- Hollands GJ, French DP, Griffin SJ, Prevost AT, Sutton S, King S, Marteau TM. The impact of communicating genetic risks of disease on risk-reducing health behaviour: systematic review with meta-analysis. *BMJ* 2016;**352**: i1102.
- Lizneva D, Kirubakaran R, Mykhalchenko K, Suturina L, Chernukha G, Diamond MP, Azziz R. Phenotypes and body mass in women with polycystic ovary syndrome identified in referral versus unselected populations: systematic review and meta-analysis. *Fertil Steril* 2016;**106**: 1510-1520.
- Lizneva D, Suturina L, Walker W, Brakta S, Gavrilova-Jordan L, Azziz R. Criteria, prevalence, and phenotypes of polycystic ovary syndrome. *Fertil Steril* 2016;**106**: 6-15.
- Marteau TM. Changing minds about changing behaviour. *Lancet* 2018;**391**: 116-117.
- National Institutes of Health. Evidence-based Methodology Workshop on Polycystic Ovary Syndrome: Final Report. 2012. National Institutes of Health, USA.
- Powers SE, Uliassi NW, Sullivan SD, Tuchman LK, Mehra R, Gomez-Lobo V. Trends in standard workup performed by pediatric subspecialists for the diagnosis of adolescent polycystic ovary syndrome. *J Pediatr Adolesc Gynecol* 2015;**28**: 43-46.
- Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In Bryman A and Burgess R. Eds. *Analysing Qualitative Data*. 1994. Routledge, London: 173-194.
- Ritchie J, Spencer L, O'Conner W. Carrying out qualitative analysis. In *Qualitative research practice: A guide for social science students and researchers*. 2003. SAGE, London: 219-262.
- Scherer LD, Zikmund-Fisher BJ, Fagerlin A, Tarini BA. Influence of "GERD" label on parents' decision to medicate infants. *Pediatrics* 2013;**131**: 839-845.
- Shaffer VA, Scherer LD. Too much medicine: Behavioural science insights on overutilisation, overdiagnosis and overtreatment in healthcare. *Policy Insights from the Behavioural and Brain Sciences* 2018;**5**: 155-162.
- Shufelt CL, Torbati T, Dutra E. Hypothalamic amenorrhea and the long-term health consequences. *Semin Reprod Med* 2017;**35**: 256-262.
- Skiba MA, Islam RM, Bell RJ, Davis SR. Understanding variation in prevalence estimates of polycystic ovary syndrome: a systematic review and meta-analysis. *Hum Reprod Update* 2018;**24**: 694-709.
- Tata B, Mimouni NEH, Barbotin AL, Malone SA, Loyens A, Pigny P, Dewailly D, Catteau-Jonard S, Sundstrom-Poromaa I, Piltonen TT *et al*. Elevated prenatal anti-Mullerian hormone reprograms the fetus and induces polycystic ovary syndrome in adulthood. *Nat Med* 2018;**24**: 834-846.
- Teede HJ, Misso ML, Boyle JA, Garad RM, McAllister V, Downes L, Gibson M, Hart RJ, Rombauts L, Moran L *et al*. 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. *Med J Aust* 2018;**209**: S3-S8.
- Teede HJ, Misso ML, Costello MF, Dokras A, Laven J, Moran L, Piltonen T, Norman RJ, International PCOS Network. Recommendations from the international evidence-based guideline for the assessment and management of polycystic ovary syndrome. *Hum Reprod* 2018;**33**: 1602-1618.
- Teede HJ, Misso ML, Deeks AA, Moran LJ, Stuckey BG, Wong JL, Norman RJ, Costello MF, Guideline Development Group. Assessment and management of polycystic ovary syndrome: summary of an evidence-based guideline. *Med J Aust* 2011;**195**: S65-112.
- The Rotterdam ESHRE/ASRM PCOS Workshop. Revised 2003 consensus on diagnostic criteria and long-term health risks related to polycystic ovary syndrome (PCOS). *Hum Reprod* 2004;**19**: 41-47.
- Wang R, Mol BW. The Rotterdam criteria for polycystic ovary syndrome: evidence-based criteria? *Hum Reprod* 2017;**32**: 261-264.
- Zawadzki J, Dunaif A. Diagnostic criteria for polycystic ovary syndrome: towards a rational approach. In Dunaif A, Givens JR, Haseltine F. Eds. *Polycystic Ovary Syndrome*. 1992. Blackwell Scientific, Boston: 377-384.