Polycystic ovary syndrome: Exploring the social construction of a contentious diagnostic category.

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Thesis Abstract

Polycystic ovary syndrome (PCOS) is an endocrine condition with wide-ranging symptoms, including hirsutism, weight gain and fertility issues. As a diagnostic category, PCOS has stimulated longstanding debate and in recent years, has been transformed from a condition of unknown aetiology to a phenomenon explained in medical literature as a lifestyle condition, aggravated by 'unhealthy' lifestyle choices and best managed through long-term lifestyle change. Recent sociological investigations into PCOS as a lived experience reveal that many women experience PCOS as extremely distressing, but this work does not fully explore the role of the PCOS diagnostic category itself in shaping PCOS as socially contextualised experience. This study seeks to bridge this gap in sociological understanding through an in-depth analysis of 184 medical texts published between 1974 and 2019, a period when the field of obstetrics and gynaecology (OG) was embroiled in a scientific controversy regarding how best to diagnose PCOS in clinical research and practice. Using controversy as a method for analysing the distinctly social processes by which PCOS has been defined as a lifestyle disorder, I examine the role of new similarity relations, consensus conferences and a long-lasting rhetorical exchange between experts of competing perspectives in the evolution of the PCOS diagnostic category. I argue that OG experts' inability to close the controversy resulted from the underdetermination of evidence by theory and led to a drive within OG to move the controversy away from its focus on diagnosis, towards a focus on lifestyle as central to PCOS. This has resulted in the widespread dissemination of lifestyle advice for PCOS in clinical settings, with pronounced implications for women's PCOS experiences. It demonstrates the pivotal role played by socially informed diagnostic categories in shaping experiences of illness and the importance of more integrated analyses of the relations between diagnosis-as-category and lived experience.

Dedication

I would like to dedicate my thesis to my grandparents:

Angeliki and Spyros Plessas

Patricia and Andrew Timmons

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List of Acronyms

AES Androgen Excess Society

AEPCOS Androgen Excess and Polycystic Ovary Syndrome Society

ASRM American Society for Reproductive Medicine

BMI Body mass index

BOWR Bilateral ovarian wedge resection

CVD Cardiovascular disease

DXM Dexamethasone

ESE European Society of Endocrinology

ESHRE European Society of Human Reproduction and Embryology

FHA Functional hypothalamic amenorrhea

FOH Functional ovarian hyperandrogenism

FSH Follicle-stimulating hormone

GI Glycaemic index

GnRH Gonadotrophin-releasing hormone

HA Hyperandrogenism

HPRL Hyperprolactinemia

ICD International Classification of Diseases

ICSH Interstitial cell stimulating hormone (later known as luteinizing hormone)

LH Luteinizing hormone

MFO Multifollicular ovaries

NICHD Eunice Kennedy Shriver National Institute of Child Health and Human Development

NIH National Institutes of Health

OG Obstetrics and gynaecology

PAO Polycystic-appearing ovaries

PCO Polycystic ovaries

PCOS Polycystic ovary syndrome

POSAA Polycystic Ovary Syndrome Association of Australia

PRL Prolactin

QoL Quality of life

RCTs Randomised controlled trials

SES Socio-economic status

T2DM Type 2 diabetes mellitus

TSH Thyroid stimulating hormone

U/S Ultrasound

List of Medical Terminology

Amenorrhea

The absence or cessation of menstrual periods (Martin, 2010).

Androgens

A group of steroid hormones which include testosterone and dihydrotestosterone. Produced by the testis and adrenal cortex in men, and by the ovaries and adrenal cortex in women (typically in smaller amounts) (Martin, 2010).

Androgen excess

The presence of excess androgens in a woman's body (Martin, 2010), commonly referred to as hyperandrogenism (HA).

Anovulation

The absence of ovulation (the release of an egg) by the ovary (Martin, 2010). It is a common cause of amenorrhea (Rebar, 2018).

Bilateral ovarian wedge resection (BOWR)

A surgical procedure that removes between half and three quarters of a woman's ovary (Zink, 2011).

Body mass index (BMI)

The sum of a person's weight in kilograms, divided by their height in metres. Used as a test of whether a person is clinically overweight, underweight or of a healthy weight (Martin, 2010).

B-scanner

A type of 2-dimensional ultrasound imaging scanner used for diagnostic purposes, and which produces static as opposed to dynamic, real-time images (Azhari, 2010; Van Holsbeke et al. 2007).

Congenital adrenal hyperplasia

A group of autosomal recessive genetic disorders (Martin, 2010, the symptoms of which include fertility issues, excess androgen levels, severe acne and altered growth. In women, it can also result in irregular menstrual periods, a deepening voice and excess body and facial hair (Mayo Clinic Staff, 2022). Many of the symptoms of congenital adrenal hyperplasia overlap with those of PCOS. For this reason, the condition is usually treated as an exclusion criterion for PCOS diagnosis i.e. the presence of congenital adrenal hyperplasia rules out PCOS.

Cushing's syndrome

A condition that results from excess amounts of corticosteroid hormones and includes symptoms of weight gain, excess body and facial hair (resulting from hyperandrogenism), increased blood pressure, skin which bruises easily, increased levels of blood glucose, and depression. Many of these symptoms overlap with those of PCOS and the presence of Cushing's syndrome is widely treated as an exclusion criterion for PCOS diagnosis i.e. the presence of Cushing's syndrome rules out PCOS (Martin, 2010).

Dexamethasone (DXM)

A corticosteroid drug used to treat and test for a range of conditions, including Cushing's syndrome (Martin, 2010).

Dexamethasone (DXM) suppression test

Commonly used to test for Cushing's syndrome which is an alternative cause of hyperandrogenism independent of PCOS; in the context of PCOS, this test can rule out PCOS by indicating that Cushing's syndrome is present (Martin, 2010).

Ferriman-Gallwey test/score

A scoring system used to evaluate levels of hirsutism as part of PCOS diagnostic practices.

Follicles

A small sac-like anatomical feature found in a range of organs, including the ovary (Martin, 2010).

Folliculogenesis

The process by which ovarian follicles develop (Monniaux et al. 2019).

Functional hypothalamic amenorrhea (FHA)

A form of chronic anovulation which can result in infertility and is understood to be the result of weight loss, stress and/or excessive exercise (Meczekalski et al. 2014)

Functional ovarian hyperandrogenism (FOH)

Synonymous with hyperandrogenism (HA); used by Dewailly (1997), a medical paper included in my sample.

Glycaemic index (GI)

A measurement system that ranks food items according to the rate at which they raise levels of blood glucose (*BDA*, 2023).

GnRH agonist test

A test for the presence of gonadotrophin-releasing hormones (GnRH). GnRH agonist tests were sometimes used to diagnose PCOS before the development of ultrasonography for diagnostic purposes (Dewailly, 1997).

Hirsutism

The presence of excessive and/or course hair on a woman's face or body (Martin, 2010).

Hyperandrogenemia

Synonymous with hyperandrogenism (HA) below.

Hyperandrogenism (HA)

The presence of excess androgens in a woman's body (Martin, 2010).

Hyperprolactinemia

A condition in which levels of the hormone prolactin (PRL) are significantly elevated. Its symptoms include irregular menstrual periods, galactorrhea (nipple discharge), reduced libido and fertility issues (Majumdar and Mangal, 2013). Many of these symptoms overlap

with those of PCOS and so hyperprolactinemia is often considered an exclusion criterion in PCOS diagnostic practices i.e. the presence of hyperprolactinemia rules out PCOS.

LH/FSH ratio

The ratio between levels of luteinizing hormone (LH) and follicle-stimulating hormone (FSH). In PCOS, this ratio is significantly raised (Zink, 2011).

Multifollicular (MFO) morphology

The presence of multiple cysts on an ovary, significantly fewer in number than those found in polycystic ovaries (Adams et al. 1985).

Normoandrogenic

The presence of normal levels of androgens in a woman's body, as opposed to excess levels which are referred to as hyperandrogenism (HA).

OG-PCOS research and practice

Clinical research and practice conducted within obstetrics and gynaecology with an explicit focus on PCOS.

Oligomenorrhea

Infrequent ovulation which may be primary or secondary; primary oligomenorrhea is present from puberty, while secondary oligomenorrhea occurs later (Zink, 2011).

Oligo-ovulation

Irregular or infrequent periods, generally defined as present in people who experience 8 or fewer periods a year (Martin, 2010).

Phenotype

A person's observable characteristics that result from the interaction between their genes (genotype) and environmental factors (Martin, 2010).

Polycystic ovarian (PCO) morphology

The presence of a significant number of follicles on the ovaries and/or enlarged ovaries (Martin, 2010).

Polycystic ovaries

The presence of a significant number of follicles on the ovaries and/or enlarged ovaries (Martin, 2010), synonymous with PCO morphology above.

Real-time ultrasound scanner

A type of ultrasound imaging scanner that produces instantaneous real-time as opposed to static images and that detects and observes moving objects (Martin, 2010).

Sclerocystic ovaries

Synonymous with polycystic ovaries/ PCO morphology.

Stroma

The connective tissue of an organ (Martin, 2010), for example the ovary.

Chapter 1. Introduction

1.1. Introduction

Like most people with polycystic ovary syndrome (PCOS), my early experiences as an adolescent living with its undiagnosed symptoms were far from easy, and my experience of receiving ambiguous and conflicting messages on being diagnosed with the condition was far from ideal. In 2013, during my first year as an undergraduate, I read Kitzinger and Willmott's (2002: 349) *Social Science & Medicine* article, which presents PCOS as 'the thief of womanhood' and explores women's experiences of the condition. One line in the paper particularly stood out; it described how, 'all interviews were conducted by the second author, who was open about having PCOS herself' (Kitzinger and Willmott, 2002: 352). This paper was the first of its kind on PCOS, but it also resonated with me on a personal level; it awakened me to the idea that not only could PCOS be understood and acknowledged, discussed, written about and researched, but that there might be a place for me as a young sociology student with experience of PCOS, to contribute to this discussion, writing and research. The paper introduced me to the sociology of health and illness (SHI), a realm of sociological research I had not previously known about (I was only in my first term) and represented the start of a personal ambition to contribute further original sociological research in this area. Although my original interest was in studying PCOS as a lived experience in its own sake, I eventually came to recognise PCOS' potential as an ideal case for exploring the social construction of scientific knowledge more broadly.

Individual diagnostic categories can offer expansive insight into the sociality of diagnosis and medical knowledge and the significant roles each of these play in shaping individual experiences and societal perceptions of illness. This is particularly true of contentious diagnostic categories which, on account of the central focus they commonly assume in medical discussion and debate, offer ample opportunity for a focused sociological analysis of the social processes by which diagnostic categories are constructed and the specific meanings they contain. PCOS is one such category. It is a condition defined variously as being reproductive, metabolic and/or psychological in nature (Joham et al. 2022a) and is associated with a wide range of symptoms, including hirsutism[1], weight gain, fertility issues, and anxiety and depression (Hart et al. 2004; Joham et al 2022b). Contemporary definitions

[1] The presence of excessive and/or course hair on a woman's face or body (Martin, 2010).

of PCOS understand it to be primarily a lifestyle disorder, linked with a number of long-term health conditions and brought on and exacerbated by a sedentary lifestyle, poor diet and obesity (Kuwar and Dongare, 2021; Pramodh, 2022; Shahid et al. 2022). The trajectory through which this definition has developed within medical literature and public discourse has been far from straightforward. PCOS was first named and identified in the 1930s (then as Stein-Leventhal syndrome) (Kovacs, 2022) and has long been the subject of questions and uncertainty from medical experts about its pathophysiology and aetiology. Since the mid-1970s however, developments in ultrasound technology and the enhanced insights these facilitated into the structure of women's ovaries, transformed these questions into outright disagreement and contention. Medical experts and researchers became increasingly divided about how to define and diagnose the condition and by the early 2000s, medical research into PCOS (which took place predominately within the field of obstetrics and gynaecology[2]) had become consumed by a state of controversy.

It is because of its highly contentious nature, that PCOS is an intrinsically interesting case for a sociohistorical analysis of diagnostic categories (Stake, 1995). This thesis explores PCOS as a diagnostic category, tracing its social construction over time between 1974 and 2019. It uses the controversy that unfolded over how to define and diagnose PCOS, as a lens through which to understand the social processes by which PCOS has come to be defined as a lifestyle disorder. In analysing and tracing these processes, the thesis presents the argument that the contemporary PCOS diagnostic category is the social product of a series of significant changes that took place within medicine during this time, as well as developments which were more specific to the field of OG-PCOS research. These broader changes within medicine related to significant trends towards the incorporation of patient voices in medical research (Rabeharisoa et al. 2014; Moreira, 2015) and the simultaneous individualisation of chronic illness (Tolvhed and Hakola, 2018). Developments within the field of PCOS research were primarily the result of a desire to deescalate the controversy that had consumed it for so long, as well as the divergences which continued to occur long after the controversy's onset between different researchers' interpretations of PCOS and its associated body of scientific evidence. In essence, the PCOS diagnostic category has evolved over time as a

[2] Obstetrics and gynaecology is referred to from hereon in the thesis as OG, while research conducted within OG which relates specifically to PCOS, is referred to as OG-PCOS research.

result of an array of social factors, and this carries important implications both for sociological understandings of diagnosis and for those living and/or diagnosed with PCOS.

1.2. Outline of Thesis

In exploring the social construction of the PCOS diagnostic category, I begin, in Chapter 2 of this thesis, by reviewing social scientific and medical literature of relevance to PCOS, setting the scene for my analysis and its central research questions and objectives. I briefly outline the history of medical understandings of PCOS and of the development of ultrasound as a medical technology, each of which offer crucial context for the controversy which later ensued in the field of OG-PCOS research. I reflect also on social scientific literature on PCOS, highlighting the absence of any considered focus on the importance of diagnosis in shaping lived experiences of the condition. In explaining how my own research seeks to address this gap, I outline the sociological theory that informs this research, drawing on concepts from within the sociology of diagnosis and sociology of scientific knowledge (SSK) and explaining their value and relevance to an applied analysis of PCOS diagnosis. I conclude the chapter by identifying my central research question and objectives.

In Chapter 3, which outlines my methodological and epistemological approach to the research, I discuss the interpretivist and constructivist paradigm in which this research sits, consistent with my ambition to explore the socially constructed nature of PCOS as a diagnostic category. I also explain my decision to conduct a sociohistorical analysis of medical literature on PCOS, which was based principally on the richness and scope of material available on PCOS, allowing for a considered analysis of the social processes that have underpinned its construction and evolution over time. A core component of this literature is its documentation of the controversy and rhetorical exchanges that ensued between OG-researchers with opposing perspectives on how to define and diagnose PCOS. In explaining my approach to analysing this controversy, I discuss the central tenets of controversy as method and am explicit about my own intentions as a researcher, concerned not with the truth or falsity of the diagnostic category, but its social construction over time.

Chapters 4 - 6 contain the substantive components of my analysis. Chapter 4 offers further crucial context for the onset of the controversy, providing an in-depth analysis of the social processes involved in the production of the first ultrasound images of ovarian morphology in PCOS and the questions and uncertainties these generated regarding how best to define and diagnose the condition. Chapter 5 traces the evolution of these questions into an outright

controversy, demonstrating the integral role played by medical researchers' divergent interpretations of scientific evidence in fuelling divisions within the field. Chapter 6 contains the final component of my analysis, exploring a distinctive shift which took place in the controversy and the pivotal role this played in the development and consolidation of the definition of PCOS as a lifestyle disorder.

Drawing on each of these chapters and the findings of my research, in Chapter 7 I reflect on the implications of this lifestyle definition for individual lived experiences of PCOS. I place particular emphasis on the intersectional contexts in which PCOS is experienced; I consider the varying social and economic resources that different women are able to access in order to manage the symptomology of PCOS and to respond to and/or implement the lifestyle advice which is commonly disseminated by the medical profession on account of its understanding of PCOS as a lifestyle disorder. I reflect also on the wider social, economic, and cultural factors behind the proliferation of this definition in OG-PCOS literature, as well as those which were more specific to the field of OG-PCOS research and related principally to the ongoing elusiveness of a clearcut aetiological explanation for PCOS.

I conclude the thesis in Chapter 8, by outlining the findings of my research and presenting these in the context of contemporary sociological understandings of diagnosis and of the social construction of scientific knowledge. I highlight the contributions my findings make to this body of knowledge, reiterating the diverse range of social factors which altered the course of the PCOS controversy and were instrumental in the development of a lifestyle definition for PCOS. I discuss the insights these findings offer into wider processes of medical knowledge construction, including its endless potential to be revised and challenged, the increasingly fluid nature of diagnostic categories and their boundaries, and the capacity for new patient voices to shape medical knowledge construction and alter the dynamics and dimensions of longstanding controversies.

In exploring the social construction of the PCOS diagnostic category through a sociohistorical analysis of medical literature, my thesis reflects the historical content of PCOS-related medical literature published between 1974 and 2019 and its almost exclusive focus on women with PCOS. Although it is important that future sociological research into PCOS recognises the more sophisticated understandings of sex that have come to the fore in both public and academic discourses in recent years and acknowledges the experiences of people

with PCOS who do not identify as women, my own research focuses predominately on the representation of women in OG-PCOS literature and on the implications of this literature for women with PCOS.

Chapter 2. Literature Review

2.1. Chapter Introduction

In this chapter, I situate my study within the broader social scientific and medical literatures. I begin by outlining contemporary understandings of PCOS as a medical condition, before providing a brief chronology of the processes by which PCOS first came to be defined as a medical condition and diagnostic category. I also consider the development of ultrasound as a medical imaging technology and discuss the role played by medical images in the social construction of medical knowledge. I follow this by outlining existing contemporary social scientific research into PCOS as a lived experience and reflect on the light this research sheds on PCOS' widely felt impact on identity and quality of life (QoL). I draw attention to the relative absence within this literature, of any considered exploration of PCOS as a diagnostic category and its role in shaping PCOS as socially contextualised experience. I then consider the value of concepts from the sociology of diagnosis and the sociology of scientific knowledge (SSK) for conducting a sociological analysis of PCOS as a diagnostic category. I conclude this chapter by outlining my study's research questions and objectives, which form the central focus of this applied sociological analysis of PCOS as a socially informed diagnostic category.

2.2. A Brief History of PCOS and Ultrasound Technologies

PCOS is a common metabolic and reproductive disorder that is thought to affect between six and 21% of women around the world (Joham et al. 2022a; Kite et al. 2019). This extensive variation in estimates of PCOS prevalence is the result of widespread differences across the globe and between different medical specialties in the diagnostic criteria used to diagnose PCOS (Ning et al. 2012; Varanasi et al. 2018). PCOS is extremely heterogeneous in nature, but symptoms commonly include hirsutism, reduced fertility, weight gain, acne, alopecia, and ovarian follicles[3] and cysts. PCOS is linked with numerous long-term health conditions, such as cardiovascular disease (CVD) and type II diabetes, as well as significant psychosocial distress, including depression, anxiety, poor body image and low self-esteem (Kite et al. 2019; Williams et al. 2015). Although PCOS has become widely known as a 'lifestyle disease', linked with obesity and poor diet, there is also significant evidence of a role played by

[3] A follicle is a small sac-like anatomical feature which can be found in a range of organs, including the ovary (Martin, 2010).

genetic factors, as well as interaction *between* genetic and environmental factors, in its development (Pathak and Nichter, 2015: 22; Sam, 2007). Practitioners most commonly diagnose PCOS through taking family histories and conducting physical examinations, blood samples and gynaecologic ultrasounds (*NICHD*, 2022). As a diagnostic category, PCOS has stimulated longstanding debate, and clinicians and researchers remain divided over how best to define, diagnose and treat it. It is the uncertainty and ambiguity of the category that render it a valuable heuristic device for exploring the social construction of diagnostic categories. Its divergent range of symptoms, the significant phenotypical heterogeneity of women diagnosed with PCOS, the variation in how the condition is diagnosed, and the expansive number of medical specialties publishing on the topic, make it an intrinsically interesting case study (Stake, 1995).

2.2.1. From Stein-Leventhal syndrome to PCOS: A brief history of PCOS up to 1974

Many of the symptoms that are now central components of, or heavily associated with the contemporary PCOS diagnostic category, have been discussed and identified in medical literature from across the centuries. One set of historical medical notes from the time of Hippocrates, details a group of women who presented with irregular menstrual cycles, infertility issues and signs of hyperandrogenism (HA)[4] (Kovacs, 2022). It described the women as being of 'masculine appearance' (Kovacs, 2022: 1). Similar reports of women 'whose bodies are of a masculine type' and 'whose nature resembles the nature of a man', alongside accompanying physiological conditions such as limited or particularly heavy menstruation, and dermatological or fertility issues, can be found in historical medical literature spanning 14 centuries (Kovacs, 2022: 1). More recent records from the 1800s onwards describe the presence of polycystic ovarian (PCO) morphology, also commonly referred to as 'polycystic ovaries'[5], in many of these women (Kovacs, 2022).

The construction and evolution of PCOS as a contemporary diagnostic category, however, can be identified as having started in the work of two researchers, Dr Irving F Stein and Dr Michael L Leventhal (Goldzieher, 2002; Kovacs, 2022). Stein and Leventhal's 1935 publication reported on the successes of using bilateral ovarian wedge resection surgery (BOWR) - whereby between half and three quarters of a woman's ovary is removed - in restoring

[4] Hyperandrogenism (HA) refers to the presence of excess androgens in a woman's body (Martin, 2010). It is associated with hirsutism, acne and alopecia (Yildiz, 2006).

[5] PCO morphology or polycystic ovaries, refers to the presence of a significant number of follicles on the ovaries and/or enlarged ovaries (Martin, 2010).

normal menstruation in a group of seven women who presented with PCO morphology and amenorrhea[6]. The publication offered one of the earliest identifications of this combination of symptoms as constitutive of a 'reproductive disorder' (Kovaks, 2022: 1). Stein and Leventhal (1935) suggested that the presence of PCO morphology in this group of women was most likely the result of a hormonal imbalance. Despite Stein and Leventhal's acknowledgement of HA in some of the women they observed, they did not engage in any discussion of its potential pathophysiological significance. Nonetheless, in providing a coherent description of the coexistence of three physiological features that have since become central to contemporary research into and discussions of PCOS - HA, amenorrhea and PCO morphology - Stein and Leventhal are widely credited with having first discovered PCOS.

There is no clear point at which the term Stein-Leventhal syndrome became accepted medical terminology, but by the mid-1950s, it was being widely used and applied in medical literature (Azziz and Adashi, 2016). Towards the end of the 1950s, some researchers had also started using the term PCOS (polycystic ovary syndrome), and during the 1970s, the use of Stein-Leventhal syndrome as a term for the condition gradually declined[7]. Although the findings of Stein and Leventhal's 1935 paper continued to shape medical attitudes towards the condition, a number of technological developments in the decades which followed raised new questions about its aetiology and pathophysiology (Daan et al. 2014). Gynaecological research conducted by McArthur in 1958, led to an association between Stein-Leventhal syndrome and increased levels of interstitial cell stimulating hormone (ICSH), later known as luteinizing hormone (LH) (McArthur, 1958; Taymor and Barnard, 1962). The advent of radioimmunoassay - a technique for determining previously undetectable antibody levels through applying radionuclide methodology (Martin, 2010) - in the 1950s, and its widespread availability from the 1970s, meant that PCOS was increasingly diagnosed on the basis of increased levels of serum androgen, LH, and LH/follicle-stimulating hormone (FSH) ratios[8] (Goldsmith, 1975; Kovacs, 2022).

[6] Amenorrhea is the absence or cessation of menstrual periods (Martin, 2010). Anovulation is a common physiological cause of amenorrhea (Rebar, 2018).
[7] Throughout this thesis, when referring to older medical literature which uses the term 'Stein-Leventhal syndrome', I refer to PCOS as Stein-Leventhal syndrome.
[8] The LH/FSH ratio refers to the ratio between levels of luteinizing hormone (LH) and follicle-stimulating hormone (FSH). In PCOS, this ratio is significantly raised (Zink, 2011).

It was developments in ultrasound technology though that meant that the visualisation and scientific assessment of PCO morphology became possible without the need for surgical intervention. Ultrasound images of PCO morphology gave rise to a host of new discoveries about the clinical and histological features of polycystic ovaries and saw the medical specialty of OG acquire increasing professional authority and jurisdiction over polycystic ovaries as a physiological entity (Abramowicz, 2021). These new ultrasound images also generated questions and changed understandings about which combinations of symptoms could be considered constitutive of PCOS and in whom the condition could present (Goldzieher and Green, 1962; Kovacs, 2022). It was on account of these discoveries that uncertainties and doubts emerged within discussions in the field of OG about whether PCOS could be considered a coherent syndrome and diagnostic category, and if so, which features of the condition constituted appropriate diagnostic criteria and signifiers. The drastic changes in the field of OG-PCOS research that arose from these discussions are what led me to identify the first ultrasound-facilitated images of PCO morphology as the most appropriate starting point for my study. It is for this reason that I provide a brief history of the development of ultrasound as an imaging technology in the section below, to further situate this study within its wider historical context.

2.2.2. A brief history of the development of ultrasound

Ultrasound is an imaging technology with 'a rich and complex history' (Casper, 1998: 83). It was first developed to search for icebergs following the sinking of the Titanic and was adapted during World War II to be used for the detection of submarines (Cartwright, 1995; Casper, 1998). It was in the late 1920s that the potential for ultrasound to be applied within medical settings started to gain recognition and, reflective of medicine's pathologisation of women's reproductive functions during this time, it was on women's bodies - and on the breast in particular - that the majority of early tests into the safety and efficacy of ultrasound as a medical device were conducted (Cartwright, 1995). Between the 1930s and 1950s, ultrasound became widely applied as a method for creating visual maps of the human body (Cartwright, 1995; Casper, 1998). The development of ultrasound for gynaecological diagnostic purposes was pioneered between 1950 and 1960, used for the detection of cystic and solid masses (Levi, 1997). Its diagnostic capabilities were then extended to be used for a

range of physiological conditions, including the detection of nonpalpable pelvic masses, ovarian tumours, early pregnancy, and the localisation of cancer and pelvic inflammatory disease. Gynaecology was one of the first medical specialties involved in pioneering and applying ultrasound for diagnostic purposes (Levi, 1997).

Ian Donald MD is considered to have been the leading 'pioneer' in this trend, thanks to his exploration of pelvic tumours in 1955 using ultrasound technology (Levi, 1997: 484). Donald introduced a range of practical and theoretical concepts aimed at advancing ultrasound practice specifically within the field of OG and presented the very first ultrasound images of the foetus and various gynaecological masses (Campbell, 2013; Levi, 1997). Levi (1997: 486) describes how Donald 'helped greatly to continuously improve diagnosis in GYN[9] and to confer seriousness' to diagnostic ultrasound as an emergent technology. Levi (1997: 486) suggests also that it was the enthusiasm instilled by Donald and his colleagues, who presented continuously on the 'wonders' of diagnostic ultrasound, that helped to garner much needed funds and wider scientific interest in ultrasound technology and enabled further research to be conducted aimed at advancing the technology. Despite this, Donald and his colleagues faced multiple challenges in their attempts to optimise the diagnostic capabilities of ultrasound technology. The technology was subject to extensive 'technical and professional battles' regarding the meaning of ultrasound images and how they should be interpreted (Casper, 1998: 84). Donald (1974) recounted the years of criticism and scepticism that was levelled towards him and his colleagues by other OG experts, on account of their efforts to spearhead the expansion of ultrasound technology. This was partly fuelled by the difficulties Donald and his colleagues faced in producing clear and visible images of deep pelvic structures, even using the most advanced imaging; this was something which raised doubts across OG over ultrasound's practicability and use.

It was a chance discovery by Donald and his colleagues in 1963 however, that helped to convince many of the remaining sceptics within the field of OG of the importance of ultrasound as a diagnostic tool. This was the discovery that the female pelvis became significantly more visible through ultrasound once the bowels were moved to one side by ensuring the patient had a very full bladder. The 'number and complexity of clinical situations' to which ultrasound could be applied multiplied dramatically after this finding,

[9] Levi (1997) uses 'GYN' as an acronym for gynaecology.

including incidences of small pelvic tumours, early normal and abnormal pregnancy, and ectopic pregnancy (Levi, 1997: 487). This was a development consistent with what Lynch (1985; 1988) argues to be the systematic procedures through which scientists transform the body in a way that renders it an analytic object suited to the demands of a particular technology, rather than adapting the technology according to the needs of the body[10]. It was this development, and the subsequent change which occurred in the tide of opinion and attitudes towards ultrasound, that led to ultrasound's dramatic expansion from the 1970s onwards, particularly in the field of foetal medicine (Casper, 1998). Donald (1974: 33) described how by the 1970s, it had become the case that 'any pregnant patient, at some time or another in her pregnancy and for one reason or another, may come under an ultrasonic probe'. This state of affairs represented the continuation of the relations between ultrasound and the female body that had epitomised the introduction of ultrasound into medicine and positioned ultrasound as a central component of medicine's visualisation, interpretation and definition of the female body (Cartwright, 1995).

Despite the widespread expansion of ultrasound technology, significant difficulty remained in ensuring that the images it produced were interpreted in a way that suited the specific medical purposes they were intended for. Casper (1998) describes how advanced technical skill is required in interpreting ultrasound images. She suggests that it was because of this that the field of sonography developed as a 'discrete medical specialty', dedicated to the intricate study and improvement of ultrasound and its images (Casper, 1998: 84-85). It is because of sonographers' specialist knowledge and skill set, that medical practitioners who regularly use ultrasound as part of their practice - in contemporary OG and contemporary medicine more widely - engage in and maintain close interdisciplinary links with the field of sonography (Casper, 1998). More advanced ultrasound devices are now available across OG, providing higher resolution images and significantly increasing the accuracy of assessments of anatomic structures and predictions of long-term treatment outcomes (Stephenson, 2005). Casper (1998: 84) describes how in most advanced countries, 'ultrasound has become a routine part of prenatal care for most women'. What this brief history of ultrasound technology demonstrates however, is not just the ubiquity of ultrasound within contemporary OG, but the socially and historically contingent nature of the processes by

[10] I unpack Lynch's (1985) work on *rendering practices* more fully in the next section of this chapter.

which this came about. It is a history that entailed large-scale historical events, chance discoveries, and the development of a new scientific specialty. It is also one which is indebted to the effectiveness with which Donald and his colleagues were eventually able to alleviate the doubts of ultrasound sceptics, securing both essential funding for continued research into ultrasound and its widespread acceptance as a valuable diagnostic tool.

2.2.3. Conceptualising medical image production

Just as the development and advancement of ultrasound imaging as a medical technology has been a socially and historically contingent process, so too is the construction and interpretation of the images it produces. This is despite the relative simplicity that is widely attached to medical images in public and popular discourse and the common perception that medical images are 'equivalent to', or render 'transparent', the human body (Joyce, 2005: 437; Van Dijck, 2005: 3, 4). In this section of my chapter, I outline the sociological research that has focused on the social processes by which scientific and medical images are made comprehensible, analysable, and visible to scientists and medical practitioners through a host of complex instruments and conventional procedures (Burri and Dumit, 2008; Lynch, 1985). I argue that medical images are a distinctly cultural product and that their production entails within it, the integration of wider cultural meanings and professional power dynamics. Given the centrality of ultrasound imaging to the development of PCOS as a diagnostic category, these important implications for perceptions of science, illness, and the human body help to set out the sociological value of this project.

Images are a ubiquitous part of science and medicine, used in everyday scientific and medical work practices and a pervasive element of medical and scientific literature (Burri and Dumit, 2008; Lynch, 1985). Burri (2012) identifies three distinctive dimensions - an image's *visual value, performance,* and *persuasiveness* - that shape the production of scientific images according to an array of technical and professional standards and cultural and aesthetic values. It is through the *visual performance* dimension of medical images that the importance of their 'aesthetic appeal' in medicine becomes most apparent (Burri, 2012: 50). Burri's (2012: 50) ethnographic fieldwork identifies multiple instances in which medical practitioners make 'specific aesthetic decisions' in the production of medical images, increasing their appeal to other medical practitioners. Examples of this include ensuring that the image is not blurred and that it is 'rich in contrast and detail' (Burri, 2012: 50). Burri

(2012: 50) also emphasises the ‘local tacit rules’ involved in organising an image’s visual signs according to the expectations and requirements of a particular medical specialty.

The importance of these rules in constructing a particular representation of the human body or of a particular natural terrain is exemplified in the work of Lynch (1985: 37), who explores the ‘complex instruments and careful preparatory procedures’ involved in scientific and medical image production. Lynch (1985: 37) stresses the artificiality of images of natural objects and argues that ‘objects and relationships which were initially invisible become visible and palpable as a result of highly technical skills and complex instruments’. It is through these instruments and procedures, which Lynch (1985: 37, 38 emphasis in original) refers to as ‘*rendering practices’*, that natural objects are transformed into ‘docile objects’, suited to scientific analysis and dissemination. Each of these practices enhances the usefulness of a particular image, emphasising or transforming entities which are of particular scientific interest and ignoring or diminishing the visibility of those which are not.

Lynch (1985: 37) identifies three specific types of rendering practices - ‘marking', 'constituting graphic space', and 'normalizing observations' – that he considers to collectively constitute an ‘externalised retina’ for perceiving the natural world through a suitably scientific lens. *Marking* is the attribution of a particular visible code to a natural entity - usually a number or combination of numbers and letters, or a particular colour - that renders it no longer just a natural entity, but also the bearer of a particular visual code. Marking instils a classificatory uniformity to all the entities that are coded in this manner, identified as ‘equivalent in all respects except for the unique identity of each mark’ (Lynch, 1985: 41). The *constitution of graphic space* entails transforming a natural area or terrain into ‘“mathematical” space’ through a process of ‘mathematization’, whereby spatial and numerical scales make the entity measurable and, subsequently, visible. Entities that are so minute within an image that their mathematisation is not feasible, are overlooked and become ‘unimportant’ to the science at hand (Burri and Dumit, 2008: 308). The *normalisation of observations* involves the use and application of a device - for example, a visual ‘dot’ or similar symbol - with the aim of normalising and rendering equivalent to one another, each marked entity within the image. In doing so, it attributes a whole new layer of meaning to a specific collection of entities and renders them not just a natural entity but an object of scientific scrutiny.

This collection of rendering practices, alongside the aesthetic values which feed into scientific and medical image production, mean that the images produced are a 'constructed artifact' - one which does not '"reveal" the inner body, but instead produce(s) the body… in unique and locally specific ways'[11] (Joyce, 2005: 437-438, brackets added). Burri (2012) identifies the sociality and ubiquity of images in contemporary society as under-recognised in sociological theory. Burri (2012: 45) calls for a 'sociology of images' to explore the expansive role played by visual representations in shaping social relations, structures, and meanings. The conceptual tools outlined in the above section of this literature review have offered valuable sociological insights into medical image production; they highlight the ways in which medical images shape, and are shaped by, the social context in which they emerge and are maintained. Given the centrality of ultrasound imaging to the development of contemporary understandings of PCOS, my study draws on these concepts to help illuminate the role that ultrasound images have played in shaping the developmental trajectory of PCOS as a diagnostic category and to develop a nuanced understanding of the discussions and interpretive disputes that ensued many years after their production.

2.3. PCOS as a Lived Experience

Before continuing to provide a framework for understanding diagnosis as process, I first consider existing social scientific literature and understandings relating to women's experiences of PCOS diagnostic practices and PCOS as a condition. Since much of this literature is underpinned by feminist conceptualisations of gender, I begin by outlining the history and central tenets of social constructionist theories of gender and pay particular attention to the concept of normative femininity. Building on this discussion, I outline existing social scientific scholarship that explores lived experiences of PCOS in relation to normative femininity, and I consider the light this literature sheds on the distinctly gendered social context in which PCOS is commonly experienced. I follow this by exploring a small body of social scientific literature that recognises the importance of intersecting identities and inequalities in shaping experiences of PCOS. I reflect also however on the limitations this literature has faced in challenging the relatively homogenised picture of women's experiences of PCOS that has developed in existing social scientific scholarship. I conclude this section of my literature review by highlighting two broad but significant gaps within existing social scientific literature on PCOS: 1) an adequate understanding of diverse

[11] For instance, by enlarging the bladder to improve ultrasound images.

experiences of PCOS among women from marginalised backgrounds; 2) an in-depth and considered analysis of the role played by the PCOS diagnostic category in shaping women's experiences of PCOS.

2.3.1. PCOS and normative femininity

Conceptual distinctions between gender, sex and sexuality are central to feminist theory, but have also been the subject of extensive feminist debate for decades (Jackson and Scott, 1996). Early feminist literature was dominated by essentialist definitions of gender, which emphasised the biological distinctions between men and women (Jackson and Scott, 1996; Robinson and Richardson, 2015). This definition was increasingly challenged by feminist theorists writing in the 1960s and 70s, spurred on by the development of the women's and gay and lesbian rights movements and the questions they posed of society's dominant understandings of gender and sexuality as natural, fixed entities (Robinson and Richardson, 2015). From this emerged the increasing conceptualisation of gender as socially constructed and the development of a binary opposition between gender - defined as the 'social and cultural distinctions between women and men' (Jackson and Scott, 1996: 2) - and sex - defined as the 'biological differences between male and female' (*ibid.*). As social constructionist feminist theory continued to develop, new strands of conceptual thought emerged. Postmodernist feminism, which became prominent in around the 1990s, emphasises the gendered nature of the body. It acknowledges the material differences between male and female bodies but presents these as 'social products' of different gendered expectations of men and women (Lorber and Moore, 2011: 4).

These feminist conceptualisations of gender as socially constructed and a belief in the gendered nature of the body, frame and underpin the social scientific scholarship discussed in this section of my literature review and its exploration of women's experiences of PCOS. More specifically, Foucauldian conceptions of power and postmodernist feminism's application of these ideas to women's bodies contributed to the development of the concept of normative femininity, which is central to social science's contemporary understandings of the lived realities of PCOS. Foucault (1995: 136-137) stresses the ubiquity of power and its role in producing 'docile' and 'subjected' bodies and argues that such bodies are produced through our engagement in self-disciplining and self-regulating behaviours. These behaviours are elicited and shaped by our subjection to the various technologies and discourses of the modern state. Bordo (2003) and Bartky (2003), who apply these ideas to

women's bodies specifically, argue that women's bodies have been disciplined and transformed into 'docile bodies' through their subjection to patriarchal definitions of feminine beauty. Bordo (2003: 166) argues that through daily disciplines of diet, makeup, dress, and hair, women impress on their bodies 'the feel and conviction of lack, of insufficiency, of never being good enough'. Bartky (2003) considers that these disciplinary and regulatory practices are the result of 'normative femininity' - an image of women constructed by patriarchy to meet the needs and interests of those in power. Normative femininity is presented as an 'achievement' to which women should aspire, epitomised by aesthetic expectations of women, such as slenderness and hairlessness, and behavioural expectations revolving predominately around demands for heterosexuality and motherhood (Bartky, 2003: 27).

It is these normative expectations that lead many women to seek medical advice relating to issues such as facial hair, increased body weight, and fertility issues, frequently culminating in a diagnosis of PCOS (Ismayilova and Yaya, 2022; Pfister and Rømer, 2017; Soucie et al. 2022). It is also for this reason that much social scientific literature on PCOS draws attention to the impact of normative femininity on women's experiences of PCOS. Kitzinger and Willmott's (2002) study represented the first sociological investigation of individual lived experiences of PCOS. It was crucial in drawing attention to PCOS experiences as a research area rich in sociological significance and to the explicitly gendered nature of these experiences. Through their use of in-depth semi-structured interviews designed to allow women with PCOS to 'tell their own stories', Kitzinger and Willmott (2002: 350) highlight the profound psychosocial distress experienced by women with PCOS as a result of their perceived 'deviation from proper femininity'. Kitzinger and Willmott (2002) report that the women in their study experienced their PCOS symptoms - namely those of hirsutism, obesity, and fertility issues - within the context of dominant feminine social norms around hairlessness, slenderness, and motherhood. In presenting with symptoms that contravened these norms, many of Kitzinger and Willmott's participants questioned their identities as feminine and as women and engaged in 'disciplinary practices' - such as shaving and weight control - in a bid to manage their symptoms and achieve a level of normative femininity.

Kitzinger and Willmott's study draws attention to an aspect of PCOS that at the time of its publication, had been overlooked in medical literature - the potential for PCOS to detrimentally impact on women's identities and QoL. They also highlight the power and

influence of socially constructed images of 'womanhood' and 'femininity' in eliciting self-disciplining behaviours and feelings of inadequacy among women with chronic conditions that challenge feminine norms and ideals (Kitzinger and Willmott, 2002: 349). In unearthing facets of the PCOS experience of sociological significance at both individual and societal levels of analysis, Kitzinger and Willmott highlighted the need for a continued sociological examination of PCOS - one which would provide answers for the explicitly gendered social context in which many women experience the condition and assist the medical profession in supporting women living with PCOS.

Since Kitzinger and Willmott's study, more recent social scientific scholarship (Dowdy, 2012; Ellerman, 2012; Hadjiconstantinou et al. 2017; McKellar, 2015; Pfister and Rømer, 2017; Sharma and Mishra, 2018; Soucie et al. 2022; Williams et al. 2015; Williams et al. 2016) has generated further evidence of PCOS as a condition that presents significant challenges to dominant norms of femininity and womanhood and that is experienced by many women as extremely distressing. Like Kitzinger and Willmott (2002), Pfister and Rømer's (2017) study is underpinned by feminist social constructionist theory, and in particular, by Butler's (1999) concept of performativity. Butler (1999) conceptualises gender as performative, something which is continuously produced through everyday practices and interactions. Pfister and Rømer (2017: 174) report that hirsutism presents a particular challenge to women with PCOS' ability to successfully 'do' and 'perform' heterosexual gender norms - particularly those around facial and body hair - leaving many women with PCOS feeling 'different', 'wrong', 'unnatural', 'abnormal', 'unfeminine', and 'masculine'. Many of their participants reported developing their own 'coping strategies' as a result - such as hiding large parts of their bodies, shaving, and avoiding social contact - in a bid to comply with dominant gender norms and be regarded as 'intelligible' and 'normal' (Pfister and Rømer, 2017: 182). In engaging in these practices, Pfister and Rømer's (2017) participants sought to manage and minimise the threat that failure to conform to heterosexual gender norms can present to individual identity and its capacity to generate the appearance of what Butler (1999: 24) refers to as, 'developmental failure'.

Pfister and Rømer (2017: 175) report that the psychosocial distress many women experience as a result of the challenges PCOS presents to normative femininity is exacerbated by the medical profession's 'trivialization' of hirsutism in PCOS. Participants who sought medical advice and support for their hirsutism recounted feeling ignored by medical practitioners

despite its significantly negative impact on their mental wellbeing and everyday lives. Pfister and Rømer's (2017) findings are emblematic of a prevalent theme within social scientific PCOS research as a whole - women's experiences of inadequate interactions with medical professionals and a perception that medical professionals frequently fail to understand PCOS' impact on their identities and QoL. They also draw attention to the relative discounting of women's voices in clinical practice settings by revealing that, despite what feminist scholars have long argued to be the pathologisation of bodies which fail to conform to the masculinist norms on which the medical model developed (Findlay 1992; Weitz, 2003), requests for medical support in treating these issues are not always heard.

Consistent with Pfister and Rømer's (2017) findings but relating to a broader spectrum of PCOS symptoms beyond just hirsutism, participants in Ismayilova and Yaya's (2022: 8) study report a lack of 'empathy and concern' from medical professionals regarding their PCOS symptoms. Soucie et al. (2022: 14) highlight the 'heterosexual and heteronormative biases' that are sometimes present in women's PCOS-healthcare experiences, something they consider to be exemplified in their participants' reports of a tendency among medical practitioners to prioritise the treatment and care of women with PCOS seeking pregnancy. Both Ismayilova and Yaya's (2022: 8) and Soucie et al.'s (2022: 9) participants report a significant degree of 'weight bias' in their interactions with medical professionals, describing 'being blamed and shamed for gaining weight' and identifying a lack of appreciation among medical professionals of the role played by insulin resistance in PCOS in contributing to weight gain. Through exploring women's individual experiences of diagnosis and of seeking medical support for PCOS, Pfister and Rømer (2017), Ismayilova and Yaya (2022) and Soucie et al. (2022) highlight the role played by interactions with medical professionals and significant shortcomings in the care and treatment provided to women with PCOS, in contributing to PCOS' widely felt negative impact on identity and QoL. They also reinforce and are emblematic of the now widely accepted understanding within social scientific research that the experiences of women with PCOS in interacting with medical practitioners, and women's experiences of PCOS more generally, are underpinned by and embedded within an explicitly gendered social context.

2.3.2. Intersectionality and PCOS

However, women's experiences of PCOS within this context vary significantly depending on a host of social, economic, and cultural factors, and this is acknowledged by a small body of

existing social scientific literature on PCOS (Hadjiconstantinou et al. 2017; Soucie et al. 2022). Soucie et al. (2022) stress the role played by intersections with socioeconomic status and ethnicity in shaping women's experiences of seeking PCOS treatment and diagnosis. They identify the significant 'financial burden' that PCOS treatment options present to some women with PCOS, as well as the role of 'racial stigma' in limiting the accessibility of PCOS diagnosis to women from marginalised ethnic backgrounds (Soucie et al. 2022: 15). Hadjiconstantinou et al. (2017: 326) reveal a certain 'taboo' in some south Asian communities attached to the use of the contraceptive pill as a method of treatment for PCOS and a level of stigma attached to childlessness experienced by African participants in their sample. They also identify important cultural differences in women's experiences of hirsutism, with one participant describing female body and facial hair as relatively normative in many African countries and communities, reducing the stigma and personal distress associated with it.

The studies of Soucie et al. (2022) and Hadjiconstantinou et al. (2017) are shaped and underpinned by an understanding of the need to consider the 'multiple axes of identity and their unique contributions to experience with a syndrome like PCOS' (Soucie et al. 2022: 18). In other words, they draw attention to the role played by structural inequalities relating to class, socioeconomic status, and race and ethnicity, as well as the culturally variant nature of gendered expectations of women, in shaping how women experience the different symptoms of PCOS and the extent to which they want, and are able, to access medical support and treatment for these symptoms. Soucie et al. (2022) advocate a more intersectional approach to researching women's diverse experiences of PCOS and to developing appropriate healthcare delivery policies designed to meet women's different treatment and healthcare needs. Intersectional approaches to research are based on the diverse and widely applied concept of intersectionality which, broadly defined, offers a way of understanding: the complex ways in which different forms of disadvantage and inequality interact; experiences of multiple identities; and the relations between specific identity categories and social divisions (Richardson, McLaughlin and Casey, 2006; Robinson and Richardson, 2015).

2.3.3. Diagnosis and PCOS: what is missing in the literature?

Despite their important role in highlighting the need for cultural differences to be taken into account in tailoring medical support and treatment for women with PCOS, the findings

generated by the studies above are insufficient to combat the somewhat homogenised understanding of PCOS - as epitomised by concerns over fertility, weight, and hirsutism - that has emerged within PCOS-related literature. This homogenised understanding is the result in part, of the absence within this literature of an adequate representation of women with PCOS from more marginalised backgrounds and a nuanced examination of the diverse ways in which PCOS is experienced. Although Soucie et al. (2022) attempted to recruit women from more diverse socioeconomic and ethnic backgrounds, they found that the traditional recruitment approaches they used were insufficient for this task. Soucie et al. (2022: 17) suggest that 'low levels of health literacy, inadequate or no health-care coverage, and barriers to accessing quality healthcare' mean that women facing significant structural inequalities are less likely to receive a diagnosis for PCOS and are subsequently significantly underrepresented in research into women's lived experiences of the condition.

It was as a result of these challenges that Soucie et al.'s (2022: 17) sample consists predominately of 'young, White, cis-gender, able-bodied' women. Not only did this limit their ability to explore the role of intersectionality in shaping PCOS experiences in any great depth, but the demographic characteristics of Soucie et al.'s sample is representative of the vast majority of women who participate in research into lived experiences of PCOS. Women with disabilities, from minority ethnic groups, of marginalised sexualities, and who are not of reproductive age, are significantly underrepresented in this body of literature. So too, are people with PCOS who do not identify as women. Although my own study is not an intersectional analysis, an awareness of the relative exclusion of these groups from existing literature is of critical importance; it enables my research to lay down useful foundations from which future research can begin to address these gaps. It is through addressing a second significant gap within existing literature on women's lived experiences of PCOS, that my research provides these foundations. This gap relates to the absence of any in-depth and considered analysis of the role played by the PCOS diagnostic category in shaping women's experiences of PCOS.

The body of research reviewed in this section of my chapter has made significant contributions to sociological understandings of the significance of wider societal gendered norms in shaping women's experiences of their bodies, selves, and individual PCOS symptoms. There has to my knowledge however, been no in-depth analysis of the interrelations between gendered norms and the knowledge contained within the PCOS

diagnostic category or the social processes by which it has been constructed. By exploring these interrelations - how gender has shaped the social construction and evolution of the PCOS diagnostic category and how individual components of the diagnostic category are perceived or experienced by women with PCOS within explicitly gendered social contexts - my own study offers an important starting point for the development of a more nuanced understanding of the roles of diagnosis and medical knowledge themselves, in contributing to, mediating, or shaping, the highly gendered ways in which PCOS is so commonly experienced. In addition to this, the literature reviewed in this section of my chapter sheds some light on the role played by interactions with the medical profession in shaping women's PCOS experiences. Although the process of diagnosis is touched on within this literature, particularly in terms of women's dissatisfaction with the advice and support received from medical practitioners, there is little consideration of how the diagnostic category itself shapes these interactions through its translation into clinical practice settings.

Not only will addressing these gaps contribute to sociological understandings of the importance of diagnosis in shaping experiences of chronic conditions, but it will also lay down vital foundations for facilitating a more in-depth and representative exploration of women's diverse experiences of PCOS. This is because, the sociocultural meanings that pervade the PCOS diagnostic category and the way in which particular symptoms are defined as diagnostic indicators for PCOS while others are not, carry varying implications for women of different social and cultural identities. A nuanced understanding of the ontological and epistemological components of the PCOS diagnostic category, as well as of the social contingencies and processes which explain why the category has developed in this way, will offer an important starting point for developing an understanding of women's varying experiences of PCOS in the context of intersecting identities and inequalities and as shaped and influenced by the contents of the PCOS diagnostic category.

2.4. Diagnosis as an Analytic Tool and an Object of Analysis

Diagnosis as a social process offers a valuable analytic focus for examining the development of medical knowledge, its implications for patients, practitioners, and wider society, and the developmental trajectories it is likely to take in the future. The sociology of health and illness (SHI) is concerned with every aspect of contemporary society that influences health and wellbeing, and as such, diagnosis has long been a focus of sociologists interested in health and illness. This is true of both sociologists 'in' medicine - who conduct sociological research

which, 'serves the needs and interests of medicine' (Nettleton, 2013: 7) - and sociologists 'of' medicine - who adopt more critical perspectives on medicine, privileging lay views on health and illness rather than the medical viewpoint (Nettleton, 2013). Sociological interest in the social and political factors that influence the application of diagnostic categories emerged out of SHI's increasingly critical perspective in the second half of the 20th century on psychiatry and its diagnostic labelling practices of people considered mentally ill. Despite SHI's longstanding recognition of the centrality of diagnosis to medical work and knowledge, the sociological study of diagnosis as a distinct disciplinary strand within SHI has only recently developed (Nettleton, 2013). Although still an emergent specialty, the sociology of diagnosis offers a wealth of tools for conceptualising diagnosis and exploring the multitude of roles it plays in shaping contemporary social life. It provides a highly useful framework for the present study and its examination of the PCOS diagnostic category.

Jutel (2006; 2009; 2010; 2011a; and Nettleton, 2011; 2011b; 2015) has been integral to the development of the sociology of diagnosis as a distinctive field of sociological enquiry in its own right. They define diagnosis as 'the pre-existing set of categories' medicine uses to classify particular conditions as 'pathological', and 'the process, or deliberate judgement' by which it applies this label (Jutel, 2009: 278). I begin my discussion of the importance of a sociological analysis of diagnosis by identifying diagnosis as a form of classification. I draw on Bowker and Star (2000) to discuss the role that classification plays as an often invisible but powerful technology, integral to the construction and maintenance of particular bodies of knowledge with extensive implications for individuals and societies alike. I move on to outline the importance of studying the historical processes by which classificatory systems develop and consider this specifically in the context of diagnostic classifications. I argue that examining specific diagnostic categories offers a lens into the subjectivity of diagnosis, the social and political factors which inform its construction, and the social conflicts and disputes by which it is so frequently consumed (Jutel, 2009). I conclude by reflecting on what Jutel and Nettleton (2011) highlight as the relative absence of diagnosis from within sociology and the benefits of a more concerted sociological focus on diagnosis. I explain how my own research study, in addressing the relative absence of the PCOS diagnostic category in existing social scientific scholarship, offers an important starting point for future, more integrated analyses of the role that socially informed diagnostic categories play in shaping experiences of illness.

2.4.1. The centrality and subjectivity of classification

Bowker and Star (2000) draw attention to the ubiquity and centrality of classification within every element of social life. They define classification as the segmentation of society and the world around us into 'spatial' and 'temporal' categories and describe how these categories assume a level of invisibility, so embedded within social life that they are commonly forgotten about (Bowker and Star, 2000: 10). Through their analysis of a number of examples of classificatory systems, Bowker and Star (2000) challenge the common assumption that classificatory categories are clearcut and mutually exclusive and demonstrate the importance of developing an understanding of their genealogy. This is with the aim of elucidating the host of political and moral meanings contained within classification systems and the implications of these systems for the societies in which they exist and the actors who interact with them.

One such example analysed by Bowker and Star is the International Classification of Diseases (ICD), which provides a very helpful insight into diagnosis as a form of classification and into the complex classificatory systems in which individual diagnostic categories exist. The ICD is a globally used system of medical classification; it consists of a standardised vocabulary of diseases - their symptomology and diagnostic signifiers - with the ostensive aim of providing a uniform diagnostic tool for medical practitioners and researchers and of promoting comparability in public health data. In analysing the ICD however, Bowker and Star (2000: 66) draw attention to the extensive subjectivity of many components of the ICD's diagnostic categories and to the debates and contention they generate. One example of this is the ICD's classification of chronic fatigue syndrome (CFS) and the longstanding debate that has ensued over how it should be named. Bowker and Star (2000) reveal the widespread discontent that exists among patients with CFS, many of whom argue that the category's name is far removed from the realities of the condition. In doing so, Bowker and Star (2000: 68) highlight the inherently contradictory nature of diagnostic classificatory tools in general, in which 'the messy flow of bodily and natural experience must be ordered against a formal, neat set of categories'; they reveal a significant disconnect between the ICD's ways of defining particular diseases and patients' first-hand experiences of living with them.

Alongside the social conflicts generated by classificatory systems and the disconnect between classificatory systems and the object reality they purport to embody, Bowker and Star (2000: 20) identify another problem fundamental to any 'overarching' classification

scheme like the ICD. Given the reality of medicine as a 'rapidly changing and complex field', in presenting a formal and ordered list of diagnostic signifiers and categories the ICD invariably creates a host of classificatory dilemmas when new medical information develops (*ibid.*). This is encapsulated in Bowker and Star's (2000) analysis of the ICD's classification of HIV, a disease which can change dramatically over time in those living with it and which also varies substantially between individuals. Despite the fluid nature of HIV and of viruses in general, the ICD provides a rigid and standardised vocabulary for classifying each virus, its symptoms, and its stage of development. Bowker and Star (2000: 90) present this example as reflective of the 'extreme variability of the object world' and the problems this generates for classification systems in general, but also of the type of work a classificatory system enables its users to do. In simplifying the realities of a virus, the ICD enables its users - medical researchers and practitioners - to 'write scientific papers, provide keywords for indexing and abstracting, compare results, and so on' (Bowker and Star, 2000: 98). In other words, the ICD has been constructed with a set of particular purposes and types of work in mind, and this appears to have assumed priority over the designers' ambition to reflect and embody object reality through classificatory categories. In this particular instance, Bowker and Star (2000) provide us with an insight into the ICD's aim to coordinate the work of its various users and, through instilling a particular body of scientific vocabulary, to create an image of illness and disease which adheres to the organisation's aim of standardising medical knowledge and practice.

2.4.2. The genealogy of classification

As well as highlighting the subjectivity, ambiguity, and contradictions contained within the ICD's diagnostic categories and the practical and political aims that feed into their development, Bowker and Star (2000) also demonstrate the importance of understanding the architecture and infrastructure of classificatory systems like the ICD. This is to elucidate the host of 'social, political, and economic work' involved in constructing and maintaining such a system and its embodiment of and construction in line with many of the interests of the modern state (Bowker and Star, 2000: 109). The functioning of the modern state is dependent in part on its access to extensive information about its citizens. Through their analysis of ICD archives, Bowker and Star (2000) reveal that the ICD, throughout its history, has amended and adapted its approach to generating information - in the context of citizen health specifically - to meet the state's changing informational needs. As states have evolved

to require increasingly complex information about their citizens' physical health, the ICD has accordingly increased the detail of the data it collects, maintained categories which do not reflect the most up to date scientific knowledge in order to promote historical comparability, and developed relations with other state information systems like social security.

By paying attention to changes in the classificatory infrastructure of the ICD over time, Bowker and Star (2000) successfully demonstrate the value of unearthing the genealogy of classificatory systems in order to facilitate a more nuanced understanding of their purpose, role, and implications for wider society. Bowker and Star's (2000) analysis reveals the ambiguity that is embedded within classification systems and the scope this offers those designing and managing classificatory systems, for constructing a system which reflects and realises their organisational aims and priorities. They draw attention to classification as a far from objective or natural reflection of our world and society, but a political and cultural construction with profound implications for all those engaging and interacting with it. In the context of diagnosis, this highlights the utmost importance of developing a genealogical understanding of individual diagnostic categories in order to expand and enhance our understanding of the processes by which they are constructed and the implications they carry for individuals and wider society.

2.4.3. Diagnosis in sociology as underdeveloped

Despite the benefits that an analysis of diagnosis presents to sociology and the detailed case and rationale Bowker and Star (2000) provide for this, Jutel and Nettleton (2011: 793) argue that diagnosis has and continues to assume, 'an absent presence' within SHI. Diagnosis is present in a large body of history of medicine and sociology of illness experience literature, whereby the naming of a disease is often treated as a helpful starting point for exploring the medicalisation of a particular condition or of the implications of illness in individuals' lives. Diagnosis is generally not however, considered in great depth within this body of literature, and its role as a powerful social technology in its own right is widely overlooked. In the sociological PCOS literature explored earlier in this chapter, diagnosis is frequently mentioned in the context of PCOS - dealt with mostly as a foundation from which women acquire a label for their symptoms and seek medical advice and support - but is not explored as a topic of sociological analysis in its own right, nor is it recognised as an analytical tool for researching other dimensions of PCOS, such as experiences of the diagnostic category itself and of the process by which it has been constructed. This is an issue that Jutel (2009) and

Jutel and Nettleton (2011) identify as common to SHI as a whole and that leads them to present a case for the benefits of a more comprehensive sociological analysis of diagnosis.

Jutel and Nettleton (2011) use Blaxter's (1978) distinction between diagnosis as category and diagnosis as process to frame their discussion; they also identify an additional dimension of diagnosis - its consequences for patients and carers. Diagnosis as category refers to the definitional components of a diagnosis - its symptoms and diagnostic indicators - while diagnosis as process refers to the implementation of that definition. Although Jutel and Nettleton (2011: 794) present these dimensions of diagnosis as 'analytically separate', they argue that both are nonetheless 'inextricably interlinked and mutually constitutive'. Jutel and Nettleton (2011) argue that diagnosis as category and as process work alongside one another to conduct the 'work' that Bowker and Star (2000: 111, 239) identify as a fundamental outcome of classification. Regarding the consequences of diagnosis, this too is intrinsically interlinked with diagnosis as category and as process, both of which can be highly influential in shaping individuals' experiences of diagnosis and of illness itself. The framework Jutel and Nettleton (2011) use to conceptualise diagnosis is of value in my own sociological examination of PCOS. Although the focus of this research is most explicitly on PCOS as a diagnostic category, it is conducted with the aim of enhancing understandings of the expansive social consequences that processes of medical knowledge construction can engender for the delivery and dissemination of diagnosis in clinical settings and their implications for individuals' lives and identities. It offers an important tool for engaging in an integrated analysis of the role played by diagnosis-as-category in shaping individual lived experiences.

The 'work' conducted by diagnosis as a form of classification takes an abundance of forms and includes its provision of a framework for organising illness - facilitating the identification of treatment, predicting likely treatment outcomes, and explaining illness onset and progression - and for administrative work - facilitating access to particular services, work-based statuses and support groups (Jutel and Nettleton, 2011: 793). Diagnosis also plays an integral role in shaping societal understandings of, and attitudes towards, normativity and deviations from it. Jutel (2009: 279) argues that by providing an explanation for individuals who are 'different (deviant) from the norm', diagnosis facilitates the 'social incorporation' of that individual in a way which does not threaten the norm(s) from which they deviate. It also, in diagnosing deviant behaviour considered to constitute a societal threat, offers 'a

cultural expression of what society is prepared to accept as normal' (*ibid.*). On account of the wide range of work conducted by diagnosis and its implications for societal values and for the incorporation and exclusion of particular individuals, Jutel and Nettleton (2011: 798) argue that diagnosis constitutes a valuable 'object of sociological scrutiny' and an important 'analytic device'.

Jutel and Nettleton (2011: 798) also provide an important rationale for the sociological examination of individual diagnoses, which they suggest offer 'a more detailed canvas against which to understand disease and its impact' and facilitate the identification of common trends and forces in the construction and dissemination of diagnosis. This too encapsulates an important aim of my own sociological examination of PCOS. In exploring the processes and intricacies by which the diagnostic category has developed and reflecting on the wider implications of these for women living with PCOS, it seeks to illuminate common patterns in the construction of diagnostic categories in general, particularly those whose symptomology is experienced in highly gendered ways. It also sheds light on the pronounced role played by individual diagnostic categories in shaping individual and societal experiences and understandings of illness, and of which specific behaviours and physiological features can be considered normative, and which should be considered pathological.

In this section of my chapter, I have identified diagnosis as a powerful classificatory tool with profound implications for individuals and society; this is due to the medical and societal 'work' it conducts and coordinates and the strands of knowledge it constructs and maintains around particular illnesses and diseases. I have outlined the benefits of exploring the genealogy of particular diagnoses and the importance of a move within sociology towards a greater recognition of diagnosis as a focus of analysis in its own right and as a valuable analytical tool. By exploring the PCOS diagnostic category - its genealogy and development over time, the ambiguities and complexities it contains, and its translation and application in clinical practice settings - this study addresses the absence of diagnosis within existing social scientific scholarship on PCOS. In doing so, it sheds light on the host of meanings that pervade the PCOS diagnostic category and the social contingencies through which it has developed. This enables the research to lay down essential foundations for a more complete sociological understanding of the consequences of PCOS for women living with the condition and for society as a whole; these include illuminating the work the PCOS diagnostic category conducts in overseeing the medicalisation, treatment, and social incorporation of women

who present with aesthetic and physiological characteristics which contravene societal expectations of femininity.

2.5. SSK: Tools for an Analysis of Diagnosis

Having made the case for the importance for taking diagnostic categories seriously, here I set out the framework I draw on throughout this research to analyse the PCOS diagnostic category. I present the sociology of scientific knowledge (SSK) as a valuable analytical framework for exploring the construction and content of diagnostic categories and explain the relevance and importance of this framework for a sociological analysis of PCOS. SSK is a sociological specialism which explores why certain ideas, beliefs and findings come to be accepted as established scientific knowledge, while others are discarded or dismissed. SSK considers the development of scientific knowledge to be an open-ended and historically contingent social process (Barnes, Bloor, and Henry, 1996; Rees, 2019). In presenting this framework, I outline the central aims and principles of SSK and discuss its concepts of finitism and similarity relations and the nuanced insights these offer into the processes by which scientific knowledge is constructed. I follow this by outlining the approach SSK adopts to the study and understanding of scientific controversies and identify controversy itself as a valuable sociological tool for exploring the content and construction of diagnostic categories. Finally, I extend SSK by drawing on Gieryn's (1983) concept of boundary work to explore the rhetorical strategies scientists commonly use to navigate controversies, before paying attention to the use of consensus conferences and the standardisation of scientific knowledge as means by which scientific communities attempt to bring controversies to a close.

2.5.1. The central aims and principles of SSK

The ideas and concepts that are now central to SSK[12] originated among a group of scholars in Edinburgh who extended Fleck's (1935[13]) and Kuhn's (1970[14]) classic analyses of medicine and science, challenging the assumption that scientific knowledge constitutes an entirely objective and reliable reflection of fixed truths about the physical world (Rees, 2019). In challenging this assumption, the Edinburgh SSK scholars developed a set of ideas and concepts that represented a shift away from the theoretical approach dominant in

[12] SSK scholars are also known as belonging to the 'Strong Programme' and the 'Edinburgh School' (Li et al. 2010; Rees, 2019).
[13] See Fleck's (1935) *Genesis and development of a scientific fact.*
[14] See Kuhn's (1970) *The structure of scientific revolutions.*

humanities and social sciences at the time, which sought only to explain the processes behind the development of incorrect scientific theories, and which did not consider established scientific knowledge as an appropriate object of historical, philosophical or sociological scrutiny (Rees, 2019). Moving from sociologies of error to exploring accepted scientific claims, SSK scholars are concerned with all forms of scientific knowledge and the social processes and factors behind why some scientific claims generate credibility amongst the scientific community and achieve the status of scientific fact, and others do not. In explaining these processes, SSK emphasises the social and human activities involved in the formation of a scientific claim and the development of that claim into established scientific knowledge (Rees, 2019).

SSK understands scientific knowledge to be both socially constructed and conventional (Rees, 2019). An understanding of science as socially constructed emphasises the social processes of 'conceptual change, adjustment, redefinition, reclassification and negotiation' that are central to science (Bloor, 2010 in Li et al. 2010: 421). Scientific practice is the result of the traditions and conventions dominant in the particular community in which scientists practise. These traditions are at times challenged as a result of new scientific evidence which confronts scientific communities with a 'choice point' (*ibid.*), necessitating a decision about whether they retain their traditional ways of knowing/practising or proceed in a new direction, consistent with the newly generated body of evidence[15]. For the purposes of my research study, a key plank of SSK's toolset is its emphasis on the ways words become attached to physical (and sometimes not-material) objects. Of vital importance in the attribution of a label to a phenomenon, SSK emphasises convention and the authority of scientific communities in shaping this process. In the following section, I set out the key concept SSK has developed for classifying and diagnosing - the concept of finitism.

2.5.2. Finitism and similarity relations

In explaining classification as a process, Barnes, Bloor, and Henry (1996) argue that individuals learn how to classify through the act of ostension. Ostension is the process by which an individual - a young child or a learner new to a particular profession or setting - learns the community-approved vocabulary to apply to a specific entity (Barnes, Bloor, and Henry, 1996; Kusch, 2002). The first step consists of the learner experiencing a phenomenon

[15] As I go on to show, it is not as simple as the new evidence generating a change in direction, as it is often such choice points which lead to scientific controversies.

(for instance, by being shown) and an authority figure (parent, trainer, teacher etc.) advising of the correct community-approved term for that phenomenon. An example of this is a child learning to identify different forms of waterfowl (Barnes, Bloor, and Henry, 1996; Kuhn, 1977). In this case, the parent showed the child a range of birds, and advised them of their names. Following this, the child upon seeing another case of a bird, attempted to label it correctly. If the child used the correct term, they were praised by their parent, and if not, they were advised of the correct name. Through this process of trial, error and correction, the child's cognitive facilities for classifying birds correctly are reconstructed and developed.

Kuhn's (1977) anecdote of the child emphasises the importance of: a) experiencing a phenomenon ostensively (i.e. observing it whilst being told the correct attributions and terminology); b) experiencing a case multiple times - since 'no single act of ostension suffices to teach the correct use of a term' (Barnes, Bloor, and Henry, 1996: 49); and c) the importance of authority in this process. The child is not expected to challenge the legitimacy of the parent's correction. Rather, they are expected to reconfigure their cognitive schema to make the parent's classification their own. SSK refers to this as the similarity relation. Similarity relations, as the name suggests, are a relation of similarity between different kinds of objects. A goose and a swan might have a significant degree of resemblance (white feathers, orange bills, wings) but competent classifiers of birds can adequately discriminate between them. This sense of the resemblance between two kinds of objects constitutes the similarity relation. Importantly, this also highlights that similarity relations cannot be reduced to language but rather the learner needs to experience large numbers of cases of a phenomenon in order that their discrimination becomes more sophisticated. Of course, the act of training is not simply to shape the learner's discrimination, it is to bring it in line with the community of competent classifiers. As a result, this model of classification is equally as valid in science and medicine, as it is to learning about birds.

In instances when a learner is faced with a phenomenon they have not previously encountered, a range of options is available to them. They could try to reconcile it with their existing schema, locating it as a new type of a previously known phenomenon. For instance, Rees (2011) discovered that forensic medical examiners (FMEs) reduced their claims-making when uncertain about the cause of a physical injury. Alternatively, they could ask an authority figure (for example, a senior colleague) for their opinion on the new phenomenon, thereby accepting the classification of the authority. In so doing, producing this as another

example of ostension (Rees, 2011). Or in some cases, the authority might themselves not have a satisfactory classification for the phenomenon as it may be something previously unencountered[16]. For instance, the phenomenon might be something which sits problematically across two existing categories.

In science and medicine, when a new entity is encountered that cannot be classified, the scientific or medical knowledge may need to be altered accordingly. For example, Bloor (1982: 273-274) asks us to imagine a simple classificatory system in which 'fish' live in the sea, 'birds' fly in the air, and among the various classes of 'animals' which live on land, is a subgroup known as 'mammals' who suckle their young. When confronted with a new living entity however, a whale, who lives in the sea *and* suckles its young, the classificatory system encounters a dilemma. This is because 'resemblance alone pulls us in opposite directions', and so existing similarity relations constructed as part of the classificatory system are insufficient to accommodate this new entity (Bloor, 1982: 274). For the classificatory system to remain intact, one of these relations must be retained and the other discarded. Through this example it is possible to identify what Barnes, Bloor, and Henry (1996: 55-58) consider to be the five tenets of finitism:

- 'The future applications of terms are open-ended.
- No act of classification is ever indefeasibly correct.
- All acts of classification are revisable.
- Successive applications of a kind term are not independent.
- The applications of different kind terms are not independent of each other'.

As the example above demonstrates, we can only decide what is correct based on the cluster of cases we have previously experienced. Before the whale had been encountered, it was correct to classify all creatures that swim as 'fish' and all land animals that suckle their young as 'mammals'. At this point in the history of the classificatory system the similarity relations that tied together each group of animals were reinforced with each new act of classification, yet it remained the case that with every new instance requiring a classificatory decision the

[16] This may be a phenomenon previously unencountered by an authority figure or by the community as a whole. If the former, the same methods of ostension would apply. For the rest of this section, I discuss the latter i.e. when the community has not encountered a particular phenomenon before.

new entity had to be considered in terms of its resemblance with other entities in the system. Once the new case of the whale had been discovered, it was necessary to revise existing similarity relations, and so as argued by Bloor (1982: 274), 'new contingencies can always prompt retrospective revisions'.

Medical diagnoses are simply an example of classification, and the history of PCOS can be explained in accordance with these tenets of finitism. For instance, finitism can help us explain the evolution of a classification (in this case, PCOS) according to how we 'develop the analogy between the finite number of our existing examples of things' (in the case of PCOS, these could be patients, images, ovaries) and 'the indefinite number of things we shall encounter in the future' (Barnes, Bloor, and Henry, 1996: 56). This means that, 'since scientific knowledge is knowledge of cases, the content or meaning of any scientific generalization is no more than the finite set of cases' on which that generalisation is based (Sturdy, 2007: 676). As I show through the rest of the thesis, new visualisation devices, new tests, and the incorporation of new kinds of patients, challenged the existing knowledge on which PCOS was based. At each point, the medical community needed to ascertain how they would interpret and incorporate this new data, generally proceeding into a scientific controversy. In the following section, I explore the sociological value of studying controversies.

2.5.3. Scientific controversies and underdetermination

The revisability of scientific classifications applies also to scientific theory (Barnes, Bloor, and Henry, 1996). The ideas of finitism are developed in part out of the Duhem-Quine thesis which argues that scientific evidence is never sufficient to inhibit the development of alternative and contradictory theories, both of which may offer adequate explanations of that evidence (Quine, 1963). This is because of what Duhem (1954) identifies as the local cultural traditions through which we interpret the world around us. This means that scientists belonging to different communities or groups with varying theoretical standpoints, may interpret the same set of experimental results in different ways, and that scientific evidence is always underdetermined by theory (Barnes, Bloor, and Henry, 1996). To put it another way, different theoretical positions might produce diverse similarity relations in how the evidence is to be interpreted/classified. The result of the Duhem-Quine thesis, also known as the underdetermination thesis, is that an apparently established scientific theory always contains within it the potential to be disproved (Bloor, 2010 in Li et al. 2010).

Furthermore, experts of opposing theoretical perspectives are able to use the underdetermination of evidence by theory to their own advantage, interpreting a particular body of evidence in line with their own perspectives or beliefs and disputing or dismissing evidence which contradicts their standpoint (Dietrich and Skipper, 2007).

The underdetermination of evidence by theory is particularly evident during scientific controversies and is a central feature in both their onset and escalation (Collins, 1981; Pinch, 2001). A controversy in science is epitomised by uncertainty or disagreement over a particular finding, theory or method of conducting science. It is epitomised also by the development of opposing sides of experts who use rhetoric in attempt to navigate the controversy and to close it in a way which adheres to their particular interpretation of science. Scientific experts embroiled in controversies also use a range of rhetorical devices - including flexible repertoires and flexible evaluations of ideals relating to scientific method and scientific norms - to limit the underdetermination of their own claims and to exacerbate that of their rivals' (Mercer, 1996). Scientific controversies offer a valuable tool to SSK because of the ways in which they 'exemplify the contingent nature of all beliefs and the ever present possibility for the stability of beliefs about nature (knowledge) to be jeopardised by under-determination' (Mercer, 1996: 39), thereby rendering 'the facts of knowledge formation visible' (Bloor, 2010 in Li et al. 2010: 429).

This is epitomised in Collins' (1975; 1981) classic controversy study in which he explores the beginnings, playing out and eventual closure of a controversy which took place in the 1970s, within the then evolving scientific field of gravitational radiation. The controversy emerged out of a claim made by one particular scientist to have discovered gravitational radiation of such a quantity that it challenged all established cosmological theories of the time. Weber[17] provided new evidence for the existence of gravitational radiation and a new case for the scientific community which, if proven correct, would challenge existing similarity relations and require a paradigmatic shift in understandings of cosmology. To begin with, other experts in the field were divided over whether they thought Weber's claim feasible, but as a result of what Collins (1981: 34) identifies as a host of social and political processes which unfolded over the course of the controversy, an 'almost universal disbelief' in Weber's

[17] In his 1975 paper, Collins refers to the scientist as O, but in his later 1981 paper, he refers to this same scientist as Weber. For ease, I refer to this scientist as Weber throughout my discussion of his work and the controversy that surrounded it.

claims developed. No scientist was ever able to conclusively identify what was wrong about Weber's findings or the way he conducted his experiment, but Collins (1981: 34) explains that in the period of time which lapsed between the publication of his two papers, many scientists engaged in 'more than purely "scientific actions"' aimed at increasing the credibility of their own evidence base in order to discredit Weber.

As a result of undertaking his study *while* the controversy was in progress, Collins (1981) was able to identify a number of specific changes that contributed to the proliferation in disbelief in Weber's claims. These included the emergence of a consensus within the field of gravitational radiation over what constituted a 'good' experiment and the increasing identification of numerous, albeit minor, errors in Weber's method which contravened this consensus. A number of scientists also used rhetoric to publicly discredit Weber, something which fuelled and garnered further disbelief in Weber's claim and turned the tide of opinion against him. Collins' (1975, 1981) analysis reveals therefore, the capacity for scientific experts whose own theoretical stance or interpretation does not adhere with a new piece of evidence or theory, to challenge that evidence or theory in line with their own interpretation of science. The success of this challenge does not necessarily equate to the falsity of the theory or evidence being challenged, nor of the superiority of the challengers' theory or evidence base. It equates instead to the challengers' accomplishment in discrediting the theory or evidence on the grounds of interpretation, thanks to skilful employment of rhetoric and the ability to set in motion a tide of professional opinion against their opponent.

2.5.4. Boundary work

Among the devices and strategies that experts embroiled in a controversy use in an attempt to navigate and eventually close it according to their own interpretation of science, is what Gieryn (1983) defines as 'boundary work'. Boundary work is the attribution of selected characteristics to the institution of science. This is with the aim of constructing a social boundary that distinguishes science from other intellectual activities, referred to by Gieryn (1983: 782, 788) as 'pseudo-science' or 'non-science'. The concept has however, proved itself an equally useful tool for the analysis of controversies internal to particular scientific disciplines (Gieryn, 1983: 788, 782). As Barnes, Bloor, and Henry (1996: 154) attest, 'it is not just the boundary between science and non-science that is 'conventionally drawn', but also the boundaries between different specialties within science. Gieryn (1983: 782) identifies

boundary work as first and foremost, a 'rhetorical style'. It takes a variety of forms, something Gieryn (1983) exemplifies in his analysis of the writings and public addresses of Tyndall - a public figure in Victorian England who sought to demarcate science from religion and mechanics, in order to promote the expansion of science as a professional and intellectual discipline and secure much-needed material and symbolic resources.

Among the boundary work devices invoked by Tyndall, were the exaggeration of science's 'intellectual imperialism', the demarcation of unfavourable characteristics to religion and to mechanics, and the construction of what Gieryn (1983: 785) terms, 'contrast-cases', in order to exaggerate the differences between science, and mechanics and religion. Contrast-cases involve exaggerating the differences between the two sides involved in a controversy with the overall effect of creating a favourable public image of one's own theoretical perspective or scientific approach, in stark contrast to one's opponents'. Gieryn's (1983) analysis of a separate case study - the practise of phrenology in early 19th century Edinburgh - offers insight into the mobilisation of boundary work by particular *groups* of scientists, whose aim is to monopolise the status and professional authority of their own scientific practise through demarcating other practises as 'non-science'. Gieryn's use of varied case studies from different historical periods illustrates the extent to which science's acquisition and maintenance of intellectual authority is a continuous process, one which takes on different dimensions within different scientific specialties. It captures the dynamism of science's boundaries, which are continuously 'drawn and redrawn' in 'flexible, historically changing, and sometimes ambiguous ways' (Gieryn, 1983: 781).

2.5.5. Standardisation

The underdetermination of evidence by theory intensifies controversies, increasing the elusiveness of consensus and thus prolonging and maintaining scientific disputes. This is because experts on either side of a controversy become embroiled in an endless cycle of discrediting one another's evidence. In such instances, leading experts or institutions within the field may employ alternative methods aimed at closing the controversy and advancing the field beyond its internal disputes. The most common among these are consensus conferences and the construction of clinical guidelines, both of which aim to generate consensus through reconciling the similarity relations of experts with competing perspectives. Despite its aim of instilling certainty and uniformity in scientific knowledge and practice, Timmermans and Berg (2003: 23) define standardisation as 'a dynamic process of

change', one which 'bring(s) into existence new ideas, entities, values, and even subjects for medicine'.

Timmermans and Berg (2003) argue that the ultimate aim of any consensus conference is to produce consensus which, once achieved, can bring about the standardisation of medical knowledge. Consensus conferences are convened with the idea that experts 'come together to discuss the contested issues and work toward a practically feasible recommendation' (Timmermans and Berg, 2003: 4). The first ever consensus conference was held by the National Institutes of Health (NIH)[18] in 1985 and involved discussions among medical experts about the safety and efficacy of various medical technologies (Van Bouwel and Van Oudheusden, 2017). Since then, the style of consensus conferences has gradually evolved into a more 'public participation' based model (Einsiedel and Eastlick, 2000: 325). This involves recruiting and consulting citizens and voluntary organisations - usually those with a direct interest in and personal experience of the issue under consideration - to review existing evidence and decide on a resolution. All consensus conferences, including those which assume a more traditional 'experts-only model', are based on principles of 'group deliberation' and 'objectivity', with achieving 'consensus as a closure of epistemic controversy' heralded as the ultimate aim (Van Bouwel and Van Oudheusden, 2017: 502). This aim is in practice, not always met, and consensus conferences have often been criticised for a 'lack of transparency in decision making and the suspicion that the resulting guidelines are often as much the result of group dynamics during the meeting as of the scientific literature' (Timmermans and Berg, 2003: 4). Consensus conferences are affected by a host of socio-political and psycho-social factors - such as 'group dynamics in the panel, partial weighting of the evidence, time pressure and style of the chair' (Solomon, 2011: 243) - each of which may exert a particular pressure on conference participants which can distort the consensual nature of the decision-making process.

Standardisation as an institutional aim and practice however, is not unique to consensus conferences and according to Timmermans and Berg (2003: 3) has, 'penetrated every corner of contemporary medicine'. Timmermans and Berg (2003) consider this to be in part because of the rise in in evidence-based medicine (EBM). EBM involves the development of clinical practice guidelines with the aim of disseminating a universal body of knowledge to medical

[18] The NIH is a medical research agency overseen by the United States government (nih.gov)

practitioners and researchers and of instilling uniformity in their medical and research practices (Timmerman and Berg, 2003). In spite of EBM's ostensive aims and its principle that all such guidelines should be based on sound scientific evidence, Timmermans and Berg (2003: 3-4) note that 'such evidence is only rarely available to cover all the decision moments of a guideline'. This means that experts involved in constructing evidence-based clinical guidelines frequently engage in 'additional, less objective steps' in order to account for absences or contradictions in the evidence base, engendering a significant component of subjectivity within the process (Timmermans and Berg, 2003: 3-4). The effectiveness of standardisation as a means of relieving disciplinary or professional uncertainty and of realising its other central aims such as facilitating cost-effective scientific practice, meeting professional and patient needs, and facilitating the introduction of new technologies, is subject to extensive debate (Timmermans and Berg, 2003). What Timmermans and Berg (2003) highlight is the importance of playing close attention to its role in redefining the purposes and practices of medicine, the devices it implements and the groups and people it interacts with, each of which carry pronounced implications for the social construction of scientific knowledge.

In this section of my chapter, I have outlined the ideas and concepts of SSK and the tools these offer for an analysis of the social construction of individual diagnostic categories. I have explained the core components of finitism and similarity relations and the insights these offer into scientific knowledge construction as an open-ended and historically contingent process. I have also identified controversy as providing an important opportunity for the analysis of this process. This is because of its illumination of particular social and historical contingencies that shape uncertain and disputed scientific knowledge, each of which must be analysed and comprehended in order for a more complete sociological understanding to be developed of science's role in shaping individuals' lives and society as a whole. Given the extensive debate and controversy that has consumed the PCOS diagnostic category for several decades, PCOS offers a useful opportunity for the ideas and principles of SSK and controversy studies to be applied to a gendered and uncertain diagnostic category. This advances sociological understandings of PCOS, and in particular, of the social and political processes which have informed its construction and which shape the diagnostic label and advice women receive in clinical practice settings. It also offers a practical case study for exploring the value of a more integrated approach to the study of diagnosis, which

combines a central focus on a diagnostic category with paying nuanced attention to the specific processes by which it has formed.

2.6. Research Questions

This chapter has explored the literature and concepts that inform this study and presented a case for the value of using SSK concepts in an applied study of diagnosis. It has situated the project within its wider historical context, setting the scene for an in-depth analysis of developments in the PCOS diagnostic category from 1974 onwards - when the first ultrasound image of polycystic ovaries was produced - before exploring the role played by medical images in the social construction of medical knowledge. This was followed by an outline of existing social scientific health literature on experiences of PCOS. Although this literature provides a useful insight into the widely felt distressing impacts of PCOS for many women living with the condition and the distinctly gendered social context in which the condition is experienced, it fails to adequately represent the experiences of women with PCOS of diverse ages, abilities, ethnicities, sexualities and social class backgrounds. Also missing from this literature, is an analysis of the role played by the PCOS diagnostic category - the meanings it contains, and the translation of these meanings in clinical practice settings - in shaping experiences of PCOS. After discussing the importance of a more considered analysis of PCOS diagnosis for developing existing sociological understandings of PCOS, I went on in this chapter to identify diagnosis as a valuable analytic focus for examining the wider societal implications of medical knowledge and presented a case for the particular benefits of exploring the genealogy of individual diagnostic categories in order to illuminate broader trends. I followed this by outlining the specific tools that SSK offers for conducting an analysis of diagnosis, identifying finitism, similarity relations and scientific controversies as particularly relevant to this study. Engaging with this diverse body of literature and concepts has set the scene for, and informs, the central question of this research:

To analyse and understand the social processes by which PCOS has come to be defined as a lifestyle disorder, and to reflect on the wider implications of this definition for women living with PCOS.

This is an aim that is guided by three key objectives:

1. To illuminate the social processes behind medical images of polycystic ovaries and their role in the shaping the medical knowledge which informs the PCOS diagnostic category.
2. To explore the importance of the underdetermination of evidence by theory in the onset and playing out of a controversy over PCOS diagnostic criteria.
3. To examine the social processes which facilitated a shift in the PCOS controversy and enabled the development of a unique 'patchwork agreement' in the field.

In the next chapter, I outline the methodological steps I have taken in line with meeting the requirements of my research question and objectives laid out above.

Chapter 3. Methodology

3.1. Chapter Introduction

This chapter outlines the methodology I have adopted in addressing my central research questions and objectives laid out in the previous chapter. First, I outline the broad research paradigm in which my research sits and explain how this has framed the key methodological decisions I have taken and the ontological assumptions which underpin my research (Broom and Willis, 2007). Secondly, I discuss the preliminary research I undertook to scope my study and explain how this research informed my decision to undertake a largely qualitative sociohistorical analysis of medical documents using an intrinsic case study approach. Thirdly, I outline the main tenets of controversy as method and explain how and why I have applied them in this project (Rees, 2009; Rees, 2015; Rees, 2019). I then engage in an in-depth discussion of the documentary-based approach used in this study. I detail the different methodological steps this has involved, including multiple stages of scanning and searching an extensive target population of documents, taking practical steps to maintain reflexivity throughout, and a rigorous sampling process (Rapley and Rees, 2018). Finally, I conclude by discussing the rationale and details behind my application of the 'framework analysis' method for analysing my data (Ritchie, Spencer, and O'Connor, 2003), before briefly outlining the ethical considerations that were necessary in conducting this research.

3.2. Epistemology and Qualitative Methodology

This research sits within an interpretivist research paradigm and assumes a constructivist ontological position. It is underpinned by an awareness of the socially constructed nature of medical knowledge and of the complexities and subjectivities involved in the construction of diagnostic categories. Consistent with the interpretivist, constructivist paradigm that frames this research, I have adopted a primarily qualitative and inductive methodological approach. Although some quantitative components were involved in the preliminary research and sampling stages of the study - necessary for scoping the study, developing a sense of the scale of available literature, and selecting an intrinsically rich but appropriately representative sample - the study's overriding qualitative approach to data gathering and analysis has enabled particular attention to be paid to the meanings that pervade the PCOS diagnostic category and to the 'patterns and irregularities' that have characterised its social construction over time (Broom and Willis, 2007: 25). It is through paying attention to these meanings, associations, and patterns, that the findings and conclusions of this study have

been drawn. Just as this research works from the assumption that scientific knowledge construction is not objective or neutral, throughout this process I have maintained reflexivity and awareness of my own positionality and subjectivity as a researcher. By adopting a qualitative methodological approach and a position of 'empathetic neutrality' (Ritchie and Lewis, 2003: 13), significant scope has been embedded within this project for my own assumptions and pre-existing ideas to be challenged and for as nuanced an understanding as possible to be developed of the social and cultural contingencies which inform processes of medical knowledge construction. In the next section of this chapter, I explain in more detail the specificities of the research design I have adopted as part of this broader epistemological and ontological approach.

3.3. Research Design

My original motivation for examining PCOS from a sociological perspective came from my personal experiences of living with and being diagnosed with PCOS. I have first-hand experience of the challenges its symptoms present to normative understandings of femininity, the implications of this for identity and quality of life, and the difficulties which are so commonly incurred in seeking reliable and consistent medical advice on managing PCOS. It was because of these experiences that I came to view PCOS as a condition rich in sociological meaning and significance, with implications for women which were intricately intertwined with wider understandings of gender and with medicine's definition of the normative female body. As I started the preliminary stages of my research however and identified the absence of the PCOS diagnostic category within existing social scientific scholarship on PCOS as something which needed to be addressed, I also became aware of the idiosyncrasies of PCOS as a diagnostic category in and of itself and of the complex socio-history through which contemporary definitions of PCOS have developed. In this section of my chapter, I outline the steps I took in conducting this preliminary research and the notable trends in PCOS-related publication rates I identified. I follow this by drawing on these trends to explain the rationale behind my decisions to adopt a largely qualitative, sociohistorical, and intrinsic case study approach to my research.

3.3.1. Preliminary research to scope study

My preliminary research involved familiarising myself with existing medical literature on PCOS with a view to developing an initial surface-level understanding of its representation within this broad body of scholarship, as well as of the scope and scale of available

literature. This entailed a rigorous process of searching and scanning available PCOS-related medical literature within a selection of different bibliographic databases and assembling a sampling frame from which key publication trends could be identified (Prior, 2003; Rapley and Rees, 2018). I began by carefully selecting which literature databases were most appropriate for conducting my search. Every mainstream search database has its own distinctive strengths and weaknesses, and methodological guidance on extensive literature searching advises against using only one database on the grounds that this is unlikely to generate a sufficiently comprehensive population sample (Li et al. 2019; Rapley and Rees, 2018; Rowe et al. 2017). In line with this guidance, I conducted my initial broad searching of literature using four different databases - Google Scholar, Web of Science, Scopus and MedLine.

I selected Google Scholar primarily because its range of available literature goes back significantly further than any of the other available databases. Through using Google Scholar, I identified three relevant medical journal articles published in 1935 and 1936 that maintained a substantive focus on PCOS (Appendix A), and another eight publications from between 1941 and 1950 (Appendix B). Google Scholar was the only database to generate any significant number of articles published before 1950. However, despite its initial benefits for identifying older medical literature relating to PCOS, beyond 1951, the quantity of material generated by Google Scholar was so extensive that I stopped using it as a bibliographic database in my preliminary research. The number of articles generated were simply too great for a project of this scale and scope, and Google Scholar did not provide appropriate filters for conducting a more advanced and focused search (Aguillo, 2011).

For conducting a search of post-1950 medical literature on PCOS, I proceeded to use the other three databases I had selected (Web of Science, Medline, and Scopus). This was primarily because of their advanced filter tools for refining large amounts of data according to various measures such as language, place of publication, and publication type and discipline, but also because they offered expansive banks of literature within clinical medicine and related fields (Li et al. 2019; Rapley and Rees, 2018).

When searching within each database, I used the following search terms:

- PCOS
- Polycystic ovary syndrome

- Stein and Leventhal syndrome
- Polycystic ovaries

As outlined in the literature review chapter, PCOS has been known by each of these names, but their use has varied over time and throughout the category's history (Azziz and Adashi, 2016). To ensure that my sampling frame contained literature covering the diagnostic category's entire history and evolution, it was important that I used each of these search terms. It was also important that I maintained detailed notetaking throughout my rigorous search process so that I had a written record and history of steps by which I identified each article (Moore et al. 2017; Rapley and Rees, 2018). I searched each database several times using each individual search term, and recorded the articles generated within a detailed chart - one per database - that outlined the publication year, database used, search term used, and the publication's specialty (Appendix C)[19]. After each round of searching, I compared these charts for possible duplicates, eliminated each duplicate, and transferred the remaining information into an Excel sheet recording the number of publications per year according to their specialty (Appendix D)[20]. As I conducted this search in early 2020, only papers published up until 2019 were included.

It was also important in conducting this preliminary research that I developed a clear definition of *medical literature* and an appropriate process for identifying and discriminating between social science and medical literature relating to PCOS. This was to ensure that my search did not incorporate literature from the social sciences, since doing so would detract from my aim of familiarising myself with PCOS-related medical literature and obscure and contaminate the search's value as a foundation on which to decide the scope of my research. The method I developed for distinguishing between medical and social science literature involved looking at the journal home page for the journal in which each article was published and checking whether clinical professionals were listed as the primary audience. Since some journals included clinical professionals but in the context of a long list of audiences including those within social science, it seemed appropriate to categorise these articles as 'interdisciplinary' (but 'social science driven' in contrast to those which are clinical practice/science driven, where clinicians or clinically related science were listed as the

[19] As these charts come to 472 pages in total, I have included a screenshot of each within Appendix C. The full charts are available if requested.

[20] As this Excel sheet is 59 KB in size and it is not possible to include it in full within this thesis, I have included a screenshot of part of the Excel sheet in Appendix D. The full document is available if requested.

primary target audience). After filtering out the *interdisciplinary* and *social-science literature* on PCOS, the remaining literature was already categorised by the search engines into certain medical specialties - these were urology, obstetrics and gynaecology, psychiatry, women's health, general practice, reproductive medicine, clinical research, paediatrics, and clinical research. I identified and incorporated all PCOS-related literature that had been categorised by the search engines as belonging within these major medical specialties into a large sampling frame. Below, I outline the broad trends in PCOS-related medical literature that I identified through this preliminary research and then move on to discuss the methodological decisions I came to as a result.

3.3.2. Key trends in publication activity

By recording the information outlined above as meticulously as possible and creating a range of statistical graphs for comparing different components of the sampling frame (Appendix E, F, and G), I developed a clear, visual representation of the very wide scope of medical literature relating to PCOS. This enabled me to identify exactly how many different types and numbers of medical specialties were publishing on PCOS and the number of articles published per annum, per specialty, and per journal. I identified the following important trends:

- Over 10,000 medical articles with a substantive focus on PCOS were published between 1935 and 2019.
- The overall rate of medical publications on PCOS increased consistently from 1935.
- There was a particular surge in publications from 2001 onwards.
- 46 different medical specialties ranging from urology to military medicine published on PCOS between 1935 and 2019.
- OG was the most active and dominant medical specialty within the PCOS-related medical literature.
- Between 2001 and 2019, there was a dramatic increase in the number of PCOS publications being generated within OG.

This extensive publication activity across medical journal literature as a whole and its exponential increase over time suggested that PCOS as a research area had acquired a status of significant priority or even urgency within medicine, particularly over the last two decades. Since 2001, medical scholars and researchers across different medical specialties

have invested increasing amounts of time and resources into researching and publishing on different aspects of PCOS (Jan et al. 2017). Given that PCOS has been the subject of clinical research and medical publications since 1935, I interpreted this more recent dramatic growth in publication activity to indicate that a period of significant change was unfolding within medical research into PCOS.

Through scanning the texts identified during my preliminary research, I also became aware of some specific developments that took place within this period; these included the 2003 Rotterdam Conference during which new diagnostic criteria were developed and introduced and the later refinement of these criteria by the Androgen Excess Society (AES) in 2006. These developments supported my interpretation of this period as an important time of change and potential instability in the social construction of PCOS as a diagnostic category. Exploring the reasons behind these changes and apparently unanswered questions within the dataset seemed likely to expose a promising number of important stories which could collectively inform a sociology of knowledge around the PCOS diagnostic category, consistent with my aim of addressing its absence within existing social scientific literature. On the basis of the above trends, I concluded that the medical knowledge within this dataset was ripe for a sociology of scientific knowledge analysis, and I came to a number of specific methodological decisions about my research. These are outlined in more detail in the sections below.

3.3.3. Adopting a sociohistorical documentary-based approach

Given the change in the amount of publication activity that took place between 1935 and 2019 and what Bowker and Star (2000) demonstrate to be the sociological importance of understanding the historical processes by which specific classifications develop, a sociohistorical documentary analysis of PCOS-related medical literature represented the most effective research design for this study. To develop a nuanced understanding of the processes by which the contemporary definition for PCOS developed and to lay down foundations for future more integrated analyses exploring the relations between the PCOS diagnosis and lived experiences of PCOS, it was essential to first explore and explain why and how PCOS-publication rates increased so dramatically at specific sociohistorical points. As Rapley (2018: 9) explains, analysing a collection of texts published over a particular time period can offer insight into how ‘practices and identities emerge, transform and mutate’, as well as how particular ‘“styles of thought” … emerge, consolidate and compete across and

between texts'. Within SSK, unlike the majority of mainstream sociological research, there is a well-established tradition of case study-oriented, sociohistorical research. The Strong Programme in particular, has placed great emphasis on the historical contingency of scientific knowledge and is committed to the analysis of historical scientific controversies (Rees, 2019). Given, as outlined in the literature review chapter, the relevance and applicability of SSK concepts for conducting a sociological analysis of diagnosis, my decision to adopt a sociohistorical approach to this research also firmly aligned with my research questions and conceptual framework.

3.3.4. The PCOS diagnostic category: an intrinsically interesting case

Through engaging in the preliminary research outlined above, I also developed an awareness of three particular features of the PCOS diagnostic category that I considered to represent exaggerated manifestations of more typical components of diagnostic categories. The first of these concerns the central focus that has been assumed by the PCOS diagnostic category in medical literature and debate. PCOS has been the subject of extensive publication activity in medicine, as well as multiple name changes, physiologic explanations, diagnostic criteria, and consensus conferences (Azziz and Adashi, 2016). In this sense it is an ample case for exploring contentious diagnostic categories and the role played by medical experts' competing viewpoints in the evolution of such categories over time. The second of these concerns the association between PCOS and a very divergent collection of symptoms. Some of these symptoms have been included as core diagnostic criteria within various iterations of the PCOS diagnostic category. Others, however, are widely acknowledged in medical literature or reported by participants in social scientific studies of PCOS lived experiences but are not considered diagnostic indicators for PCOS. This makes the PCOS diagnostic category an ideal case for exploring the reasons and sociohistorical processes by which particular features of a condition come to be framed as more medically significant or more appropriate as diagnostic indicators than others. Thirdly, and as outlined in the previous chapter, PCOS is a condition that is experienced in highly gendered ways; this makes it an important case study for examining the intersections between diagnostic categories and wider expectations and experiences of gender.

It was on these grounds that I identified the PCOS diagnostic category as suited to an *intrinsic case study approach* (Stake, 1995). This involves selecting a particular case on account of an 'intrinsic interest in the case itself', its 'particularity', and its 'uniqueness'

(Simons, 2009: 30; 14). The principal aim of the intrinsic case study approach is to explore a particular case in depth and in detail with a view to using its idiosyncrasies as analytic devices for exploring elements of social life which might be underdeveloped in existing research (Simons, 2009; Stake, 1995). Medical phenomena are particularly suited to this kind of study since, as outlined by Löwy (1988: 133-134), they embody both 'individual and social significance'; they are significant for the individuals who experience and interact with them directly, but also for society as a whole and its understandings of normativity and deviance. By exploring the idiosyncratic elements of the PCOS diagnostic category in detail, it has been possible for this research to bring into heightened focus wider trends in medicalisation and the social construction of medical knowledge that take place beyond the boundaries of the diagnostic category, but which may be less visible in other less particular medical phenomena. This is a realistic aim for intrinsic case study research in general since, as Simons (2009: 29) argues, 'studying the particular in depth can yield insights of universal significance', and as suggested by Stake (1995: 4), 'often an unusual case helps illustrate matters we overlook in typical cases'.

Case study research can be qualitative or quantitative, but a particular feature of qualitative case study research is its emphasis on 'interpretation in context' (Simons, 2009: 14). In the context of documentary case study research, this not only involves noting a document's objective features and content - such as its publication date or authorship - but also paying attention to its underlying meanings (Stake, 1995). Although some quantitative methods were necessary in the early stages of my research for acquiring an overview into PCOS-related publication trends, employing a quantitative approach to the research as a whole would not have allowed for a sufficiently nuanced understanding of PCOS's development as a diagnostic category over time. Taking into account the plethora of social meanings that pervade the PCOS diagnostic category - evident in the extensive medical literature and discussion which surrounds it, alongside its pronounced implications for individual identity and quality of life - I have adopted a largely qualitative case study approach to this study. This has enabled me to develop a thorough understanding of the specific contexts in which PCOS has been constructed and discussed in medical literature and to pay careful attention to specificities in the use of language and terminology by different medical experts, alongside changes in these practices over time. It has also meant that, as new meanings or issues became apparent over the course of my research, I have been able to adapt the

themes and focus of my research accordingly. This in itself has facilitated an even greater understanding of the PCOS diagnostic category and has meant that, in accordance with the central principles of qualitative case study research, my research has been a highly iterative process (Stake, 1995).

The depth of analysis and immersion in the data involved in conducting qualitative, intrinsic case study research has enabled me to pay nuanced attention to the specific sociohistorical contingencies, processes, networks, actors, and meanings that lie behind each component of the PCOS diagnostic category. As a result, my study provides a valuable starting point for addressing the absence within existing social scientific literature on PCOS, of any detailed consideration of the diagnostic category's role in shaping PCOS experiences. Simultaneously, it brings into sharper focus the wider contextual factors that have shaped the construction of the category over time and that play a role in shaping medical knowledge construction more broadly (Simons, 2009).

3.4. Controversy as Method

The onset of an expansive controversy within the field of OG-PCOS research over the issue of PCOS diagnostic criteria further signified the heuristic value of the PCOS diagnostic category as an individual case for sociological analysis (Rees, 2009; Rees, 2019). Scientific controversies in general offer a unique 'window' into processes of scientific and medical knowledge construction (Rees, 2009: 5) and have long been central to the methodologies of sociologists of science and the Strong Programme in particular (Rees, 2019). This is because, in moments of 'transition' and 'disagreement' in science and medicine exaggerated focus is placed on the underdetermined nature of scientific and medical evidence (Rees, 2009; Rees, 2019). In these instances, evidence becomes central to disputes between experts of opposing perspectives and heightened attention is brought to the fundamental limitations of scientific evidence in generating conclusive answers in the face of differing interpretations (Rees, 2019). As a result, it becomes possible to engage in a more nuanced analysis of 'the complex negotiations and social influences' that are necessary in generating consensus over contentious knowledge (Rees, 2015: 3) and the extent to which, highly dependent on the contingencies which unfold over the course of a controversy, 'current scientific knowledge might have been otherwise' (Rees, 2019: no page number).

In the case of the PCOS diagnostic category, it was the trends identified during my preliminary research that signified that a state of controversy had unfolded in the field of

OG-PCOS research. This was largely because of the dramatic surge in literature and developing corpus of texts in the field and the existence of consensus conferences which, as outlined above, signified that OG continued to face challenges in developing a consensus over medical explanations for PCOS and found itself in a state of disciplinary crisis. On delving more deeply into the literature during the sampling and analysis stages of my research, I also became aware of an extensive series of exchanges - in the form of published letters and articles directly addressing competing viewpoints - that took place over several years between OG-PCOS experts of opposing positions on the issue of PCOS diagnostic criteria and which continuously debated the existing evidence base regarding PCOS and its physiological features and aetiology. These exchanges strengthened and supported my interpretation of OG-PCOS research as a field consumed by a state of scientific controversy.

Rees (2009: 10), in her examination of a controversy that unfolded within the field of primatology from the 1970s onwards around the issue of primate infanticide (the killing of infants by adult primates), identifies three milestone events around which 'dissent and impassioned disagreement' developed in the field. These involved the application by some primatological researchers of a contentious concept in their interpretation of field research, their publication and extension of these concepts to human activity, and the increasing dissemination of these ideas to a wider audience beyond the boundaries of primatology. Much like the trends described above, such events were accompanied by a tidal wave of publication and research activity over the issue of primate infanticide and the development of questions over which kind of evidence could be considered valid in resolving the debate, as well as a range of 'dramatically dissimilar definitions' of primate social structure (Rees, 2009: 12). They signified to Rees (2009) that a significant shift had taken place in the mood, ambition, and motivations of primatological researchers who became engaged in multiple decades of debate over the reasons behind primate infanticide. A similar shift in the emotional, social, and political context of discussions around PCOS was evident in the post-2001 literature included in my sampling frame, and it was on these grounds that I adopted an SSK-informed approach to the study of controversies as a key method of my research.

By 2019, the final year of medical literature reviewed in my preliminary research, PCOS-related publication and consensus conference activity, and the dialogues taking place between OG-PCOS experts, showed no signs of abating. This suggested that the controversy over PCOS diagnostic criteria remained active and open-ended. As a result, the methods I

adopted to examine the controversy were specific to its status as ongoing and unresolved. Rees (2009: 5) identifies two main 'choices' open to researchers of controversies - the choice to study past controversies which are already resolved, and the choice to study enduring controversies relating to issues which are 'still under debate'. My choice to study the latter, presented a number of opportunities and risks unique to the study of ongoing controversies. For Collins (1975; 1981), whose study of the 1970s controversy over gravitational radiation was conducted while the controversy was still taking place, 'it is only by examining scientific controversies while they are in progress that the mechanism by which ships (scientific findings) get into bottles (validity) can be understood' (Collins, 1981: 45[21]). Without examining this process as it happens, it is easy to assume that established scientific knowledge has always been accepted and that the evidence behind it was never disputed or open to negotiation (Collins, 1981). By extension, it becomes difficult to identify the minutiae of the social processes by which scientific knowledge came to be defined as established; this is minutiae which are vitally important for understanding the sociality and complexity of science.

Despite the opportunities presented to researchers of ongoing controversies, it is essential to also be aware of the risks involved in such an undertaking and, as Rees (2009) exemplifies in her own study, to be explicit about one's own intentions as a researcher. The contentiousness of PCOS as an area of medical knowledge, alongside what has been evidenced to be its profoundly disruptive impact on the lives of many women diagnosed and living with PCOS, means that PCOS is a sensitive and emotionally provocative research area. It is important in conducting my own sociological examination of the PCOS controversy, that I am explicit that my interest is not in intervening in the controversy or commenting on the validity or morality of any of the claims made by experts engaged in it. Instead, I am concerned with developing original sociological knowledge from the unique insights that exploring such a controversy can offer into the social construction of contentious diagnostic categories. To do this, I have adopted the principles of 'impartiality' and 'symmetry' in using controversy as a method (Bloor, 1991: 7). This has involved examining all the claims made and evidence presented within the literature without any consideration of their 'truth or falsity'; instead, my sole intention has been to analyse how evidence has been used to

[21] Of course, adherents to SSK challenge this view given their long tradition of employing historical case studies to understand the resolution of scientific controversies.

construct particular knowledge claims and the implications of this for the social construction of the PCOS diagnostic category.

3.5. Conducting a Documentary Analysis

Conducting a sociohistorical documentary analysis of such an expansive body of medical literature required making a number of decisions about the specific focus and scale of my study. To ensure that my sample of documents was sufficiently robust, capable of addressing my research questions and of providing foundations for formulating valid and reliable conclusions about trends in medical knowledge construction, in advance of the sampling process I developed a clear framework of reasons and criteria for deciding which documents to include in my sample (Prior, 2003). In the sections below, I first discuss the mechanisms I put in place to ensure I maintained reflexivity throughout the sampling (and later analysis) process. This was so that my immersion in the data did not unduly influence my ability to identify important texts and meanings that were of central importance to my research questions. I then outline the decisions and steps I took to develop a manageable but intrinsically interesting and representative sample of PCOS-related medical literature, one which enabled me to explore the sociohistorical meanings and reasons behind the trends outlined above and to achieve an appropriate level of sample saturation (Rapley and Rees, 2018).

3.5.1. Maintaining reflexivity

Throughout the sampling process I kept a careful record of each decision I made regarding the inclusion or exclusion of a particular article from my sample, as well as noting down any emerging stories and trends, key actors, and apparent gaps within the sample. The degree to which I became immersed in the literature throughout the sampling process - something I knew could distort my perspective and make it difficult to take a step back (Rapley, 2018) - meant that maintaining a reflexive approach was vitally important. Schwandt (2007: 261) defines reflexivity as a 'process of critical self-reflection on one's bias, theoretical predispositions, preferences'. In Rapley's (2018) guide to different analytic practices he advises his readers that, regardless of their research method, they should 'be reflexive about (their) own practices' and 'critically reflect on how (they) have rendered a specific version of the world' (Rapley, 2018: 144, brackets added). Both Schwandt's (2007) and Rapley's (2018) definitions of reflexivity have been helpful in guiding my own adoption and development of

a reflexive approach to sampling; this was an approach I continued to maintain during the analysis stages of my research.

Given my personal experiences of PCOS, entering the sampling and analysis research stages without some kinds of pre-existing assumptions or expectations about what the data might contain was infeasible and unavoidable. Ensuring that these assumptions were identified though, put to one side, and prevented from unduly shaping my sampling and analytical decisions could be managed through engaging in critical self-reflection regarding each of my research practices and decisions. I devised two main strategies for maintaining this critical self-reflection throughout the sampling and later analysis stages:

1) using writing as a key reflexive activity
2) discussing my analytic interpretations with my supervisors.

My reflexive writing largely took the form of written reflections which I stored within my University's digital portfolio site (initially, Eportfolio and later NUReflect), as well as detailed meeting notes outlining the discussions and decisions I made during regular supervision meetings. These written reflections and supervision notes were only visible to myself and my supervisors, and I also often raised and discussed my written reflections with my supervisors during supervision meetings. I also shared my indexing decisions and analytic interpretations with my supervisors through Microsoft Access. Recording and writing down my reflections, thoughts, and decisions, and discussing these with my supervisors, helped me to identify any potential bias or misinterpretation in my reading of the data (Prior, 2003). It also increased the transparency of my decision-making and provided a helpful reminder of the grounds on which I made each decision. These related to the initial criteria I developed for selecting my sample, my application of this criteria to each specific document, and the interpretations of the data I developed during the analysis process (Prior, 2003).

Writing is an intrinsically important research activity that is beneficial not just as a record of a researcher's decisions and interpretations but also as an aid for analysing the data, helping to shape and nurture the analytical and thinking process (Moore et al. 2017). This was the case in terms of my own reflexive writing practices. During the sampling stage of the research, not only did I use my writing activities to reflect on theory, literature, and decision-making, but also to identify what appeared in my dataset to be important emerging networks of actors, key individual actors, and specific key moments in the ongoing

development of PCOS as a diagnostic category. Many of these reflections gradually developed over the course of my research into the key analytic themes and findings that are discussed in the analysis chapters of this thesis. In the sections below, I draw on a number of my written reflections to illustrate the nature of the decision-making I undertook throughout the sampling and analysis stages of my research.

3.5.2. Sampling

I had originally planned to incorporate extracts from medical textbooks *and* articles from medical journals within my sample. This was on the basis that both source types offer rich insight into the processes by which assumptions regarding medical issues become transformed into accepted medical knowledge (Rees, 2019). However, as outlined above, the broad searching process I conducted during my preliminary research revealed a much larger quantity of data available than I had previously anticipated. Given the focus of this research on the sociality of medical knowledge, as well as the relative inaccessibility of medical textbook extracts in contrast to journal articles, I identified medical journal articles as offering the richest platform for examining the playing out of PCOS-related controversies and debates and for tracing the evolution of 'open questions' into more accepted strands of established medical consensus (Rangel et al. 2017).

As outlined earlier in this chapter, OG maintained an overwhelming dominance within medical literature on PCOS between 1935 and 2019 and assumed a leading role in the dramatic surge that took place in PCOS-publication activity between 2001 and 2019. It was for this reason that focusing my sample specifically on OG papers, rather than analysing PCOS-related medical literature more generally, enabled me to develop an in-depth understanding of the leading and most dominant forces that have shaped contemporary definitions of PCOS. This was important for laying down a solid knowledge foundation from which the importance of the PCOS diagnostic category in shaping PCOS experiences could be explored in future research. Regarding my sample's specific sociohistorical focus, my final sample includes OG papers published between 1974 and 2019. Including a small body of papers published between 1974 and 2000[22] enabled me to develop an understanding of the sociohistorical context and key contributing factors behind some of the more dramatic changes that took place in the field within the post-2001 literature. I decided on 1974 as the

[22] These papers were not selected during my initial random sampling phase, but in a later phase of the sampling in which I aimed to achieve sample saturation. This is explained in more detail later in the chapter.

start date for my sample, because this marked the onset of a period of significant advancements within ultrasound technology which were of relevance for the field of OG-PCOS research. It also enabled me to explore important changes in the nature of evidence and arguments presented in the literature during this time, as well as a landmark consensus conference held in 1990. The latter time frame of my sample - papers published between 2001 and 2019 - enabled me to explore in detail the surge in publication activity that occurred from 2001 onwards and the various specific milestone developments in OG's deliberation and definition of the PCOS diagnostic category that took place in this period.

My search identified a total of 3175 OG articles relating to PCOS published between 2001 and 2019. I reduced this number to a smaller sample of 300 articles (approximately 10% of the original sample) using the Google Random Generator tool. Using a random selection method such as this one for sampling papers from an extensive sampling frame is an approach advocated by Prior (2003) on the grounds that it provides a helpful deterrent against an overly biased selection process in favour of documents which fit a researcher's pre-existing assumptions or arguments. This sample size was, however, still too great for the scale of this study. By reviewing existing documentary analyses of diagnostic categories and following expert guidance on recommended strategies for conducting sociological documentary research (Rapley, 2016; Rapley, 2018; Rapley and Rees, 2018; Ritchie and Lewis, 2003; Scott, 1990), I decided on a target sample size of approximately 150 articles. Both Rasmussen's (2020) and Carlin and Kramer's (2020) studies engage in in-depth analyses of the representation of particular diagnostic categories (MUS - medically unexplained symptoms - and PCOS) within a body of influential, highly cited but not exhaustive medical articles; they explore samples of 107 and 61 papers respectively. Aiming for a similar but slightly larger target sample size seemed a sensible strategy for ensuring that my own sample contained sufficient representation of important and influential papers within the field, without setting a target figure which was overambitious within the scope of this study.

3.5.3. Surface level familiarisation

To reach a more manageable sample size, I engaged in a period of careful, documented decision-making (Rapley and Rees, 2018). Rather than continuing with the random selection process advocated by Prior (2003), at this stage in refining my sample and given the expansive range of issues addressed by PCOS-related literature even within OG alone, a level of familiarity was now required in selecting a sample of documents that would enable me to

adequately address my research questions. As Prior (2003) acknowledges in relation to random sampling selection, 'it is often the case that there are sound reasons for side-stepping such requirements', and 'there might be good reasons for selecting only certain kinds of document or certain kinds of event where documents come into play' (Prior, 2003: 154). My ambition to use controversy as a method for exploring the social construction of the PCOS diagnostic category meant it was essential that my sample did not omit any key actors, networks, or developments which had been integral to the playing out of this controversy. It was on these grounds that I developed a sample that was sufficiently representative that it encapsulated PCOS-knowledge trends taking place in OG as a whole, but which also acknowledged the intrinsic particularity of certain documents in order to ensure that milestone developments in these trends were not omitted from my analysis.

In refining my sample according to these principles, I began with a process of surface level familiarisation; this involved reading all 300 article abstracts and undertaking preliminary coding. As part of this process, I jotted down apparent themes in the dataset, viewing these not as potential themes for the analysis stage of the research but as a useful guide for narrowing down my sample (Rapley and Rees, 2018). I also developed a fuller and more complete idea of potential key stories and actors within the dataset. I used the broad themes I identified to organise the articles into thematic 'cluster' folders, which I stored within Microsoft Access. Many of the articles were allocated to two or more folders (as well as subfolders) because of their reflection of more than one theme. The folders included:

- Apparent key actors
- Articles challenging established narratives
- Articles from special issues
- Articles highlighting gaps in PCOS knowledge
- Articles that put forward particular symptoms and particular 'types' of PCOS
- Articles that offered either particularly conventional or particularly unconventional definitions of PCOS.

3.5.4. Evaluating each document

I followed my 'surface level familiarisation' stage of sampling with another stage of reading, engaging this time with each article in its entirety to evaluate its validity and reliability as evidence (Prior, 2003). Reliability in qualitative social science research relates to the extent

to which its findings are 'independent of the particular circumstances in which the research was carried out', while validity refers to 'whether the research findings are actually providing appropriate and valid evidence for the claims being made by the researcher' (Prior, 2003: 149). Both validity and reliability are central tenets on which the quality of evidence within the social sciences is assessed, but establishing what counts as '"good", reliable and well-validated evidence' is a far from straightforward or objective process (Prior, 2003: 148). As Prior (2003: 148) points out, the interpretation of evidence is 'always open to social negotiation'. This is a perspective also conveyed by the Duhem-Quine thesis outlined in the previous chapter and its emphasis on the underdetermined nature of evidence by theory (Duhem, 1954; Quine, 1963). Taking into account the difficulties involved in ascertaining the reliability and validity of documents, I carefully selected a framework of criteria for evaluating my remaining 300 documents - the criteria developed by Scott (1990) for assessing documentary sources (Figure 1.) - and for refining them into a smaller target size of 150 documents. This was an approach I considered to be suited to the demands and nature of my research and its concern with developing a representative sample, as well as to the importance of paying careful attention to the meanings and context of each document.

Scott's (1990) criteria	Definition
1. Authenticity	The degree to which each document 'is actually what it purports to be' (Scott, 1990: 19).
2. Credibility	The 'sincerity' and 'accuracy' of a document (Scott, 1990: 22) - the extent to which it contains distorted, untrue, or inaccurate information.
3. Representativeness	The 'survival' and 'availability' of documents within the target population as a whole, in order to ascertain the extent to which each individual document is 'representative of the totality of relevant documents' (Scott, 1990: 24).
4. Meaning	4a) The literal meaning of a document - the specific way in which an author intended the document to be understood at 'face value', using terminology common at the time of publication (Scott, 1990: 30). 4b) The interpretive meaning of a document - the meaning of the document as a whole in the context in which it was produced (Scott, 1990).

Figure 1. Criteria for evaluating documents adapted from Scott (1990: 19-30)

In the sections below, I explain the considerations I took into account in applying each of these criteria. I begin by discussing authenticity and credibility as criteria alongside one another because I found that in the context of medical journal papers, these criteria closely inform one another. I follow this by discussing my assessment of the literal and interpretive meaning of each document, before reflecting on my assessment of their representativeness; this is a discussion I build on later in the chapter when outlining the steps I took to construct the appropriate quotas for my sample.

3.5.5. Assessing authenticity and credibility

As outlined in my literature review chapter, the rhetorical strategies employed by actors engaged in a controversy play an integral role in demarcating the boundaries of scientific knowledge and are thus of intrinsic interest within this particular study. It was because of this analytical focus that I considered any doubts I had over the sincerity or accuracy of content contained within a particular medical journal article to be grounds, not for its exclusion from my research example but instead, for including it and engaging in a careful, detailed analysis. A number of documents were included in my sample on this basis. For instance, I interpreted a series of papers containing exchanges between leading experts involved in the controversy and which presented opposing opinions and multiple contradictions relating to PCOS and the evidence surrounding it (Azziz, 2004; Azziz, 2005; Azziz, 2006a; Azziz, 2006b; Balen et al. 2009; Franks, 2006; Dewailly, 2006), as suggestive of at least some degree of insincerity or inaccuracy involved in their publication. My ambition to examine the sociality of the PCOS diagnostic category meant that the inclusion of these papers within my sample was essential in addressing the central question of my research.

Assessing a document's authenticity also involved reflecting on each document's authorship - particularly the authors' names and the date and location of publication - and ensuring there were no errors or inaccuracies (Scott, 1990). These were really important details to pay attention to because they offered insight into the document's broader context and the author's professional background. I also used the names of the authors (particularly lead authors and those I identified as apparent key actors within the dataset as a whole) to find out about any wider professional networks they belonged to and other documents or research they had been involved with. An example of this is provided in the written reflection I made during my sampling process in December 2020, under the heading of 'Key actors and networks':

> ***Ricardo Azziz***
>
> *Ricardo Azziz is proving to be a very key actor in the PCOS debates, particularly ones around the controversial Rotterdam criteria introduced in 2003.*
>
> *He was on the editorial board for Fertility and Sterility between 1999 and 2002 and on the editorial advisory board between 2002 and 2007.*
>
> *He was also on the editorial board for Journal of Clinical Endocrinology and Metabolism between 1993 and 1996 and between 2005 and 2008.*

He is a member of many other committees, boards, and associations, and has had an abundance of high-ranking professional appointments. See CV for detail.

A 2007 workshop group (discussed in article 40, 2008)

This was a Thessaloniki ESHRE[23]/ASRM[24]-Sponsored PCOS Consensus Workshop Group March 2–3, 2007, and involved a number of very INFLUENTIAL ACTORS within the PCOS literature – Basil Tarlatzis, Bart Fauser, Richard Legro, Stephen Franks, Rogerio Lobo, Ricardo Azziz (and other names I don't recognise).

The group was supported by an unconditional grant from NV Organon and by ESHRE and ASRM.

Consensus documents

I am finding that CONSENSUS DOCUMENTS are a particularly helpful way of identifying and tracing important networks. These are the reports arising out of consensus workshops and conferences and detail the agreements/consensuses arrived at by leading experts in the field. One such document in my sample is Article 40, a consensus document arising out of the 2007 ESHRE/ASRM sponsored Thessaloniki workshop group.

The reflection contained in the extract above, which identifies Azziz as a potential key actor in OG-PCOS research and consensus documents as particularly useful texts for tracing key networks in the field, demonstrates an important strand of the decision-making and evaluative processes I engaged with in compiling my sample. Through identifying these elements of the authorship and document type of particular publications as having been integral to the social construction of the PCOS diagnostic category, I developed a robust rationale for their inclusion within my sample. These were reflections that gradually evolved into key focal points of my analysis and so are also testament to the iterative nature of my research and the role played by my written reflections in shaping my interpretation and analysis over the course of the study.

3.5.6. Assessing meaning

To ascertain the literal meanings of each document, I engaged in some additional work to ensure I understood the scientific methodology behind the arguments and findings presented. In particular, I consulted two different medical dictionaries - Martin (2010) and Zink (2011) - so that I could acquire an accurate definition and understanding of any scientific concept or phenomenon I was unfamiliar with. I also consulted other relevant journal articles and textbooks to inform my understanding. Since my sample included

[23] European Society of Human Reproduction and Embryology.
[24] American Society for Reproductive Medicine.

documents published over a 45-year-time-period, I also paid careful attention to time-dependent differences in the operationalisation and application of particular medical terms and concepts. As Scott (1990: 30) points out, 'the particular way in which a concept was defined and applied in practice changes over time from place to place, and the researcher must discover as much as possible about these changes'. This was true of the varying ways in which PCO morphology was defined over the course of the controversy. Not only did the definition become increasingly refined and specific and the subject of extensive debate, but some researchers avoided the term altogether. Carmina et al. (1997) for instance, opted to refer to 'polycystic appearing ovaries' rather than PCO morphology[25]. Differences in the definitions and terminology used to discuss particular features of PCOS were of intrinsic interest to my research and so I selected some papers on this basis (Adams et al. 1985; ESHRE/ASRM, 2004; Swanson et al. 1981). Analysing these papers enabled me to develop an understanding of the role played by scientific terminology in the rhetorical strategies medical experts engaged in while navigating the controversy, as well as of the specific social and cultural contingencies which shaped how particular elements of PCOS were defined and discussed.

To establish the interpretive meaning of individual documents, I paid careful attention to the wider contexts in which they were produced and whether I had identified the author(s) of each article as belonging to any particular network. This enabled me to ascertain a possible motivation behind the publication of each document and to decide whether this motivation may have been directly related to the controversy. A number of papers were included within my sample along these grounds, particularly those by key actors such as Azziz, Dewailly, and Franks, and by the organisations they were active members of, such as the AES and European Society of Endocrinology (ESE). In selecting my sample, I also took into account the timing of particular consensus conferences. As discussed in the previous chapter, a consensus document is often produced under the pressure of a particular time limit or of enabling or feigning consensus (Solomon, 2011; Van Bouwel and Van Oudheusden, 2017). Sampling and analysing these documents seemed likely to offer further important insight into the sociality of the PCOS diagnostic category and the social processes by which it has been constructed. I also took care to include in my sample, those papers that were clearly

[25] The reasons for Carmina et al.'s (1997) choice of terminology are explored in Chapter 5.

written in direct opposition to the decisions made at consensus conferences. This enabled me to further explore the role of controversy and disagreement in shaping the PCOS diagnostic category, as well as the implications of the decisions made at consensus conferences for the rest of the field.

3.5.7. Assessing representativeness

Having already identified a number of key themes, actors, and stories through my earlier 'surface level familiarisation' with the dataset, on entering into this more in-depth and evaluative stage of sampling I was able to ascertain the extent to which the themes and authors of each paper were representative of the dataset as a whole. Any paper that was authored by an actor I had identified as a leading figure within the field or that contained a theme that appeared to be central to the controversy - relating for example, to the issue of the validity of PCO morphology as a diagnostic criterion for PCOS - were included in my sample on account of their representativeness of key features of the dataset. In October 2020, I wrote the following reflection:

> *During the surface level familiarisation and 'clustering' process, two authors of journal articles - Richard S. Legro, M.D., and Ricardo Azziz, M.D., M.P.H., M.B.A - had been identified as potential 'key actors' on the basis of the sheer number of publications they had authored or co-authored with other researchers, as well as on the basis that both had written a number of introductions to special issues. After establishing that all of the articles allocated within the 'key actors' cluster folder were selected for inclusion within the refined sample, I was satisfied that these two authors had been sufficiently represented.*

Including a sufficient number of papers from Legro and Azziz within my sample helped to ensure it was representative of both experts' extensive publication activity on PCOS between 2001 and 2019.

However, not all the papers included in my more refined sample were selected on the basis of their representativeness. In tracing the socio-history of the PCOS diagnostic category as robustly as possible, it was important that individual publications - which were integral to, or reflected important developments in, the construction of the diagnostic category - were not omitted from my sample. In many instances it was my awareness of the uniqueness or particularity of such documents that led me to include them in the sample. In particular, the 2004 Rotterdam report (ESHRE/ASRM, 2004), the 2008 Thessaloniki ESHRE/ASRM report (Thessaloniki ESHRE/ASRM-Sponsored PCOS Consensus Workshop Group, 2008), and the

2018 international evidence-based guideline for PCOS (Teede et al. 2018), all stood out during this stage of the sampling because of the key milestones they appeared to represent within the sample population as a whole. These documents were unrepresentative of the larger dataset in that they contained landmark decisions, recommendations, and commentary that carried the potential to change the landscape of OG-PCOS research as a whole. Each one represented a break from the continuing and somewhat circular nature of the dialogue and discussion over PCOS diagnostic criteria that epitomised much of the controversy. As Scott (1990: 24) argues, it is always necessary for a researcher to acquire awareness of, and to acknowledge, 'to what extent and in what respects those documents are unrepresentative'. In this instance, it was my awareness of the relative unrepresentativeness of particular papers that enabled me to identify them as integral to the social construction of the PCOS diagnostic category over time. Had these papers been representative of the sample as a whole, they would not have contained the uniqueness and richness of data that had made them so intrinsic to the evolution of PCOS as a diagnostic category.

Although the search strategies used to generate my target sample of 150 articles were extensive, they were by no means exhaustive. I kept in mind throughout my analysis that a minority of important articles may have been overlooked. Since the study aims to examine trends and changes over time in the evolution of the diagnostic category, seeking out documents that were illustrative of a general change within the literature was crucial. Also crucial, was the identification of key, stand-out moments throughout the condition's history that may have triggered or partly triggered this broader change. It was possible that particular articles, or a group of articles by a particular author - not previously identified in the initial search and sampling strategies - offered important insight into key moments in the development of the diagnostic category. In these instances, I was prepared to amend the sample, either by returning to my initial sample list to identify potentially stand-out articles or to bring new articles into the sample altogether; this was in order for the sample to develop a degree of sample saturation (Rapley and Rees, 2018).

As recorded in a written reflection I made on 10th November 2020:

> *A key article not in my sample has come to my attention - Azziz R. Diagnostic criteria for polycystic ovary syndrome: a reappraisal. Fertil Steril 2005; 83: 1343–6.*
>
> *This will now be included in my sample for the following reasons:*

- *It provides the earliest explicit discussion of diagnosis out of any of the other articles in my sample.*
- *It is by Azziz, editor of Fertility and Sterility and a key actor so far in the PCOS literature.*
- *One article already in my sample is a reply to a letter about this 2005 article in question.*

Other articles by Azziz around PCOS diagnosis were also published in 2006 and not all are included in the sample. They may need to be added to ensure data saturation.

E.g. Azziz 2006 - CONTROVERSY IN CLINICAL ENDOCRINOLOGY Diagnosis of Polycystic Ovarian Syndrome: The Rotterdam Criteria Are Premature.

Another key article, of a similar name to the above but in defence of the Rotterdam Criteria was also published in 2006 and is by Stephen Franks (another key actor). It should therefore also be added to the sample to further achieve data saturation and because it is a key part of this debate.

Franks' article is:

- *Franks, S. (2006) Controversy in clinical endocrinology: diagnosis of polycystic ovarian syndrome: in defense of the Rotterdam criteria. J Clin EndocrinolMetab 2006; 91: 786–789.*

Further justification for including this article as an addition to my sample was provided on 13th November 2020, when reading Article 40 (2008) - the consensus document which arose out of a 2007 ESHRE/ARSM consensus workshop group. Franks' (2006) paper was identified in this article as providing a key discussion of the advantages and disadvantages of the 2003 Rotterdam criteria.

The above written reflection is just one example of the kinds of thoughts and findings that led me to include additional articles in my sample in a bid to achieve *sample saturation*. Doing so ensured that papers that were of intrinsic interest to my research on account of its central research questions were not overlooked in my analysis. Through this process, I incorporated a small number of papers published outside of OG, predominately from within reproductive endocrinology. Reproductive endocrinology was originally established as a 'subspecialty of obstetrics and gynecology' (Barnhart and DeCherney, 2015: 24). In contemporary PCOS-related clinical practice, women most commonly receive specialist medical advice from either obstetricians and gynaecologists or from reproductive endocrinologists (Cussons et al. 2005). Given the close interdisciplinary relationships between reproductive endocrinology and OG, particularly in the context of PCOS, incorporating these papers did not interfere with my ambition to understand significant changes that had occurred in the definition of PCOS over time. As a result of adding

additional articles to my sample to achieve sample saturation, I have a final sample of 184 articles. These can be found in Appendices I and J.

3.5.8. Constructing sample quotas

As well as carefully evaluating each document, as an additional mechanism for ensuring the sample I selected was both representative and intrinsically interesting, I refined my sample in a way that took into account key trends in OG publication activity. I first established the numbers and percentages of publications focusing substantively on PCOS published within OG between 2001 and 2019 (Appendix H). It was then possible to set a quota number of articles that could be selected per year from within the randomly generated sample of 300 article. I calculated these quotas by applying the percentage values to the target number of 150, to determine how many articles could be included in the sample per year. This ensured that my refined sample contained a proportionate number of articles per year relative to the differences in annual publication rates within OG shown in the total population sample. One or two issues arose however when applying these quotas. Although for the most part, the more active years in publication activity were proportionately represented within my sample, some years within my sample did not adhere completely to the allocated quotas or ratios. For 2011 for instance, despite the allocated quota having been 11 articles, there were only ten suitable articles within the randomly generated sample, and so all of these have now been included within the smaller refined sample.

It was clear from these issues that the quotas (Appendix H) I established beforehand needed to be used more as a guidance tool rather than something to be rigorously adhered to. Nonetheless, the numbers of articles I selected did not stray significantly from these quotas and the resulting sample of 150 articles offered an accurate reflection of the differences in the number of articles published within OG per year. Those years in which relatively few articles were published, and which were subsequently allocated a much lower quota - such as 2001, 2002, 2003, 2005 and 2012 - contain a similarly small number of articles within this refined sample. Furthermore, those years with higher numbers of articles published, and which have been allocated a higher quota - such as 2010 and 2011 - also reflect these trends and the quotas given. One additional factor that I needed to consider in refining the sample from 300 articles down to the target number of 150, were the key themes, actors, and trends I identified during my earlier surface familiarisation stage and which I had used to form the organisational cluster folders. It was important that these themes were not

discarded in the process of refining my sample but were instead adequately reflected and played an intrinsic role in shaping it. To ensure this was the case, I undertook a number of searches and checks to ensure that the key themes identified in the early surface familiarisation process were adequately represented within the refined sample.

3.6. Framework Method

Following my familiarisation with and refinement of my sample, I undertook the more in-depth analysis of my material. I considered a number of different factors - the intended primary focus of my analysis, the importance of context in acquiring this focus, my own analytical role as researcher, and practical considerations relating to remote working as a result of Covid-19 - in developing an appropriate and effective analytical approach (Rapley, 2016; Ritchie, Spencer, and O'Connor, 2003). Knowing that some level of remote working would be in place for a significant length of time due to the ongoing Covid-19 pandemic, it was important to consider which kind of online platform could be used for sharing my analysis so that each project supervisor could provide some input. This was also important given the increasing expectation among some journals and reviewers that to increase the transparency of an analysis and reduce the risk of a biased or one-sided interpretation of the data, a qualitative analysis should not be the work of a lone researcher but involve wider input from other researchers (Rapley, 2016; Ritchie and Lewis, 2003). Given the nature of my study, the material being examined, and the overarching questions being addressed, retaining the texts and particular extracts of the texts in as much of their original context as possible was also incredibly important (Moore et al. 2017; Rangel et al. 2017).

Since this documentary study involved analysing literature discussing a truly divergent range of issues and symptoms relating to PCOS, the contextual background to issue presentation was important for developing nuanced understandings that did not misinterpret the information being relayed (Rapley, 2016). I considered that a more computer aided (CAQDAS) approach to analysis was likely to remove key extracts of texts from the original context in which they were written, understood, and displayed, while also obscuring the overall structure of the data (Ritchie and Lewis, 2003). Not only was a CAQDAS approach likely to generate a degree of misinterpretation - with medical terminology and medical issues examined in extracts removed from their wider context - but attempting to gain an understanding of how an article sat within a wider system of controversy, competition, and debate, as well as against the condition's broader history, would not have been possible

through an examination of individual extracts separated from their original texts. It could also have interfered with my ability to pay careful attention to specific ways in which textual information was ordered, something which could offer insight into the implied importance or relations between individual aspects of information (Silverman, 2007).

It was on the grounds of these considerations that I identified framework analysis as the most effective analytical approach for this study. This involved applying a systematic, matrix-based method and being totally immersed in my data (Ritchie, Spencer, and O'Connor, 2003). I systematically revisited my data throughout the framework analysis process but also approached it from 'different levels of abstraction' at each stage (Ritchie, Spencer, and O'Connor, 2003: 220). The framework approach involves always keeping in mind the data in its rawest form so that the researcher never loses touch with its original context (Ritchie, Spencer, and O'Connor, 2003). Framework analysis centres around the use of a thematic framework, which form the rows and columns of a large matrix[26] (*ibid.*). I used my thematic framework to organise and classify the data according to key themes, concepts, and categories. Rather than 'coding' the data, I conducted a process of indexing, developing themes out of the text itself rather than on the basis of pre-existing assumptions, expectations, and wider reading (Ritchie, Spencer, and O'Connor, 2003). As my analysis progressed, I developed and refined each theme and subtheme through my ongoing immersion in and familiarisation with the data. My approach to data analysis was inductive - rather being shaped and framed around preconceived ideas of what the data might contain, all themes and subthemes were developed out of and remained firmly rooted within the data (Ritchie, Spencer, and O'Connor, 2003).

My framework analysis involved four distinct stages (Rapley, 2016; Ritchie, Spencer, and O'Connor, 2003):

1) Constructing an initial list of interesting themes
2) Refining the initial list of interesting themes
3) Creating a thematic framework
4) Indexing.

[26] My matrix takes the form of a large Excel sheet containing multiple cells which I have used to order and organise my data according to the thematic codes which make up my thematic framework.

Having already undergone a process of familiarisation with my data, I conducted another stage of re-reading. During this, I compiled a list of everything interesting and notable within the texts, including possible themes and concepts (Moore et al. 2017; Ritchie, Spencer, and O'Connor, 2003). Conducting this process effectively depended on engaging in a 'close, detailed reading' of each text, while examining it for everything that was 'key, essential, striking, odd, interesting' (Rapley, 2016: 334). At this stage more than any other within the analysis process, it was essential that I maintained an open mind and that I was 'prepared to be led down novel and unexpected paths' (Rapley, 2016: 336). Without this mindset, crucial themes, concepts, and ideas may have been overlooked and obscured.

In December 2020, I recorded the following reflection while constructing this initial list of interesting themes:

> *3 processes by which I'm adding things to the long list:*
>
> 1. *In the early stages, I would see a word or theme that I assumed would be significant and would come up again and again. This was immediately added to the long list.*
> 2. *Occasionally, a theme or word that has appeared once or twice before, appears again, and at this point I recognise that this is a recurring or significant theme - it is therefore added to the long list.*
> 3. *Anomalies - now I have worked through 6 years of articles, I have gained a sense of the typical language used by the authors. Every now and then a word or phrase is used which stands out e.g. the description of women with PCOS as 'healthy' (very rare at this point), an acknowledgement/thanks given to the women who participated in the study (once so far), an acknowledgement of the psychological element of PCOS (once so far in the sample). These items are added to the long list because of their anomalous nature.*
>
>   *A challenge has been deciding how specific or narrow the items added to my long list should be. I am working with an extremely heterogeneous body of literature, despite its focus on a single condition. This means that despite many consistencies in language use and research strategies, there are also significant disparities, and the material also covers a huge range of different issues relating to PCOS. At this point, and following the advice of my supervisors, my long list items are fairly specific (e.g. relating to a specific treatment, PCOS subgroup, perceived risk or coexisting condition) but are still of relevance to the entire dataset.*

This process of list-making was to a large extent intuitive, but also required that I was totally immersed in the data so that potential, underlying patterns could be pursued and identified (Rapley, 2016). I then needed to refine my list by identifying links and overlaps between the items listed and through constructing the themes and subthemes that would form my

thematic framework (Rapley, 2016; Ritchie and Lewis, 2003). To ensure I did not form these links too early, in a way which might restrict or frame other aspects of the analysis and obscure more nuanced dimensions of the text, I made sure that throughout stage one of my framework analysis I withheld from making any 'analytical' or 'explanatory' notes (however preliminary or 'solely for purposes of reflection' these might have been). Instead, I concentrated only on listing words, ideas, and themes that were rooted firmly in the data (Rapley, 2016).

The next stage of my framework analysis involved constructing a thematic framework by grouping existing subthemes and subcategories together to form larger, broad headings. I used numbers and specific terminology reflecting the 'essence' of each theme or subtheme - but also using language which was close to the language used within the texts - to construct and differentiate each heading (Ritchie, Spencer, and O'Connor, 2003: 221). I grouped the framework thematically and organised it into a hierarchy of main themes and subthemes. After constructing my framework - although this was revisited and reshaped throughout (Rapley, 2016) - I could begin the indexing process. This involved returning to each article repeatedly and applying the relevant thematic code to each quote or extract of the article. Rapley (2016: 337) recommends engaging with 'line-by-line coding' - or in this case, indexing - so that the indexing process remains firmly rooted in the data. Adopting this approach, I highlighted and labelled sections of text - words, lines, sentences, paragraphs - using a particular thematic code. Ritchie, Spencer, and O'Connor (2003: 225) point out that 'labelling at this stage is intended only as a first step in sorting the data for later retrieval', and that there will be more opportunities later to add or refine categories to the developing thematic framework. Nonetheless, once I had conducted a first round of indexing, I inserted particular extracts and quotes into the relevant rows and columns of my matrix. This in itself allowed for further refinement of the categories and the identification of potential links and overlaps. As part of this indexing process, it was useful to pay renewed attention to the articles' authorship, as well as their possible contributions - individual or collective - towards efforts focused on building consensus around the PCOS diagnosis. It was also important to again consider the professional backgrounds of each key author and whether there was

evidence of any developing networks or relations between them. A screenshot of the matrix I constructed by engaging in this extensive indexing process, can be found in Appendix K[27].

After conducting a significant body of indexing, I resumed the writing activities that had been central to my initial sampling refinement processes and used these to guide my development and refinement of the thematic categories (Rapley, 2016; Ritchie, Spencer, and O'Connor, 2003). This encouraged me to reflect on the existing data and the indexing I had undertaken and allowed me to further identify cross-sectional links between data, as well as to examine the coherency of data collected under particular index headings (Rapley, 2016). This was an essential process for generating the kind of reflexivity required in framework analysis - thematic headings and codes needed to be adjusted, reconsidered, and modified as new dimensions and patterns within the data became apparent. Following this, I was able to develop the more explanatory accounts and identify patterns, associations, and notable clustering of themes that form the centre of my analysis chapters (Rapley, 2016; Ritchie, Spencer, and O'Connor, 2003). This was hugely important in enabling my analysis to identify trends over time, as well as to trace and describe the development of open-ended questions into assumptions or medical 'facts'.

3.7. Research Ethics

Given the documentary-based nature of this study, few ethical considerations have been necessary in conducting this research. The data for my project consists entirely of existing medical documents that were readily available through online literature databases and my University's library. As a result, I have not needed the authors' permission to access any of these documents and to analyse them as part of my research. Nonetheless, I have developed a data management plan that carefully details the nature of my data formats and the ways in which I have stored, organised, and backed up the data, and ensured that it is accessible for long term reuse. I have also acquired copyright permission for all the images contained in this thesis.

Given my first-hand experience of PCOS, much of the content of this research project and the literature that forms the centre of its analysis resonates with me at a personal level. It carries meaning in regard to my health status and also regarding my own experience of the

[27] As the matrix I constructed by applying the framework approach is too large to include within the thesis, I have included a screenshot of one segment of the matrix in Appendix K. The full matrix is available if requested.

potential for PCOS to impact on identity and quality of life. With this in mind, as part of the ethical considerations of this project, it was necessary to put a number of steps in place to protect my wellbeing. These have included regular supervision meetings as well as accessing support from my University's Wellbeing Service and my designated Wellbeing Adviser, enabling me to discuss my research - my findings, my research progress, and my general wellbeing while undertaking the project - in a supportive setting.

Chapter 4. 1974 - 1989: Ultrasound Advancements and Uncertainty in the Field

4.1. Chapter Introduction

This chapter presents an analysis of the earliest section of literature in this study's sample - material published between 1974 and 1989. It focuses on the significant advancements that took place in ultrasound technology during this period and the substantial progress they facilitated in OG researchers' abilities to visualise the ovaries. It also analyses the social processes that were involved in the production of seminal images of polycystic ovaries (also referred to as PCO morphology) and the new questions and uncertainties which were subsequently expressed within the field of OG-PCOS research regarding the significance of PCO morphology to PCOS. This uncertainty became integral to the onset of a scientific controversy among OG researchers regarding how best to define, diagnose, and treat PCOS. Here, an in-depth analysis of the starting points of this uncertainty sets the scene around the arguments that would later come to the fore in the controversy and consensus conferences explored in the later chapters of this thesis.

First, I begin this chapter by outlining early advancements in ultrasound technology that were relevant to PCOS research in the 1970s and reflect on their implications for the developing OG-PCOS research landscape and PCOS diagnostic category. Secondly, I analyse literature that presented increasingly refined images and findings relating to ovarian structures in PCOS, including the first images of PCO morphology. I focus in particular on the socially informed 'rendering practices' by which a number of these seminal ultrasound images were produced (Lynch, 1985) and the original insights they facilitated into PCO morphology as a feature of PCOS. Thirdly, I conclude this chapter by analysing a small body of papers that evidence the increasing uncertainty that was developing in the field of OG-PCOS research over the role of PCO morphology in PCOS and that cast questions over established understandings of the PCOS diagnostic category. Through paying careful attention to the context in which these questions developed, this chapter sheds light on the role that ultrasound technology played in generating uncertainties that carried the potential to fundamentally alter the existing PCOS diagnostic category.

4.2. 1970s: Early Developments in Ultrasound Technology

Direct associations between cysts on the ovaries and PCOS were being made in medical research from 1935, following the publication of Stein and Leventhal's paper (Stein and Leventhal, 1935; Kovaks, 2022). The detailed description Stein and Leventhal were able to

provide of these cysts resulted from their use of BOWR – a fairly invasive, surgical procedure which is unable to produce visual images of ovarian structures (Farquhar, 2004). When using the alternative non-surgical method of transabdominal pneumography in their examinations, Stein and Leventhal (1935) were only able to detect and produce images of enlarged ovaries as opposed to images of the cysts themselves. At the time of Stein and Leventhal's (1935) research, transabdominal pneumography was also a very expensive technique that was difficult to transport and, since laceration of an internal vessel during transabdominal needle puncture could lead to internal bleeding, it also presented considerable risk to patient safety (Stevens and McCort, 1964; Wallace et al. 1974). Despite the disadvantages of transabdominal pneumography as a technology for researching and diagnosing PCOS, ultrasound technology was at this point insufficiently advanced for gynaecological diagnostic purposes (Levi, 1997). Stein and Leventhal (1935: 18) hailed pneumography and the images it produced as 'a most valuable aid in gynecology, and especially so in recognizing relatively small ovarian swellings which may escape detection on bimanual examination'. This was testament to the 'contingent and situational' nature of what Burri (2012: 52) defines as *visual performance*, whereby what is considered to be an aesthetically appealing but also practically useful image is shaped by wider contexts of social practice.

Developments in ultrasound technology and the visual representations they produced soon rendered transabdominal pneumography a much less revered technology within OG research and practice. Zemlyn's (1974) comparative investigation into the respective value of transabdominal ultrasonography and transabdominal pneumography for detecting and diagnosing Stein-Leventhal syndrome, later to be defined as PCOS, played a particularly important role in laying down foundations from which ultrasound could become recognised as a valuable tool for researching and diagnosing the condition. Zemlyn explored each technology's effectiveness for measuring ovarian size and found that both technologies were of value in facilitating the detection of normal and polycystic ovaries. Zemlyn (1974: 331) described each technology as a 'reliable diagnostic technique for polycystic ovaries'. It was ultrasound however, that Zemlyn (1974: 331) argued should be recommended and adopted as the 'primary approach' for detecting and diagnosing Stein-Leventhal syndrome. Zemlyn (1974) reached this conclusion for the following reasons:

> *Other investigative techniques such as pneumography, culdoscopy, laparoscopy, or exploratory surgery are more uncomfortable, hazardous, and expensive.*
>
> *Ultrasonography can identify fibroids and may prevent further aggressive investigative measures in patients with a palpable pelvic mass caused by one or more myomata.*
>
> Zemlyn, 1974: 331

Whereas the use of ultrasound for detecting enlarged ovaries required the patient to be in a supine position, pelvic pneumography involved the injection of around 1000 CC of nitrous oxide and required the patient to sit at a 45-degree angle and in a head-down position (Weigen and Stevens, 1967). The patient was then required to 'remain flat for several hours' after the examination (Kupersmit, 1972: 685). This made pelvic pneumography a more uncomfortable and inhibitive diagnostic procedure for the patient. The 1970s represented a period in the history of medicine in which awareness was growing of women's dissatisfaction with many elements of gynaecological practice (Petravage et al. 1979). The development of a less risky and less disruptive procedure represented a favourable option for many women and an important opportunity to improve patient-practitioner relations. Further testament to what Zemlyn identified as ultrasound's superiority as an investigative and diagnostic technology for Stein-Leventhal Syndrome, Zemlyn (1974) provided a seminal definition, which had not been possible before the advent of ultrasound technology, of enlarged ovaries as indicative of Stein-Leventhal syndrome:

> *The normal ovary is usually about one-third to one-fourth of the uterine size. An ovary is considered enlarged when it is one-half or more of the area of the uterus. This has its greatest application in evaluating possible clinical Stein-Leventhal syndrome, when the uterus is generally normal or small in size.*
>
> Zemlyn, 1974: 334

Prior to his study, ultrasound had not been considered an effective technology for visualising the ovaries or for diagnosing Stein-Leventhal syndrome (Levi, 1997). Since Zemlyn's (1974) study was the first to explicitly recognise the value of ultrasound technology in both these regards, it represented the onset of a period in which ultrasound would significantly transform the landscape of debates and discussions in PCOS research. Despite the obvious advantages of ultrasound over pneumography however, it was still not possible at this point in the technological advancement of ultrasound for cysts or follicles on the ovaries to be

visualised or measured. In terms of OG's '"social" programme of perception' - its system of methods and techniques for rendering the body and its components visible and perceptible - cysts and follicles were altogether non-compliant (Lynch, 1985: 59). Although cysts on the ovaries had always been assumed to be widely present in PCOS on account of their discovery in a small number of women through more surgical procedures like ovarian wedge resection, they were neither visible nor analysable through existing imaging technologies. They were subsequently defined as unknowable by OG researchers and as insignificant to established PCOS diagnostic practices. It was perhaps for this reason that despite Zemlyn's (1974) findings few subsequent papers documented the use of ultrasound for diagnosing or visualising Stein-Leventhal syndrome until 1981, by which time a more advanced ultrasound technology - high-resolution, real-time ultrasound scanners - had become more widely available within OG (Levi, 1997).

4.3. 1980s: Increasing Refinement and Specificity of Ultrasound Images

The increased availability of high-resolution, real-time ultrasound scanning[28] within OG by the early 1980s in advanced industrialised nations, meant that ultrasound images could be produced more rapidly. OG researchers now had the ability to place ultrasound scanning probes more 'accurately on the region of interest in order to observe its structure and appreciate moving structures within it' (Martin, 2010: no page number). As a result, the 1980s saw a number of studies conducted within OG-PCOS research that offered unprecedentedly detailed descriptions of the ovarian structure in women with PCOS and that produced the first ultrasound images of polycystic ovaries (Balen et al. 2003). These studies engaged OG researchers in practices and conventions that had been impossible just a few years previously, and which enabled OG researchers to construct new expertise and authority over the ovary in PCOS and the cysts and follicles with which it had long been associated. A number of key papers from this period presented findings and images of polycystic ovaries that contributed to OG's expanding authority over this strand of medical knowledge. These are analysed in the sections below and show the way in which ovarian cysts were gradually becoming more visible to clinical imaging.

[28] Real-time ultrasound imaging is different from static ultrasound imaging in that real-time images are produced instantaneously and enable moving objects to be detected and observed (Martin, 2010). Real-time images are also associated with greater 'accuracy, sensitivity and specificity' than static images (Van Holsbeke et al. 2007: 830).

4.3.1. The visualisation of polycystic ovaries

In 1981, Swanson et al.'s study was the first to use ultrasound technology to produce an image of polycystic ovaries and to provide a definition of polycystic ovaries as visible on ultrasound. This was a definition that was not limited to a description of ovarian size, but which incorporated the specificities of the cysts themselves (Balen et al. 2003; Swanson et al. 1981; Szydlarska et al. 2017). Swanson et al. (1981) explained that:

> *It is generally believed that the tiny cysts of polycystic ovary syndrome cannot be detected by ultrasound. However, with high-resolution, real-time ultrasound, we have found it possible to detect small cysts (2 to 6mm in diameter) within an ovary.*
>
> Swanson et al. 1981: 219

In providing the first ultrasound-informed definition and visualisation of polycystic ovaries, Swanson et al.'s (1981) study transformed cysts on the ovaries into something visible and measurable (Burri and Dumit, 2008). In the course of applying this technology in their study, an individual cyst or follicle was ascribed a certain *materiality;* it became what Lynch (1985: 43) defines as a 'civilized' or 'docile object', compliant with the need within OG as a medical specialty to develop a safer, more precise, and reliable method of detecting and diagnosing PCOS. Swanson et al.'s study involved a complex operational procedure composed of different instruments and tools of varying degrees of complexity, as well as certain manual tasks and standard measurements for evaluating the size of each cyst and of the ovaries. These tools and practices collectively constituted what Lynch (1985: 38) defines as *rendering practices* ('marking', 'practically constituting graphic space', and 'normalising observations'), all three of which are identifiable in the account that Swanson et al. (1981) provided for the procedures involved in creating an ultrasound image of PCO morphology. In introducing the technical tools involved in their study, Swanson et al. (1981) explained that:

> *All pelvic sonograms were initially performed with static B-scanners (Picker model 80-L, Digital 3.5 MHz). If the static scan showed evidence of enlarged or polycystic ovaries, or if the patient had clinical evidence of polycystic ovaries, a real-time sector scanner was also performed.*
>
> Swanson et al. 1981: 219

The above quotation and accompanying image and caption (Figure 2. below), offer an example of two specific aspects of the 'marking' process by which Swanson et al. (1981) rendered polycystic ovaries visible and detectable - the *labelling* of an object and *upgrading*

its visibility (Lynch, 1985). When using the static B-scanner[29], the researchers in Swanson et al.'s study interpreted the visualised ovaries as either normal in size or visibly enlarged. In instances in which the researcher identified an ovary as enlarged, or in patients presenting with clinical evidence of polycystic ovaries - such as HA or anovulation - the ovary became a possible indicator for PCOS. It was then considered appropriate for the researcher to take a new image using a more advanced scanner, thus upgrading its visibility and allowing for the possible detection of PCO morphology. In the accompanying image (Figure 2. below), white arrows have been used to illustrate the position of the enlarged ovaries in relation to the uterus and to fully direct the observer's attention towards the ovaries rather than other phenomena visible in the image. A 'legend' was also provided below the image, explaining what the image represents and where the observer's gaze is being directed. Both the arrows and legend increased the 'ostensive power' of the image (Rees, 2011: 868), transforming it into a resource through which other OG researchers could learn how to identify an enlarged ovary visible through ultrasound as indicative of PCOS.

[29] Swanson et al. (1981) refer to B-scanning, which is a type of 2-dimensional ultrasound imaging used for diagnostic purposes and which produces static as opposed to dynamic, real-time images (Azhari, 2010; Van Holsbeke et al. 2007).

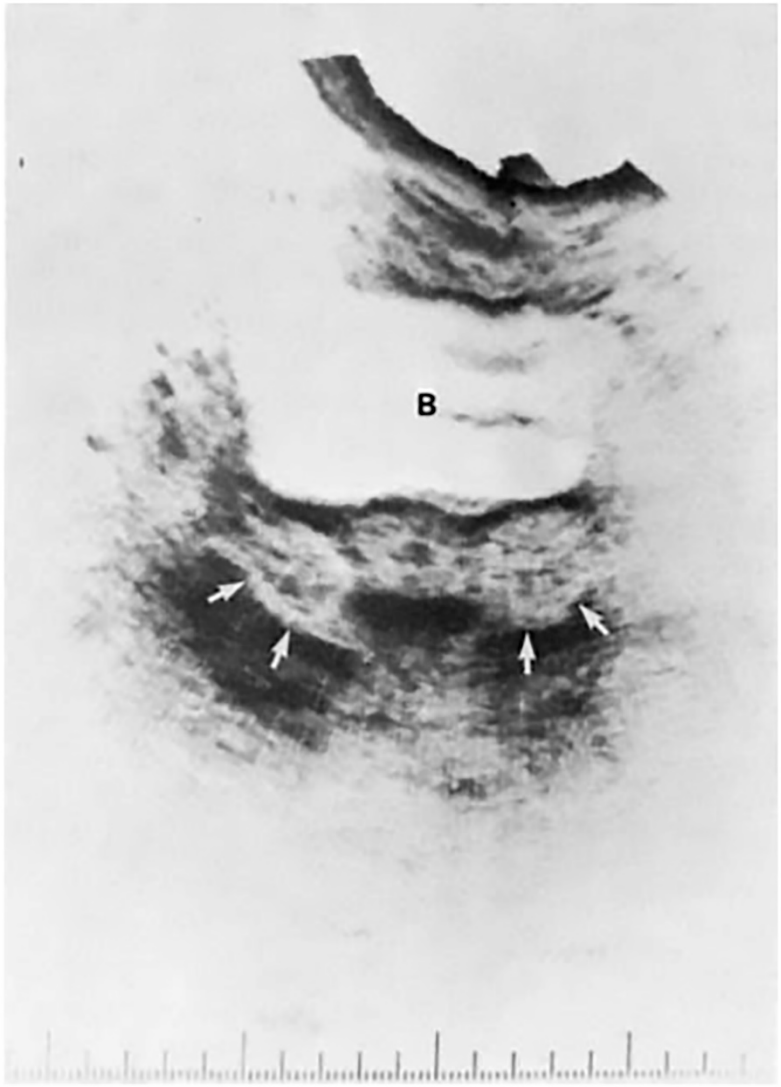

FIGURE 1. Contact B-scan in a patient with polycystic ovaries. The enlarged ovaries (arrows) are adjacent to the uterus, behind the urine-filled bladder (B). Individual cysts cannot be defined in this scan.

Figure 2. Static B-scan image produced by Swanson et al. (1981: 220) to assess ovarian size[30]

For an ovary to be labelled as enlarged in the first place, the researcher needed to assess the size of each ovary they were evaluating against established definitions of normal-sized or enlarged ovaries (Barnes, Bloor, and Henry, 1996; Kusch, 2002). Although Swanson et al. (1981) did not reference Zemlyn's (1974) study presented above (and may not have been aware of it), they referenced a study by Sample et al. (1977 - citation 3) which provided a definition for 'normal' sized ovaries. Swanson et al. (1981) and their researchers used this

[30] Republished with permission of JOHN WILEY & SONS, INC. from *Journal of Clinical Ultrasound*, Volume 9, M. Swanson, E.E. Sauerbrei and P.L. Cooperberg (1981) 'Medical implications of ultrasonically detected polycystic ovaries', pages 219-222, Copyright (2022); permission conveyed through Copyright Clearance Center, Inc.

definition as a standard against which to evaluate the sizes of the ovaries they visualised using static-B ultrasound scanners. Against this standard, Swanson et al. (1981) labelled the ovaries in their images as either normal-sized or enlarged. Those they labelled as enlarged were considered sufficiently dissimilar by Swanson et al. (1981) from the normal-sized ovaries described by Sample et al. (1977) to be classified as constituting a different 'kind' of ovary, one which could signify PCOS. This is brought into sharper focus in the extract of text presented below, in which Swanson et al. (1981) described the ovaries in women they identified as presenting with polycystic ovaries as significantly larger than the normal-sized ovaries described by Sample et al. (1977).

> *Sonography of the normal female pelvis shows that ovaries in normal postpubertal women (13 to 20 yr of age) are ellipsoid structures, with volumes ranging from 1.8 to 5.7 cc (mean, 4.0 cc). In our 22 patients with polycystic ovaries, the mean volume (12.5cc) was three times the normal mean volume as determined by Sample et al.[3] The volume of the smallest polycystic ovary was just above the upper limit of normal. In each patient, the volumes of the left and right ovary were usually the same. These observations are consistent with previous clinical and pathologic data: although polycystic changes can occur in normal or even small ovaries, the ovaries in polycystic ovary disease are usually enlarged symmetrically (two to five times normal size)[4].*
>
> Swanson et al. 1981: 222

Once the ovaries had been identified as *enlarged* by Swanson et al. (1981), a real-time sector scan was performed that permitted - for the first time in the diagnostic category's history - the visualisation of cysts on the ovaries using ultrasound technology. Although this was an ostensibly methodical and objective process, a number of social conventions were involved in making it possible. Rather than just visualising these cysts and follicles, it was important for Swanson et al. to ascribe them a more multi-layered materiality. They did this through developing mathematical measurements and definitions of the cysts that would comply with OG's wider system of diagnostic classification, thus strengthening the specialty's authority over polycystic ovaries as a field of diagnosis and research. The formula below provided by Swanson et al. (1981) represents the *mathematization* of an individual cyst or follicle, a process argued by Lynch (1985) to constitute part of the wider rendering practice of *practically constituting graphic space:*

> *Although ovarian enlargement was usually well demonstrated in the static scans (Fig 1), individual cysts were difficult to visualise. Real-time scanning clearly outlined cysts that ranged in size from 2 to 6mm. In some patients, the size of the cysts was uniform, and they were arranged along the periphery of the ovary, whereas the cysts in other patients were more variable in size and distributed throughout the parenchyma. The average volume of polycystic ovaries was 12.5 cc (4 x 2.6 x 2.4 cm), with a range of 6 cc (3 x 2 x 3 cm) to 30 cc (5 x 4 x 3 cm).*
>
> Swanson et al. 1981: 220

This formula constituted a 'measuring device' by which the researcher was able to transform an otherwise invisible entity into something measurable and visible. Through applying this formula to the ovarian structure, an otherwise minute physiologic feature was rendered a material object.

The two images below (Figure 3.) produced in Swanson et al.'s study and presented in their paper, offer a useful illustration of the third kind of rendering practice identified by Lynch (1985) as common in the production of a scientific image - the *normalisation of an observation* - and were integral to the production of the first ever ultrasound image of cysts on the ovaries. These images were produced using real-time ultrasound scanners rather than the lower resolution static B scanners. Swanson et al. presented them in their paper using visual marks and signs. These marks and signs (a collection of arrows in the first image and a collection of lower-case 'c's in the second) constitute a specific graphic rendering device, used in the creation of new scientific images to normalise an individually visualised object in relation to the other individually visualised objects contained within the image (Lynch, 1985). Although we know from the legend provided under each image that the cysts differed from one another in terms of size, the use of a particular symbol to universally delineate each individual cyst denoted uniformity - the normalisation of each individual cyst in the image as the same and equal in meaning to one another.

As a result of this rendering practice, the cysts in each image were no longer just cysts but a collective indicator for PCOS. In denoting uniformity to each of the cysts and classifying them as 'polycystic ovaries', Swanson et al. (1981) judged the cysts to be sufficiently similar based on their shared positioning and distribution across an enlarged ovary. This was a judgement that was consistent with existing definitions of polycystic ovaries developed out of the finite number of cases previously encountered in the field (Stein and Leventhal, 1935) and meant

that a collection of otherwise differing entities were rendered homogeneous (Rees, 2011). The visual marks and signs that Swanson et al. used to define each cyst as such helped to manage and restrict the possibilities for other researchers to interpret differently sized cysts as indicative of something other than PCOS, thereby serving to maintain a shared vision and interpretation (Rees, 2011) of this type of entity within OG-PCOS research and practice.

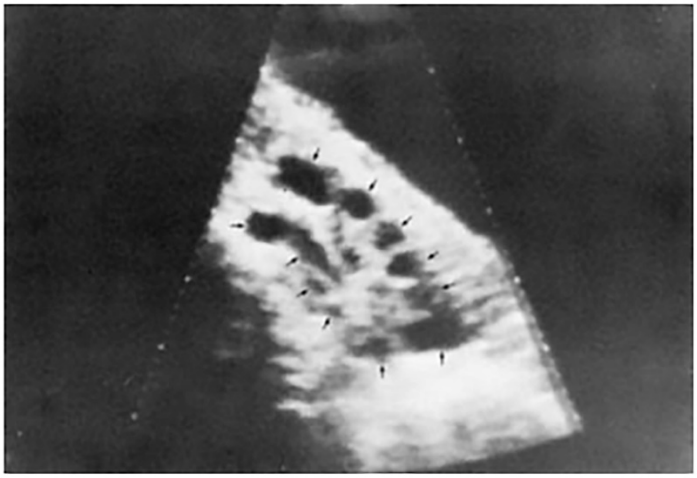

FIGURE 2. Real-time sector scan of a patient with polycystic ovaries. In this plane of section, there are at least 11 discrete, echo-free cysts (arrows) in the periphery of this enlarged ovary. The cysts range in diameter from 2 to 6 mm.

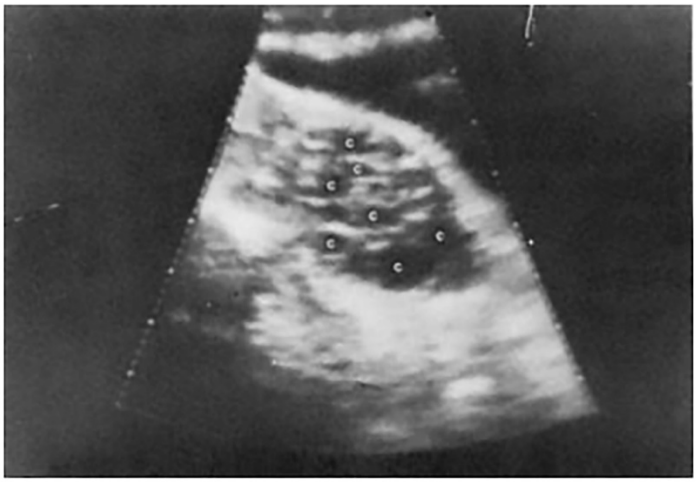

FIGURE 3. Real-time sector scan of another patient with polycystic ovaries. There are several variable-sized cysts (c) throughout the parenchyma of this enlarged ovary.

Figure 3. Real-time image of polycystic ovaries produced by Swanson et al. (1981: 220)[31]

[31] Republished with permission of JOHN WILEY & SONS, INC. from *Journal of Clinical Ultrasound*, Volume 9, M. Swanson, E.E. Sauerbrei and P.L. Cooperberg (1981) 'Medical implications of ultrasonically detected polycystic ovaries', pages 219-222, Copyright (2022); permission conveyed through Copyright Clearance Center, Inc.

These same images (Figure 3.) also constituted the culmination of the collective series of rendering practices outlined above (Lynch, 1985). Through marking each individual cyst, arranging it into graphic space, and normalising it in relation to every other cyst, otherwise invisible and unknowable cysts were rendered visible, material, and analysable objects that could serve as a potential diagnostic indicator for PCOS. This process, by which the first image of cysts on the ovaries indicative of PCOS was produced using ultrasound technology, is illustrative both of the constructive nature of image production in medical research and practice and of the role of images in the social construction of medical knowledge. The images produced by Swanson et al. (1981) were not simply identical replications of these interior structures of the ovary; they were the result of a series of similarity judgements, the construction of equations and formulas, and the ascription of visual and linguistic labels to each visualised entity and on the images themselves. As well as increasing OG's authority and expertise over PCO morphology, Swanson et al.'s (1981) study also served to sustain and accelerate ultrasound's trajectory towards becoming a highly regarded technique for diagnosing and detecting PCOS. This was evident in a series of papers published shortly after Swanson et al.'s study, which endorsed the use of ultrasound for these purposes (Parisi et al. 1982; Parisi et al. 1984; Venturoli et al. 1983).

4.3.2. Increased specificity in defining polycystic ovaries

This increasing reputational authority of ultrasound imaging in the diagnosis of PCOS was a trajectory which continued into the mid-1980s, and in 1985, Adams et al. provided, what was without precedent at that time, a detailed definition of polycystic ovaries visualised through ultrasound. They reported that:

> *In 55 patients, ovaries had a typical polycystic pattern; this was defined by the presence of either multiple cysts (ten or more) from 2-18 mm in diameter distributed evenly around the ovarian periphery with an increased amount of stroma[32], or (less commonly) multiple small cysts 2-4 mm in diameter distributed throughout abundant stroma. In PCO, ovaries were larger than those of normal women.*
>
> Adams et al. 1985: 1376

The variation in the size of the cysts identified by Adams et al. as constitutive of PCO morphology was significantly greater than that provided in Swanson et al.'s earlier 1981 study, increasing the range of possibilities through which cysts on the ovaries could be

[32] In anatomy, stroma is the connective tissue of an organ (Martin, 2010).

classified as signifying PCOS. This is an early example of the PCOS classificatory schema being expanded to encompass new empirical findings, without significant repercussions for the PCOS diagnostic category itself. The practical applicability of the definition developed by Adams et al. (1985), as well as its unparalleled specificity, meant that it became the most widely used definition of polycystic ovaries on ultrasound. This dominance remained for almost two decades, until a more refined definition was introduced at the 2003 Rotterdam Conference. The widespread adoption of Adams et al.'s (1985) definition was evidence not only of the expanding conceptualisation of polycystic ovaries in 1980s OG-PCOS research, but also a change in the status of ultrasound as an accepted diagnostic technology in the years which elapsed between Swanson et al.'s (1981) and Adams et al.'s (1985) papers. This was to the extent that findings from ultrasound images that challenged extant knowledge were no longer artefacts of the imagery producing process, considered insufficient to bring about any change in the OG-PCOS knowledge landscape and taken as evidence of the need to continue improving ultrasound technology. Instead, ultrasound had become sufficiently domesticated within the field that the images it produced could, and did, result in substantive changes to OG-PCOS knowledge and diagnosis.

To render these cysts both visible and measurable to other OG researchers in the field and produce ultrasound images with similar ostensive capabilities to those generated by Swanson et al. (1981), Adams et al. (1985) paid considerable attention to constituting and establishing the cysts as material entities in graphic space. One way they achieved this was through mathematising the cysts in terms of their closeness to ovarian stromal tissue. This is evident in the legend for the image presented below (Figure 4.) in which polycystic ovaries are defined as cysts that are distributed evenly and peripherally around stromal tissue, a physiological entity which is also described as 'increased' in women with this kind of ovarian morphology (Adams et al. 1985: 1376). The 1 cm white dots in the image were used as markers to provide a scale for the size of the ovary, while the differences in shading on the ovary itself indicated dense stromal tissue and peripherally distributed cysts.

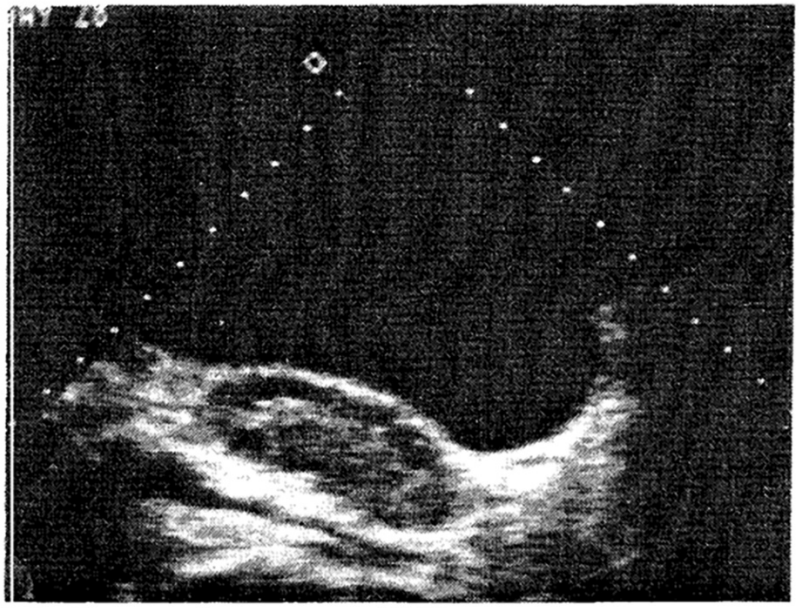

Fig 1—Ultrasound appearance of PCO.

The ovary is enlarged and contains many cysts distributed peripherally around a dense core of stroma.

Figure 4. Image of polycystic ovaries (PCO) produced by Adams et al. (1985: 1376)[33]

Another way in which Adams et al. (1985) rendered the cysts as material entities in graphic space was through the procedure they developed for measuring ovarian size, something which enabled them to visually situate the cysts within an enlarged ovarian space. The following procedure was developed by Adams et al. (1985) for measuring ovarian size:

> *Ovaries were identified and measured in three planes; the volume was calculated assuming the shape to be that of a prolate elipse. Uterine dimensions were measured in the sagittal plane and expressed in terms of cross-sectional area, which was defined as the product of the maximum length of the uterus (from cervix to fundus) and maximum antero-posterior diameter at the fundus.*
>
> Adams et al. 1985: 1375

Through increasing the specificity with which polycystic ovaries could be detected, measured, and analysed, Adams et al.'s (1985) study contributed to the ongoing transformation of polycystic ovaries into a 'scientifically *knowable'* entity (Lynch, 1985: 43,

[33] Republished with permission of ELSEVIER from *The Lancet,* Volume 326, Issue 8469-8470, Adams, J., Polson, N. Abdulwahid, Morris, D.V, Franks, S., Mason, H.D., Tucker, M., Price, J. and Jacobs, H.S. (1985) 'MULTIFOLLICULAR OVARIES: CLINICAL AND ENDOCRINE FEATURES AND RESPONSE TO PULSATILE GONADOTROPIN RELEASING HORMONE', pages 1375-379, Copyright (2022); permission conveyed through Copyright Clearance Center, Inc.

emphasis in original). The specific role of polycystic ovaries in the pathophysiology of PCOS, but also in a more practical sense as a diagnostic indicator for PCOS, was now open to increasing scientific scrutiny.

4.3.3. A newly discovered cystic abnormality

It is important to note that as well as producing images depicting cysts that were constitutive of PCO morphology, Adams et al. (1985) also produced images of cysts on the ovaries of some patients in their study whose clinical and endocrinological features did not correspond with any of the existing definitions for PCOS. In other words, these patients differed substantially from the finite number of cases that Adams et al. and other OG researchers had previously encountered (Parisi et al. 1983; Parisi et al. 1984; Sample et al. 1977; Swanson et al. 1981; Venturoli et al. 1983; Zemlyn, 1974). These cases featured ovaries of a smaller, more normative size and stromal tissue of more normal levels. The number of cysts that were visible on the ovaries of this group of patients were also significantly fewer than the number of cysts considered to be constitutive of PCO morphology. The clinical presentation of this group of patients also differed substantially from that considered typical of women with PCOS. Adams et al. (1985: 1375) described for example how, '*Unlike PCO patients, women with MFO [multifollicular ovaries] were not hirsute and serum concentrations of luteinising hormone and follicle stimulating hormone were normal and decreased, respectively'.* These differences presented a significant similarity relation between these two types of cystic abnormality - polycystic ovaries and multifollicular ovaries. Adams et al.'s (1985) identification of cysts on the ovaries of women without PCOS presented a significant challenge to OG-PCOS research and its developing classificatory schema - that of how to differentiate via ultrasound between PCOS cysts and non-PCOS cysts.

Adams et al.'s (1985) discovery of a new kind of cyst exemplifies the finite nature of the cases on which all scientific knowledge is based (Barnes, Bloor, and Henry, 1996; Bloor, 1982). Adams et al. (1985), and by extension the field of OG-PCOS research more widely, were presented with a classificatory dilemma. Ultrasound technology had provided practitioners with new kinds of exemplars and cases of PCO morphology, and as a result PCOS had come to signify enlarged ovarian size, a particular number of cysts, and a particular amount of stromal tissue. Adams et al.'s new data challenged that and potentially required a reconceptualising of the similarity relations related to PCOS (Bloor, 1982). However, rather than challenging the existing similarity relations associated with PCOS,

Adams et al. suggested an entirely new category of ovary - the multifollicular ovary (MFO); this provided a classification for the newly observed phenomena found in ultrasound but also maintained the legitimacy of the existing PCOS diagnosis as understood.

Adams et al. (1985) distinguished between the two types of cysts both in terms of the differences in ovarian size between patients presenting with cysts on the ovaries, as well as in terms of various other clinical and endocrine features presented in the patient. Adams et al. (1985) described how in relation to the newly classified MFO morphology:

> *Ovaries in 21 women showed a multifollicular pattern; both ovaries were either of normal size or slightly enlarged and filled with six to ten cysts 4-10 mm in diameter but with no increase in stromal tissue.*
>
> Adams et al. 1985: 1376

The distinction presented by Adams et al. (1985) between two different types of ovarian morphology, provides an early illustration in the socio-history of the PCOS diagnostic category of the increasing complexity that advancements in ultrasound technology brought to OG's practices for classifying and diagnosing PCOS. Although the development of high-resolution ultrasound provided unprecedented insight into the ovarian structure of women with PCOS, it also drew attention to a different group of patients who were endocrinologically and clinically distinct from women with PCOS but who also presented with multiple cysts on ovaries. In terms of the implications of this for clinical research and practice, OG researchers now needed to engage in more nuanced observations in order to demarcate PCO morphology from the newly identified MFO morphology (Van Dijck, 2005). The discovery of a new cystic abnormality reminiscent of, but different from PCO morphology, also generated increased scope for uncertainty and interpretive flexibility among OG researchers producing ultrasound images. It increased the potential for individual researcher subjectivity to shape classificatory decisions (Van Dijck, 2005) since, given the overlap between these clinical manifestations, individual practitioners could view the same image and diagnose different conditions.

4.3.4. Continued expansions in the use of ultrasound

Despite the growing complexity and uncertainty that researchers faced in detecting and defining PCO morphology on ultrasound, studies continued to be published reporting the enhanced insights that ultrasound offered into the ovarian structure of patients with

diagnosed or suspected PCOS. In the same year as Adams et al.'s study, Franks et al. (1985) presented findings generated by their study's use of ultrasound imaging that related to the ovarian structure displayed in women with ovulatory disturbances indicative of PCOS. Franks et al. (1985: 605) described how, '*with the use of pelvic ultrasound imaging we have found that more than half of the women presenting to our clinic with ovulatory disturbances have polycystic ovaries'.* They also described hirsutism as '*common'* among this group (*ibid.*). These findings strengthened the association between PCO morphology, ovulatory disturbances, and hirsutism that was first presented by Stein and Leventhal (1935), and which had come to be seen within the field of OG-PCOS research and practice as indicative of PCOS; they thereby reified established understandings of PCOS as a diagnostic category. A number of other studies that used ultrasound technology in this period continued to strengthen these associations, while also contributing to the still growing case for the widespread use of ultrasound as a diagnostic tool. Matsunaga et al.'s (1985: 227) study examined the ovarian morphology of eleven patients with suspected PCOS and described how ultrasonography proved itself, *'a pertinent diagnostic tool for a non-invasive diagnosis of PCOS'.* Similarly, a later study by Adams et al. (1986: 358) reported that ultrasound *'has provided us with a precise and non-invasive method of assessing the presentation and prevalence of polycystic ovaries in women with amenorrhoea, oligomenorrhoea, or "idiopathic" hirsutism'.*

The expanding use of ultrasound within OG was accompanied by increasing opportunities for training and accreditation, so that researchers and practitioners were trained in the production of particular types of ultrasound image in line with the epistemological and classificatory requirements of OG as a scientific specialty (Lewis, 2018). This involved OG researchers and practitioners learning to make similarity judgements between the phenomena they encountered in a newly produced ultrasound image and the finite number of cases identified in existing studies containing ultrasound-facilitated visualisations of PCO morphology (Rees, 2011; Sturdy, 2007). By instilling a collective understanding of signs within an ultrasound image that indicated an enlarged or polycystic ovary, OG's classificatory schema for PCOS as signified by a particularly sized ovary and the distribution of a particular number of cysts and volume of stromal tissue within the ovary was strengthened and sustained.

Another less empirical and more opinion-based paper published by Jacobs in 1987, further emphasised ultrasound technology's value and promise in advancing PCOS research. Jacobs described PCO morphology as an important indicator of PCOS and presented PCO morphology as central to its definition. He argued that a true appreciation of the morphological appearance of polycystic ovaries had not been possible until the advent of high-resolution ultrasound. Testament to what Jacobs (1987: 128) himself acknowledged to be the decidedly 'personal perspective' from which his paper was written, the empirical findings he referenced to support his case and the manner in which he presented them ensured that this argument was as unambiguous and central to the paper as possible. In relation to the ultrasound image of polycystic ovaries (indicated by the presence of cysts ranging between 2 - 18 mm in diameter) generated in Adams et al.'s 1985 study, Jacobs (1987: 113) explained for instance that, '*these findings are mentioned to emphasize that ultrasound almost certainly identifies the specific ovarian lesion that underlies the Stein-Leventhal syndrome'.*

Jacobs (1987) went on in his paper to present these findings as being in stark contrast to those of earlier studies undertaken before significant advances in ultrasound were made, placing further emphasis on his argument that '*it is only since the advent of high resolution ultrasound imaging that an accurate estimate of the prevalence of polycystic ovaries has become possible'* (Jacobs, 1987: 115). Reciting Adams et al.'s (1985) paper, Jacobs (1987) argued that:

> *Their figure of 25% for patients with amenorrhea contrasts with the estimate of 6% obtained in a survey of the same clinic carried out by my colleagues and me 10 years previously. The difference is attributable no doubt to the improvement in diagnostic sensitivity provided by the ultrasound technique but the newer data correspond well with the estimate of Hull and his colleagues of the prevalence of polycystic ovary syndrome in patients with menstrual symptoms and infertility.*
>
> Jacobs, 1987: 115

To conclude his championing of the developments in ultrasound technology as responsible for the advances made in PCOS knowledge and research in the decade preceding his paper, Jacobs (1987) described how:

> *One has the sense of being on the threshold of an understanding of the condition very different from the traditional view that perturbations of the extraovarian endocrine milieu are the primary mediators of the condition. Advances in methods of*

> *ascertainment of cases, in our understanding of intraovarian control mechanisms and in our appreciation of the role of insulin and other peptide signals, all indicate to me that the next few years will not lack for reports of new data and, though less creditably, of reviews as personal and as speculative as this one.*
>
> Jacobs, 1987: 128

Jacobs' (1987) more opinion-based paper provides a very useful encapsulation of just how transformative the developments and expansions in ultrasound technology had been in facilitating the enhanced visualisation of ovarian structures in women with PCOS. It is also reflective of the sense these developments created within OG of it being on the cusp of achieving significant advancements in knowledge and understandings of PCOS. Jacobs' 'sense of being on the threshold' in this regard and his direct attribution of this to the advances made within ultrasound technology, are reminiscent of the esteem in which medical imaging technologies are so often held within media and public discourses (Joyce, 2005; Van Dijck, 2005). However, although as Jacobs (1987) predicted, the PCOS knowledge and research landscape was indeed on the brink of an all-sweeping transformation in understandings of PCOS, the remainder of this chapter argues that the realities of this change were not quite what Jacobs and many of his contemporaries appear to have had in mind. The period that followed the ultrasound technology's introduction into the PCOS knowledge and research landscape was marked by the emergence of a tidal wave of uncertainty and contention over exactly which empirical findings, hypotheses, and arguments constituted legitimate medical fact and scientific knowledge. This began with the acknowledgement by some OG-PCOS researchers that the widespread application of ultrasound technology had made it apparent that PCO morphology was in fact present in a significantly broader population of women than previously assumed. The papers explored in the following section of this chapter reflect the increasing uncertainty that developed within OG-PCOS research as a result.

4.4. Late 1980s: Ultrasound and Increasing Uncertainty

Alongside the increasingly nuanced observations that were required of OG-PCOS researchers when using ultrasound and the heightened scope for divergences in the interpretation of ultrasound images, ultrasound developments within OG also generated a body of new evidence which raised significant questions and uncertainties over established understandings of PCOS within the field. These related to the prevalence of PCO morphology

across a far broader population of women than those traditionally defined as having PCOS (Roberts and Haines, 1960; Netter, 1961), whose clinical features were inconsistent with traditional definitions of the condition. In this final section of my chapter, I analyse a series of extracts from two papers (Polson et al. 1988; Franks, 1989) that generated further evidence in support of these trends, and which addressed the new questions and uncertainties they provoked within the field.

Both Polson et al. (1988: 870) and Franks[34] (1989: 94) conducted research in women they defined as '*normal'* - women who did not consider themselves to have any significant reproductive or endocrinal issue and who had not sought medical advice or treatment for any of the main symptoms of PCOS, such as irregular menstruation, hirsutism, acne, or fertility issues. Both studies found PCO morphology to be common among this population of women, but particularly so among those presenting with irregular menstruation. 86% of the women presenting with irregular menstruation in Polson et al.'s (1988) study had polycystic ovaries and 75% in Frank's (1989) study. Both studies reached similar conclusions on the basis of these findings, describing PCO morphology as '*common'* among the normal population of women (Polson et al. 1988: 870; Franks, 1989: 92) but also placing significant emphasis on the strong correlation between the presence of PCO morphology and irregular menstruation. It was on these grounds that both Polson et al. (1988: 870) and Franks (1989: 92) suggested that this newly identified group of women who presented with PCO morphology, were likely to represent one end of a continuum or '*spectrum'* of women with PCOS - women who presented with some, but not all the features traditionally associated with PCOS. Both studies' reference to a PCOS 'spectrum' demonstrated an important change in the wider OG-PCOS knowledge and research landscape. It signified an acknowledgement among some OG-PCOS experts at least, of PCOS's heterogeneity and the need to adapt the terminology used to discuss the condition in line with this new body of evidence.

Franks (1989: 87, 88) explicitly addressed the '*changing perspective'* - accompanied by increasing '*controversy'*, '*uncertainty',* and '*debate'* - that was taking hold of the field and placed particular emphasis on the integral role played by advancements in ultrasound technology in driving this change:

[34] Franks was also a co-author and researcher in Polson et al.'s (1988) study, alongside Polson, Adams and Wadsworth.

> *Traditionally, since the classical description of the syndrome by Stein and Leventhal in 1935, the diagnosis has rested primarily on the typical appearance of bilateral sclerocystic ovaries[35] in women presenting with anovulation or hirsutism (or both). But the results from subsequent publications indicated that there could be a wide variety of clinical presentations in women who had evidence of polycystic ovaries (PCO) at ovarian biopsy (Goldzeiher & Axelrod, 1963; Goldzeiher & Green, 1962; Jeffcoate, 1963; Smith et al. 1965; Givens, 1977, 1984; Yen, 1980). Although most of the women had menstrual disorders or hirsutism, there were also those who had evidence of ovulatory cycles and others who were non-hirsute.*
>
> *In recent years the availability of high-resolution ultrasound scanning has offered a non-invasive means of defining the typical polycystic morphology of ovaries in women with reproductive disturbances (Swanson et al. 1981; Parisi et al. 1982; Adams et al. 1985, 1986). It is this technique which, in combination with endocrine evaluation, has provided a new perspective on the range of clinical and biochemical features in women who have polycystic ovaries.*
>
> Franks, 1989: 87, 88

In spite of Polson et al.'s (1988) view that the newly identified group should be considered as belonging to the same 'spectrum' as those with traditionally defined PCOS, their reflections on the implications of this new body of evidence for OG's understandings of PCO morphology were testament to the uncertainties and questions which were developing within the field. Polson et al. (1988: 872) considered it '*debatable whether ovaries of this type can be said to be abnormal*' given their extensive prevalence as a common ovarian feature. They also questioned whether '*the polycystic ovary is itself a variation of the normal morphology of the ovary*' (*ibid.*). By raising doubts over the extent to which PCO morphology could be considered an abnormal or pathological entity, Polson et al.'s (1989) study offers important insight into the extent to which scientific and medical knowledge is contingent on and evolves according to available scientific and medical evidence (Barnes, Bloor, and Henry, 1996; Sturdy, 2007). Since Stein and Leventhal's (1935) research, PCO morphology had been considered an integral component of PCOS, but the new cases provided by ultrasound technology into its prevalence beyond the traditional boundaries of the PCOS diagnostic category contributed to a change in Polson et al.'s interpretation of PCO morphology and its significance to PCOS. Polson et al. (1988: 872) reached the conclusion that given PCO morphology's common comorbidity with at least one clinical feature traditionally considered

[35] Sclerocystic ovaries is a term synonymous with polycystic ovaries/ PCO morphology.

indicative of PCOS - irregular menstruation, hirsutism, or both - polycystic ovaries should indeed be considered a '*distinct morphological entity*'.

Nonetheless, the questions and reflections raised in both papers are evidence of the increasing uncertainty that was developing within the field of OG-PCOS research over the significance of PCO morphology to and within PCOS. This uncertainty continued to increase in the decade that followed, as new ultrasound-facilitated findings raised further evidence of the presence of PCO morphology in populations of women who did not conform with traditional understandings of PCOS. These uncertainties set in motion the beginnings of a longstanding scientific controversy within OG-PCOS research, which is explored in the next chapter of this thesis.

4.5. Chapter Summary

This chapter has outlined how significant advancements in ultrasound technology facilitated the production of images of polycystic ovaries of unprecedented specificity and detail. It has argued that OG-PCOS researchers who engaged in the production of these images adopted a range of social conventions that enabled them to construct expertise and authority over this newly visualised entity. Despite OG-PCOS researchers' efforts to construct a uniform and shared vision through which other researchers in the field could interpret and detect PCO morphology using ultrasound, the visualisation of MFO - a different type of ovarian structure, similar yet distinct from polycystic ovaries - generated new complexities and challenges; it increased the skills and nuance required in the interpretation of ultrasound images, as well as the possibility for images to be interpreted in divergent ways. Alongside this, a growing body of ultrasound-facilitated evidence indicated that PCO morphology was present in a significantly broader population of women than those traditionally defined as presenting with PCOS. The recognition of PCO morphology as more commonly present in women than was originally conceptualised, gave way to new uncertainties and questions in the field regarding the extent to which PCO morphology represented an abnormal or pathological entity. It also generated a change in OG researchers' perspectives towards a greater recognition of the heterogeneity of PCOS. Through exploring the role played by ultrasound technology in generating uncertainties about the PCOS diagnostic category - its core features and boundaries - this chapter provides a solid analytical foundation for the scientific controversy which unfolded in the field regarding how to define and diagnose PCOS.

Chapter 5. 1990 - 2010: The Onset of a Scientific Controversy

5.1. Chapter Introduction

This chapter traces the escalation of the questions and uncertainties I identified in the previous chapter, regarding the exclusivity of PCO morphology to PCOS and brought about through advancements in ultrasound technology, into a full-blown and longstanding controversy within OG-PCOS research. In tracing the onset and playing out of this controversy, I analyse a body of OG-PCOS papers that were published between 1990 and 2010. I begin the chapter by outlining the decisions made at a 1990 Conference held by the NIH and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)[36]. I refer to this conference from hereon in the thesis as the NIH-NICHD Conference. The NIH-NICHD Conference introduced the first uniform set of diagnostic criteria for PCOS (Dunaif et al. 1992). These criteria formally defined PCOS as a disorder of HA and oligo-ovulation[37] and omitted ultrasound and PCO morphology from the diagnostic category's compulsory components (Dunaif et al. 1992). Working from the foundation of the 1990 Conference decisions, in the second section of this chapter I analyse the interpretation presented by some OG-PCOS experts of an increasing body of evidence for the presence of ovulation in women with HA and PCO morphology as indicative of the need to expand the 1990 NIH criteria[38]. Thirdly, I analyse the counter-response from more traditionally minded PCOS experts who actively cast doubt over the value of ultrasound in facilitating a more inclusive approach to PCOS diagnosis. I argue that these developments offer important insight into the endless revisability of medical classification systems (Bloor, 1982) and the scope for experts of competing schools of thought to interpret a particular body of medical evidence in divergent ways (Duhem, 1954; Quine, 1963).

After outlining OG-PCOS experts' divergent responses to the 1990 NIH criteria and the increasing evidence of women who presented with some but not all its core components, I move on in the chapter to reflect on the implications of the increasingly pronounced division that was developing within the OG-PCOS research field. One result of this was the

[36] The NICHD is an American medical research organisation.

[37] Oligo-ovulation is a medical term referring to irregular or infrequent periods, generally defined as present in people who experience 8 or fewer periods a year (Martin, 2010;).

[38] The criteria devised at the 1990 NIH-NICHD Conference are referred to in OG literature as the NIH criteria for PCOS. This is the terminology I use throughout the thesis when discussing this particular set of PCOS diagnostic criteria.

development of stringent tools and guidelines by supporters of a broader, more inclusive diagnostic category, and it is the role these played in bringing about ultrasound's increased standardisation and routinisation within OG (Jordan and Lynch, 1998) which forms the focus of the fourth section of this chapter. In 2003, a second consensus conference, often referred to as the Rotterdam Conference, drew heavily on these newly developed tools and guidelines in their development of a new set of diagnostic criteria for PCOS known as the *Rotterdam criteria.* I move on in the chapter to outline the Rotterdam criteria and argue that their introduction represented an important turning point in OG-PCOS research and in the evolution of existing uncertainties and questions around PCO morphology in PCOS diagnosis, giving rise to a full-blown controversy. In exploring the nature of this turning point, I analyse PCOS experts' divergent reactions to the decisions made at the 2003 Conference and pay particular attention to the importance of the underdetermination of evidence by theory in shaping the strategies they used to navigate the controversy (Bonk, 2008; Dietrich and Skipper, 2007; Duhem, 1954). Although both groups of experts placed persistent emphasis on the need for further scientific evidence to resolve the debate and close the controversy, I argue that by 2010, as a result of the underdetermined nature of this evidence, the controversy remained far from resolved.

5.2. Background to the Controversy: the 1990 NIH-NICHD Conference

The 1990 NIH-NICHD Conference was held in Bethseda, Maryland, and was the first ever consensus conference to focus exclusively on PCOS. The Conference was convened with the following specific aims:

- *synthesizing current research in the field*
- *exploring areas of promise for future investigation*
- *developing diagnostic criteria for the syndrome*

Dunaif et al. 1992: xv[39]

[39] Throughout this section, I refer to Dunaif et al. (1992) and to Zawadski and Dunaif (1992) as my sources for outlining the details of the 1990 NIH-NICHD Conference. Dunaif et al. (1992) were the editors of a collection of papers entitled Polycystic Ovary Syndrome, each of which was presented at the 1990 NIH-NICHD Conference and later written up as book chapters. Zawadski and Dunaif (1992) co-authored the final chapter of the collection, which contains detailed information regarding the conclusions reached at the 1990 NIH-NICHD Conference.

The Conference had varying degrees of success in achieving its aims. While many of the papers presented at the Conference successfully synthesised new and current research into PCOS and identified areas for further investigation, significant obstacles arose in the Conference committee's attempts to develop a standardised set of PCOS diagnostic criteria. In this first section of the chapter, I outline the agreements that were eventually reached at the Conference and pay particular attention to the Conference's decision to omit ultrasound technology and PCO morphology from what it defined as the compulsory components of PCOS diagnosis (Dunaif et al. 1992). These issues became particularly central to the debate and eventual controversy that later ensued among OG-PCOS researchers and so outlining their origins here provides vital contextual information for my argument in the remainder of this chapter.

As outlined in the previous chapter, evidence was already emerging in the late 1980s of the presence of ultrasound visualised PCO morphology in women who did not conform with traditional definitions of PCOS (Franks, 1989; Polson et al. 1989). At the 1990 NIH-NICHD Conference, new evidence was presented that identified the presence of PCO morphology on ultrasound among women with hirsutism but regular menses (Franks, 1992). Although much of this evidence pointed further to the presence of PCO morphology in a significantly broader group of women than those traditionally defined as having PCOS (Roberts and Haines, 1960; Netter, 1961), among the experts who participated in the 1990 NIH-NICHD Conference, it proved insufficient in obtaining a uniform endorsement of ultrasound visualised PCO morphology as an essential component of PCOS diagnosis. The outcome of this was that PCO morphology was not included in the Conference's final report as a core criterion of PCOS. Exclusion from the core criteria did not however, equate to exclusion from PCOS diagnosis altogether. The decision was made for ultrasound visualised PCO morphology to be included as a possible diagnostic criterion for PCOS, and practitioners could exercise their own discretion regarding whether to incorporate it into their diagnostic practices or not.

Nonetheless, in their report which followed the Conference, Zawadski and Dunaif (1992: 383) stressed the '*particularly controversial*' nature of PCO morphology's inclusion even as a potential diagnostic indicator for PCOS. They explained that this contention resulted from the apparently normal appearance of the ovaries in up to 30% of women diagnosed with

PCOS, raising doubts over the value of PCO morphology as a PCOS diagnostic signifier. Zawadski and Dunaif (1992: 383) also pointed to the challenges of developing precise criteria for PCO morphology because so '*few patients actually undergo surgery'* and the limitations that remained in the size of the ovarian features that ultrasound was able to visualise. It is important to note though, given the controversy which later unfolded, that ultrasound visualised PCO morphology was not necessary for the diagnosis of more traditionally defined PCOS; this could be identified on the basis of clinically[40] and biochemically detectable HA[41] and oligo-ovulation alone. The Conference's ultimate decision not to endorse ultrasound visualised PCO morphology as a standardised or compulsory diagnostic criterion was, as a result, likely to be contentious among supporters of a more inclusive PCOS diagnostic category who disagreed with any perceived prioritisation of this narrower, traditional representation of PCOS.

Alongside introducing PCO morphology as a possible diagnostic criterion, the NIH-NICHD Conference agreed on the following as constitutive of compulsory diagnostic criteria for PCOS:

[40] At this time in the history of the PCOS diagnostic category, generally accepted clinical signs of hyperandrogenism within OG were (and still are) hirsutism, acne and androgenic alopecia (Yildiz, 2006).
[41] Biochemical indicators of PCOS generally include elevated testosterone levels, reduced levels of sex hormone binding globulin (SHBG), raised levels of luteinizing hormone (LH) relative to levels of Follicle Stimulating Hormone (FSH), as well as raised levels of androstenedione and dehydroepiandosterone sulphate (O'Driscoll et al. 1994; Sterling, 2011).

- *(i) hyperandrogenism and/or hyperandrogenemia*[42]
- *(ii) oligo-ovulation*
- *(iii) exclusion of other known disorders such as Cushing's syndrome*[43]*, hyperprolactinemia*[44]*, or congenital adrenal hyperplasia*[45]

Zawadski and Dunaif, 1992: 383

Following the conclusion of the Conference, the above criteria became known in OG literature as the *NIH criteria for PCOS* and are referred to as such from hereon in the analysis. The NIH-NICHD Conference reinforced the more traditional definitions of PCOS as principally a disorder of HA and irregular menstruation but, in the years which immediately followed the Conference, evidence of a wider spectrum of PCOS features beyond those formally recognised at the NIH-NICHD Conference continued to grow. The necessary implications of the emerging diversity within the evidence base for the continued efficacy of the NIH criteria were subject to competing interpretations by different schools of thought within the OG-PCOS researcher community. Divisions began to develop in the field between OG-PCOS experts who favoured a narrower set of diagnostic criteria and who dismissed evidence of PCO morphology in women without the traditional characteristics of PCOS as representative of something other than PCOS, and those who favoured a more inclusive set of diagnostic criteria for PCOS on account of this growing evidence base. The table below (Figure 5.) summarises the key differences between these two expert subgroups, both of whom became integral to the later developments explored in this chapter.

[42] Hyperandrogenemia is synonymous with hyperandrogenism (HA).
[43] Cushing's syndrome is a condition that results from excess amounts of corticosteroid hormones and includes symptoms of weight gain, excess body and facial hair (resulting from HA), increased blood pressure, skin which bruises easily, increased levels of blood glucose, and depression. Many of these symptoms overlap with those of PCOS and the presence of Cushing's syndrome is widely treated as an exclusion criterion for PCOS diagnosis.
[44] Hyperprolactinemia is a condition in which levels of the hormone prolactin are significantly elevated. Its symptoms include irregular menstrual periods, galactorrhea (nipple discharge), reduced libido and fertility issues (Majumdar and Mangal, 2013). Many of these symptoms overlap with those of PCOS and so hyperprolactinemia is often considered an exclusion criterion in PCOS diagnostic practices.
[45] Congenital adrenal hyperplasia refers to a group of autosomal recessive genetic disorders (Martin, 2010). Its symptoms include fertility issues, excess androgen levels, severe acne and altered growth. In women, it can also result in irregular menstrual periods, a deepening voice and excess body and facial hair (Mayo Clinic Staff, 2022). Many of the symptoms of congenital adrenal hyperplasia overlap with those of PCOS and for this reason, the condition is usually treated as an exclusion criterion for PCOS diagnosis.

PCOS expert subgroups	Traditionally focused group	Inclusivity focused group
Approach to relative focus of diagnostic category	Support a narrower definition of PCOS.	Support a wider definition of PCOS.
Approach to utility of ovarian morphology / ultrasound	See ovarian morphology as secondary as a diagnostic criterion, and therefore considers ultrasound findings optional.	See ovarian morphology as equally important as a diagnostic criterion, and therefore consider ultrasound findings to be essential.
Association with different conference positions over time	More closely aligned with 1990 Conference agreements. Become 'Rotterdam opponents' as controversy unfolds.	More closely aligned with 2003 Conference agreements. Become 'Rotterdam supporters' as controversy unfolds.

Figure 5. Summary of differences between PCOS expert subgroups

In the following section, I explore the interpretation held by more inclusivity focused experts that the new and growing evidence base contained a similarity relation that was strongly indicative of an ovulatory PCOS contingent - a contingent which was unclassifiable in terms of the NIH criteria for PCOS. It was this, and the corresponding response of more traditionally focused experts to dismiss the significance of this similarity and seek to retain and preserve the NIH criteria, that generated increasing divisions in the field.

5.3. Similarity Relations and the Revisability of Classification Systems

This growing body of evidence pointed specifically to the presence of ovulation in a significant number of women with clinical signs of HA and ultrasound visualised PCO morphology (Bunker et al. 1991; Eden, 1991; O'Driscoll et al. 1994). The 1990 NIH-NICHD recommendations had retained the exclusion of ovulatory women from the PCOS classification system as a standardised diagnostic practice. Some PCOS experts however, identified what they considered to be a key similarity - in the form of HA and PCO morphology - between this evidence base and women considered to have PCOS according to the NIH criteria. In terms of this interpretation, a particular contingent - an ovulatory version of PCOS - had been overlooked by the NIH-NICHD recommendations and revisions needed to be made to the prevailing PCOS diagnostic criteria for this contingent to be included and classified. This interpretation of the evidence base offers an important example of what Bloor (1982: 274) identifies as the ever-present possibility for new findings to provoke

'retrospective revisions' of medical classification systems. In exploring this example of classic finitism, it is helpful to consider a paper by Franks (1995), which directly addressed the question of whether ovulatory women with HA and PCO morphology should be included in the PCOS diagnostic category, before considering an analysis of Dewailly's (1997) more explicit critique of the 1990 NIH criteria.

5.3.1. An additional PCOS contingent

Franks (1995) interpreted the evidence base relating to ovulatory women with HA and ultrasound visualised PCO morphology (Bunker et al. 1991; Eden, 1991; O'Driscoll et al. 1994) as illustrative of a distinct similarity between ovulatory and anovulatory women in the form of HA and PCO morphology. This was a similarity that was so significant that from Franks' perspective, it necessitated an amendment to the PCOS classification system. Franks (1995) argued that:

> *It is a moot point whether patients with polycystic ovaries, hyperandrogenism, and regular menses should be considered to have the polycystic ovary syndrome. [1,15,16] They do not fit the classic definition of the syndrome, which includes anovulation, but there is clearly considerable overlap between this group and those with anovulation. For example, it is well recognized that women with the polycystic ovary syndrome and oligomenorrhea[46] may occasionally have spontaneous ovulatory cycles.[3, 23]*
>
> Franks, 1995: 853

In the above extract, Franks (1995: 853) identified a distinct *'overlap'* between the newly published cases that he addressed in this paper (cited as [1], [15] and [16]) and those cases traditionally defined and identified as PCOS. This overlap took the form of HA and PCO morphology and when considered in terms of a Kuhnian-informed SSK lens (Kuhn, 1977; Rees, 2011), constituted a distinctive similarity between these new cases and past cases which have traditionally been labelled PCOS. In presenting HA and PCO morphology as key similarities between cases [1], [15] and [16] and NIH-defined PCOS, Franks' (1995) paper presented a strong case for the revision of oligo-ovulation into a no longer compulsory diagnostic criterion for PCOS. Franks (1995) strengthened this case by citing evidence ([3] and [23]) that inverted the widely held idea that all women with PCOS and oligomenorrhea are completely anovulatory. Franks employed this evidence to cast doubt over the NIH criteria's

[46] Oligomenorrhea refers to infrequent ovulation which may be primary or secondary; primary oligomenorrhea is present from puberty, while secondary oligomenorrhea occurs later (Zink, 2011).

classification of oligo-ovulation as a compulsory indicator of PCOS in the first place and to demonstrate far greater similarity in the ovulatory status of each group than implied by the boundaries of the NIH-defined PCOS diagnostic category.

Franks (1995) also outlined his own findings relating to the correlation between the presence of PCO morphology and at least one other PCOS symptom - either HA or oligo-ovulation - among his study participants. Among these participants, PCO morphology was identified as the standout diagnostic characteristic, present among some women with HA but with regular ovulation and others without HA but with oligo-ovulation. This evidence, alongside Franks' signposting to the uncertainty which existed around the future prognosis and '*reproductive function'* of this group of women, strengthened the case for including PCO morphology as a diagnostic criterion independent of HA and threatened existing definitions of PCOS as a condition in which HA was always present. Franks (1995) explained that:

> *We found ultrasonographic evidence of polycystic ovaries in 22 percent of 257 volunteers, none of whom had found it necessary to seek medical attention for gynecologic symptoms…*
>
> *Overall, 94 percent of the normal women with polycystic ovaries had at least one symptom that could be considered to be a clinical marker of polycystic ovary syndrome. The effect of polycystic ovaries on the future reproductive function of these women remains unclear.*
>
> Franks, 1995: 853

Franks' emphasis in the immediate aftermath of the NIH-NICHD Conference, on the significance of PCO morphology as necessarily similar to women with varying contingents of PCOS threatened the stability of the boundaries the Conference had attempted to put in place - namely, its decisions to: (i) not endorse ultrasound as a widely recommended diagnostic technique for PCOS, (ii) confine the category to only the most traditionally identified symptoms, and (iii) exclude PCO morphology as a valid diagnostic criterion. Franks' analysis raised the possibility of expanding the diagnostic category beyond its existing focus on women with clinically or biochemically detectable signs of HA and oligo-ovulation and suggested that PCO morphology, rather than HA, provided the strongest diagnostic indicator for PCOS. Since PCO morphology did not constitute an essential diagnostic criterion among women with NIH-defined PCOS, Franks' argument was likely to be contentious among those who favoured retaining more traditionalist definitions of the

condition. A change in compulsory PCOS classificatory criteria risked bringing about a major shift in the network of signs and symptoms that made up the PCOS classification system (Bloor, 1982), the most principal of which was that measurable and detectable HA was essential for PCOS diagnosis.

Viewed through a finitist lens, Franks' (1995) paper, and its identification of a similarity made visible by significant recent advancements in ultrasound technology, reminds us of the endless possibility for previously undiscoverable or overlooked classificatory contingencies to acquire recognition and visibility at any point in the history of a diagnostic classification system and to provoke questions over the signs and symptoms on which that system is based (Bloor, 1982; Rees and White, 2023). Franks' argument that the PCOS label should be applied in these instances highlighted the revisability of classifications in light of the new contingents to be recognised or discovered (Bloor, 1982). Here I have considered the implications of Franks' interpretation of this particular body of evidence both in terms of the stability of the recently introduced NIH-NICHD recommendations and its continued classification of HA and oligo-ovulation as the central features of PCOS, and more widely in terms of our understandings of the revisability and open-ended nature of classification (Bloor, 1982).

5.3.2. A critique of the NIH criteria

Although Franks' (1995) paper identified a strong similarity relation between ovulatory and anovulatory women with HA and PCO morphology, it did not explicitly criticise the 1990 NIH criteria for PCOS. One OG-PCOS researcher though, Dewailly (1997: 360), described the NIH-NICHD recommendations as '*conservative'* in their approach. As well as echoing many of Franks' viewpoints regarding the breadth and heterogeneity of PCOS signs and symptoms beyond those defined in the NIH criteria, Dewailly (1997) also explicitly highlighted what he considered to be the inadequacy of the NIH criteria for facilitating the accurate detection of the full breadth of the PCOS diagnostic spectrum. Dewailly presented an unequivocal case for the revision of the NIH criteria, arguing that:

> *It has been controversial for many years as to whether the definition of PCOS should be based upon 'loose' clinical criteria or should require more stringent hormonal and/or morphological criteria. The 1990 NIH-NICHD consensus conference achieved an empirical definition stipulating that clinical symptoms (hyperandrogenism and/or anovulation) should serve as the selecting criteria while hormonal results should serve as excluding 'anything which is not PCOS', i.e. other well-characterized causes of*

> *hyperandrogenism and/or anovulation. Ultrasonographic criteria were not included in this definition. This conservative approach offers several advantages in clinical practice: it is simple, economic and safe. On the other hand, it probably mixes different entities. This hinders clear-cut and homogenous results in clinical research. Further, it does not take into account 'silent' cases of PCOS, that, although asymptomatic, may have some significance for the prognosis of these women (see below).*
>
> Dewailly, 1997: 360

In the extract above, Dewailly criticised the 1990 NIH criteria for excluding patients who did not present with (in Dewailly's opinion) the more obvious manifestations of PCOS such as clinically detectable HA and anovulation. As mentioned earlier, exclusion from the core 1990 NIH criteria for PCOS did not necessarily equate to exclusion from PCOS diagnosis altogether. In Dewailly's response to the criteria though, his emphasis on the exclusionary effects of the NIH criteria offered an effective rhetorical device for conveying what he considered to be the harmful effects of a more narrow PCOS diagnostic category. Dewailly's allusion to '*silent*' cases of PCOS referred to those that could only be detected via ultrasound technology through the visualisation of PCO morphology. Dewailly (1997) argued further that:

> *Therefore, no gold standard exists to accurately define PCOS. Actually, a definition of PCOS is required that is adapted to what he/she wants to do with it! For clinical practice, the NIH consensus conference definition is certainly the best. If one wishes to identify FOH[47] more selectively, the DXM[48] suppression test is certainly a necessary prerequisite. The GnRH agonist test[49] is then the main discriminating procedure. If another doctor wants to deal with 'true' PCOS, morphological evidence is then mandatory, and is afforded by ultrasonography providing the use of stringent and well-calibrated diagnostic criteria.*
>
> Dewailly, 1997: 361

Referring to non-NIH defined PCOS as '*true*' and '*silent*' PCOS, Dewailly's (1997) paper used rhetorical tropes to cast doubt over the value of the more rigid boundaries of the NIH diagnostic category and depicted the NIH criteria as responsible for excluding genuine contingents of PCOS. Like Franks, Dewailly also raised the issue of the uncertain prognosis of

[47] FOH stands for functional ovarian hyperandrogenism, which is synonymous with hyperandrogenism (HA).
[48] DXM stands for dexamethasone, which is a corticosteroid drug used to treat and test for a range of conditions, including Cushing's syndrome (Martin, 2010).
[49] The GnRH agonist test is a test for the presence of gonadotrophin-releasing hormones (GnRH). This was sometimes used to diagnose PCOS before the development of ultrasonography for diagnostic purposes (Dewailly, 1997).

women with '*true'* or '*silent*' PCOS, providing a compelling rationale for including this group within the PCOS diagnostic category. Dewailly's (1997) paper drew attention to the need for flexibility in PCOS diagnostic practice and, in highlighting the importance of ultrasound in facilitating this flexibility, laid out a possible route through which the PCOS diagnostic spectrum *could* be expanded and amended. This more targeted response to the NIH criteria suggested not just that the PCOS classification system needed to be revised, but that the NIH criteria were altogether inadequate for responding to the breadth and heterogeneity of PCOS symptoms.

In the analysis above, I have outlined the case made by Franks (1995) and Dewailly (1997) for the inclusion of ultrasound-observed PCO morphology as a PCOS diagnostic indicator independent of HA. In the next section, I explore the rhetorical strategies used by more traditionally focused experts, who were opposed to this idea, to convey the continued value and relevance of the NIH criteria and its centralisation of HA as a PCOS diagnostic indicator. I also analyse their alternative interpretation of Franks' (1995) and Dewailly's (1997) evidence base, an interpretation which was in line with their commitment to preserving the existing PCOS classification system.

5.4. Efforts to Defend the NIH criteria: HA as a PCOS requisite

Across the OG-PCOS research field in the decade or so which followed the 1990 NIH-NICHD Conference, agreement that the spectrum of PCOS symptoms and signs went beyond just HA and oligo-ovulation had become fairly unanimous. The presence of ovulation in at least some women with PCOS, was now widely acknowledged in OG-PCOS literature. Interpretations of the implications of this newly recognised PCOS contingent for the PCOS classification system, however, were divided, and in this section, I explore the rhetorical strategies used by some OG-PCOS experts to present a case for retaining the narrower, more focused NIH criteria on the grounds that they provided the most useful device for navigating and managing the heterogeneity of the condition. These strategies involved casting doubt over the value of ultrasound technology as a diagnostic device and presenting ovulation in PCOS as limited to a very small number of women. The experts who mobilised these strategies were motivated by a more traditionalist commitment towards ensuring that HA remained central to definitions of PCOS. Such developments illustrate the distinctive boundary that was being drawn up between the opposing sides involved in this debate at that time in the development of the diagnostic category.

In 2001, an NIH-funded meeting was held in North Carolina with the aim of identifying research gaps and priorities, as well as new approaches and strategies for the management and prevention of PCOS (Chang et al. 2002). Following the conclusion of the North Carolina meeting, Chang (2002: 361) published a paper that explicitly addressed the issue of diagnostic criteria in PCOS, and which reported on many of the discussions and decisions that took place at the meeting. Chang[50] acknowledged and accepted the evidence outlined in the sections above, that ovulation *could* be present in PCOS, but presented this feature as being limited to a small number of women. From Chang's perspective and that of many of those attending the meeting, greater flexibility was required in the application of the existing NIH diagnostic criteria but no fundamental change to the criteria itself was necessary. Chang (2002) explained that:

> *In a reconsideration of establishing diagnostic criteria, there was strong sentiment that the current recommendation was adequate and any additional modification was not necessary. There is little question that the majority of women with PCOS do exhibit hyperandrogenism and chronic anovulation. Not only have these criteria provided uniformity of subject selection in clinical investigation, they have been particularly useful in establishing a universal diagnosis in clinical practice. On the other hand, as the spectrum of knowledge about this enigmatic disorder increases, so it is that extensions of the classical description have become evident. No longer must a patient exhibit oligomenorrhea or amenorrhea, as there are clear examples of PCOS in ovulatory women.*
>
> Chang, 2002: 364

The above extract represented an important rhetorical response to Dewailly's (1997: 360, 361) earlier representation of the NIH criteria as having overlooked *'silent'* and '*true'* cases of PCOS. Chang acknowledged that an ovulatory contingent of PCOS existed, but also minimised its significance for the overall PCOS classificatory system. Chang achieved this by signposting to the limited frequency of ovulatory PCOS relative to the occurrence of anovulation in women with PCOS. What Chang termed the '*classical description'* of PCOS, a reference to the NIH's 1990 definition of the condition, provided another important rhetorical strategy for detracting from any perceived need to amend or revise the NIH diagnostic criteria. Chang presented ovulatory PCOS as simply an '*extension'* of the classically

[50] Upon reviewing this chapter, Chang had already appeared in my dataset in Dunaif et al.'s (1992) collection of papers presented at the 1990 NIH-NICHD Conference. In this paper, co-presented with Cragun, Chang emphasised the centrality of HA and chronic anovulation to definitions of PCOS.

described, or NIH-defined PCOS. In doing so, Chang inferred that ovulatory PCOS could be suitably diagnosed and detected without any amendment to the NIH criteria; this undermined Dewailly's (1997) suggestion that in terms of existing classificatory practices for PCOS, ovulatory women had been altogether excluded. From Chang's standpoint, preserving and protecting the NIH criteria in this way would help to retain the centrality of HA to definitions of PCOS.

Chang reported significant scepticism among those who attended the meeting towards the universal endorsement of PCO morphology as a diagnostic criterion. While the reasons Chang (2002) gave for this scepticism related to OG's limited understanding of the derivation and genesis of polycystic ovaries, it is important to remember that the inclusion of ultrasound visualised PCO morphology as a diagnostic criterion also risked opening up diagnosis of PCOS to women without clear clinical or biochemical signs of HA; this was something to which traditionally focused experts were staunchly opposed. Ultrasound offered the most tangible route through which a more inclusive diagnostic category could be developed. In a bid to stave off the integration of ultrasound visualised PCO morphology into the diagnostic category and retain HA as a central and essential criterion, Chang highlighted the technology's potential limitations. Chang (2002) raised the following questions regarding the inclusion of ultrasound visualised PCO morphology:

> *Certainly the radiographic depiction of polycystic ovaries in a woman with hirsutism and irregular menstrual bleeding makes the diagnosis irrefutable. However, is the ovarian morphology of PCOS unique to the syndrome or does it represent a broader based expression of ovarian growth and development independent of either normal or abnormal function?...*
>
> *If ovarian ultrasound were to be included as part of the diagnostic criteria, then what would constitute the morphological detail which defines a polycystic ovary?...*
>
> *Should it be required that all cases of PCOS demonstrate polycystic ovaries on ultrasonographic examination? Given our minimal knowledge of the morphological process from which the polycystic ovary is derived, it would seem prudent to appreciate the advantages of ultrasound imaging until a time when the relationship of the polycystic ovary to the syndrome is precisely understood. The one criterion that is common to all patients is hyperandrogenism and, thus, it could be considered a requisite feature of the disorder.*
>
> Chang, 2002: 362-363, 364-365

From Chang's perspective, and that of many of those attending the meeting, a more flexible definition of PCOS was warranted to accommodate for ovulatory women with PCOS, but HA still needed to remain central to this definition. While it was appreciated that '*ovarian ultrasound is a convenient imaging marker for PCOS*', the conclusion was reached that '*to the extent it is an essential element for the diagnosis of PCOS remains to be determined*' (Chang, 2002: 363).

Shortly after Chang's (2002) paper was published, a separate paper[51] was submitted by Ricardo Azziz[52] (2003) which centred around the argument that *Androgen Excess Is the Key Element in Polycystic Ovary Syndrome.* Like Chang (2002), Azziz (2003) recognised the heterogeneity of PCOS but represented androgen excess, similar to HA, as the consistent feature across different expressions of the condition. Azziz (2003) described androgen excess as '*the universal and pervasive abnormality in PCOS'* and provided the following evidence to support this argument:

> *The importance of androgens[53] in producing the PCOS phenotype[54] is highlighted by studies in female to male transsexuals, where androgen supplementation alone produces a polycystic ovarian morphology. Hyperandrogenemia is also a common feature among those women with normal ovulatory function but polycystic ovarian morphology, which may represent an occult form of PCOS (25, 26). Androgen levels have also been found to be one of the most predictable markers of inheritance in family studies of patients with PCOS.*
>
> Azziz, 2003: 253

In the above extract, Azziz (2003) drew on a different body of evidence (25 - Carmina et al. 1997 and 26 - Chang et al. 2000) to discuss the same phenomenon identified by Franks (1995) and Dewailly (1997) - the presence of ovulation in women with PCO morphology and HA. What is significant about the evidence cited by Azziz is that it was produced by investigators who were explicit that they did *'not consider women with PAO/PCO who have*

[51]Azziz's (2003) paper, *Androgen Excess Is the Key Element in Polycystic Ovary Syndrome*, was submitted in April 2002, before the Rotterdam Conference was held in May 2003.

[52]Azziz was a member of the editorial boards for *Fertility and Sterility* (between 1999 and 2002) and *Journal of Clinical Endocrinology and Metabolism* (between 2002 and 2007). Azziz was also on the editorial board for *Journal of Clinical Endocrinology and Metabolism* between 1993 and 1996, and between 2005 and 2008. Azziz has been an extremely influential actor in the PCOS controversy.

[53] Androgens are a group of steroid hormones which include testosterone and dihydrotestosterone. Androgens are produced by the testis and adrenal cortex in men, and by the ovaries and adrenal cortex in women (typically in smaller amounts) (Martin, 2010).

[54] A phenotype is a person's observable characteristics that result from the interaction between their genes (genotype), and environmental factors (Martin, 2010).

no known endocrine disturbance to have polycystic ovary syndrome (PCOS) and therefore prefer not to use the term 'PCO' which is often equated with PCOS' (Carmina et al. 1997: 905). In other words, Carmina et al. (1997) were not of the view put forward by Franks and Dewailly that PCO morphology necessarily represented a diagnostic indicator for PCOS and so made the active decision to avoid the term PCO in their investigation, opting instead for PAO - polycystic-appearing ovaries. In outlining the results of this evidence, Azziz stressed the commonality of HA among this group of ovulatory women before highlighting the value of androgens as a predictable PCOS marker. In mobilising evidence that presented PCO morphology as incidental rather than causative of PCOS, Azziz (2003) rhetorically positioned HA as the most important indicator for the condition.

Azziz's (2003) paper offered important insight into the strategies that the underdetermination of evidence by theory can make available to experts embroiled in a conflict in which competing explanations of scientific or medical phenomena are presented (Bonk, 2008; Dietrich and Skipper, 2007). Here Azziz strategically invoked evidence that was concurrent with his own commitment to retaining HA at the centre point of PCOS definitions. Although this body of evidence applied to the same broad phenomena as that invoked by Franks (1995) and Dewailly (1997), these authors located HA as having a greater similarity relation for a diagnosis of PCOS than PCO morphology. This was the result of the alternative traditions and perspectives through which each group of experts interpreted the same scientific phenomenon. Azziz's commitment to maintaining HA as central to PCOS diagnosis meant he was unable to accept the importance of the evidence presented by Franks (1995) and Dewailly (1997) for the inclusion of PCO morphology as a PCOS diagnostic indicator, independent of HA.

A common thread that ran between Chang's (2002) and Azziz's (2003) papers, was the persistent emphasis both placed on excess androgens and/or HA as central to PCOS pathophysiology and on the subsequent need for it to remain reflected in definitions of the condition. Failing to protect HA as a compulsory PCOS criterion risked a fundamental shift in the PCOS classification system as a whole (Bloor, 1982; Kuhn, 1970). What Chang's (2002) and Azziz's (2003) papers offer to my analysis is evidence that on one hand, acknowledgement and acceptance was growing even among more traditionalist PCOS experts regarding the need for more inclusive and flexible PCOS diagnostic criteria, but that on the other hand, there remained a steadfast commitment among these experts towards

maintaining the NIH criteria, and in particular, its operationalisation of HA as central to PCOS.

5.5. The Routinisation of Ultrasound

In this section, I explore the processes by which a small group of inclusivity focused OG-PCOS researchers - Dewailly (1997), Dewailly et al. (2002), Jonard et al. (2003), and Balen et al. (2003) - were actively engaged in the development of tools and guidelines designed to facilitate the more widespread *routinisation* of ultrasound within OG (Jordan and Lynch, 1998). I argue that the researchers in question engaged in these strategies in response to the efforts of Chang (2002), and the authors of the 1990 NIH criteria (Dunaif et al. 1992), to present ultrasound technology as unsuited to the demands of routine diagnostic practice. I focus on the initial challenges they faced in making a case for the endorsement and acceptance of ultrasound as a routinely applied diagnostic device and argue that by developing detailed technical guidelines and operationalising more specific ultrasound signifiers, this group of experts laid down important foundations for the more seamless acceptance of ultrasound as a fundamental PCOS diagnostic technology.

Although significant procedures had been put in place in the 1980s to standardise the content and detail contained in ultrasound-generated images, the technology had more recently come into question because of variances in the ultrasound equipment used across the field of OG research and practice, uncertainty over the origins of the ovarian structures being visualised by the technology, and differences in the interpretation of these structures and what they signified. As mentioned earlier in this chapter, the 1990 NIH-NICHD Conference cited the extensive variation in ultrasonographic practices and equipment between different research centres as a key factor informing its decision not to endorse ultrasound technology. That state of affairs did not significantly change in the decade that followed the 1990 Conference. In 2002, Dewailly et al. described the extensive variation in research findings that continued to result from differences in ultrasonographic practices and reported the impact this was having on research attempting to establish the value of PCO morphology as a diagnostic indicator. This heterogeneity in ultrasound-facilitated research practice and findings sustained the uncertainty and debate over ultrasound's role and value within OG-PCOS practice and research, and as Dewailly et al. (2002: 72, brackets added) described, '*whether U/S [ultrasound] should be used as a universal standard (was) still disputed'*.

This uncertainty over ultrasound's value within routine diagnostic practice was increased by the technology's inability to detect follicles smaller than 2 mm in size (Jonard et al. 2003). Ultrasound was only of value in detecting later stages in the development of follicles on the ovaries, where the cysts had grown above 2 mm in size. This was problematic because the excess in follicles that occurred in the later stages of folliculogenesis[55] visible on ultrasound was not exclusive to PCOS. MFO could also result from a range of other pathological or physiological conditions, including '*mid-late normal puberty, central precocious puberty, hypothalamic anovulation, hyperprolactinaemia and, most importantly, the early normal follicular phase in adult women, in only one ovary'* (Dewailly et al. 2002: 63; Jonard et al. 2003). The key similarity involved in diagnosing PCO morphology in PCOS - the number and distribution of follicles - overlapped problematically with the similarity involved in the diagnosis of MFO independent of PCOS. This left extensive scope for significant interpretive flexibility of findings (Collins, 1981) - since MFO could either be interpreted as being indicative, or existing independently, of PCOS - and contributed to extensive variation in research findings across the field (Jonard et al. 2003: 598-599; Dewailly et al. 2002).

These issues in the routine application of ultrasound within OG provided significant scope for more traditionalist experts to use the variability of ultrasound findings - which was such that different doctors operating in different clinics were unlikely to reliably reach the same diagnosis - as part of their rhetorical strategy for arguing against any amendment to the PCOS diagnostic criteria. It was for this reason that supporters of a more inclusive diagnostic category needed to put new mechanisms in place for securing the continued standardisation and routinisation (Jordan and Lynch, 1998) of ultrasound technology for diagnosing PCOS. These included the development and operationalisation of more specific ultrasound signifiers and the development of specific technical guidelines for sonographers engaging in PCOS diagnostic practice. Consideration of these mechanisms forms the basis of the analysis in the remainder of this section.

In a key contribution to the evidence base, Jonard et al. (2003) developed the following modification of Adams et al.'s (1985) operationalisation of PCO morphology:

[55] Folliculogenesis is the process by which ovarian follicles develop (Monniaux et al. 2019).

`increased ovarian area (>5.5 cm2) or volume (>11 ml) and/or presence of >12 follicles measuring -9 mm in diameter (mean of both ovaries)'.

Jonard et al. 2003: 602

The modified definition increased the threshold for the number of follicles per ovary deemed an appropriate indicator of PCOS. This was important because it had been established that the presence of more than 12 follicles on an ovary was likely to be specific to PCO morphology and unlikely to co-present in MFO independent of PCOS. In Balen et al.'s (2003) report, they endorsed Jonard et al.'s (2003) modified definition and presented this alongside a number of other recommendations for procedures to be followed in defining PCO morphology on ultrasound. These were as follows:

1. The PCO should have at least one of the following: either 12 or more follicles measuring 2-9 mm in diameter or increased ovarian volume (>10 cm3). If there is evidence of a dominant follicle (>10 mm) or a corpus luteum, the scan should be repeated during the next cycle.
2. The subjective appearance of PCOs should not be substituted for this definition. The follicle distribution should be omitted as well as the increase in stromal echogenicity and/or volume. Although the latter is specific to polycystic ovary, it has been shown that measurement of the ovarian volume is a good surrogate for the quantification of the stroma in clinical practice.
3. Only one ovary fitting this definition or a single occurrence of one of the above criteria is sufficient to define the PCO. If there is evidence of a dominant follicle (>10 mm) or corpus luteum, the scan should be repeated next cycle. The presence of an abnormal cyst or ovarian asymmetry, which may suggest a homogeneous cyst, necessitates further investigation.
4. This definition does not apply to women taking the oral contraceptive pill, as ovarian size is reduced, even though the `polycystic' appearance may persist.
5. A woman having PCO in the absence of an ovulation disorder or hyperandrogenism (`asymptomatic PCO') should not be considered as having PCOS, until more is known about this situation.
6. In addition to its role in the definition of PCO, ultrasound is helpful to predict fertility outcome in patients with PCOS (response to clomiphene citrate, risk for ovarian hyperstimulation syndrome (OHSS), decision for in-vitro maturation of oocytes). It is recognized that the appearance of PCOs may be seen in women undergoing ovarian stimulation for IVF in the absence of overt signs of PCOS. Ultrasound also provides the opportunity to screen for endometrial hyperplasia.

Balen et al. 2003: 509

Balen et al. (2003) also provided the following guidelines for the ultrasound assessment of ovaries in PCOS and developed a suggested template for ultrasound reports (Figure 6.),

concordant with the requirements of the modified measurement for PCO morphology they introduced:

> *The following technical recommendations should be respected:*
> - *State-of-the-art equipment is required and should be operated by appropriately trained personnel.*
> - *Whenever possible, the transvaginal approach should be preferred, particularly in obese patients.*
> - *Regularly menstruating women should be scanned in the early follicular phase (days 3±5). Oligo-/amenorrhoeic women should be scanned either at random or between days 3±5 after a progestogen-induced bleed.*
> - *If there is evidence of a dominant follicle (>10mm) or a corpus luteum, the scan should be repeated the next cycle.*
> - *Calculation of ovarian volume is performed using the simplified formula for a prolate ellipsoid (0.5 3 length 3 width 3 thickness).*
> - *Follicle number should be estimated both in longitudinal, transverse and antero-posterior cross-sections of the ovaries. Follicle size should be expressed as the mean of the diameters measured in the three sections.*
>
> Balen et al. 2003: 509

Table IV. The ultrasound scan report

Name and age of patient
Identifying unique hospital record number
Date of scan
Relation to menstrual cycle
Relevant treatment (COCP, GnRHa, etc.)
Type of scan (transabdominal/transvaginal, etc.)
Ovarian morphology: each ovary recorded separately
Volume (and area – optional)
No. and size/range of cysts
Stromal echogenicity (if local grading system exists)
Doppler studies (if performed)
Uterine morphology, cross-sectional area and endometrial thickness
Other features
Hard copy and/or electronic copy
Grade and signature of person performing scan
Grade and signature of person verifying scan (if relevant)

Figure 6. Balen et al.'s (2003: 512) suggested template for ultrasound scan reports

Collectively, these measures laid down important foundations for the routinisation of ultrasound as a mundane and widely applied technology in everyday OG-PCOS research and practice. Although these measures were developed by researchers who were primarily active in European countries, they were intended to facilitate the widespread application of ultrasound for diagnosing PCOS among practitioners and researchers across the western world. They also undermined claims by more traditionalist PCOS experts that ultrasound findings remained too inconsistent for inclusion in diagnostic criteria and had a significant influence in shaping the decisions made at the 2003 Rotterdam Conference explored in the section below.

5.6. The Rotterdam Conference and Report

A second consensus conference on PCOS convened in Rotterdam in 2003, was held with the express aim of reviewing and revising the 1990 NIH criteria (ESHRE/ASRM, 2004). Unlike the 1990 NIH-NICHD Conference, a level of consensus *was* reached at the Rotterdam Conference and a consensus report was released (ESHRE/ASRM, 2004). Analysis of the report's contents and the components of the new diagnostic criteria it introduced for PCOS offer a basis on which to consider both the rhetorical strategies contained within the report itself, as well as the wider implications of these criteria for OG-PCOS research and practice. I argue that these rhetorical strategies were employed by the report's authors with the aim of consolidating the emergent boundary in the field between the older NIH criteria and what it framed as a newer, more inclusive, and flexible approach to PCOS diagnosis.

5.6.1 The Rotterdam criteria

The following criteria for PCOS were agreed at the Rotterdam Conference:

> *1. Oligo- or anovulation*
>
> *2. Clinical and/or biochemical signs of hyperandrogenism*
>
> *3. Polycystic ovaries and exclusion of other etiologies (congenital adrenal hyperplasia, androgen-secreting tumors, Cushing's syndrome)*
>
> ESHRE/ASRM, 2004: 20

The report stated that two of these three criteria must be present for a PCOS diagnosis and endorsed ultrasound as a device for the visualisation of its third diagnostic criterion - PCO morphology. This meant that ovulatory women with HA and PCO morphology could now be

diagnosed with PCOS, but in addition, non-hyperandrogenic women with PCO morphology and irregular menses could in theory be diagnosed with PCOS. In effect therefore, as well as reclassifying PCO morphology as an official diagnostic criterion for PCOS, the Rotterdam report also relegated HA to a non-compulsory feature of the condition and significantly expanded the boundaries of the PCOS diagnostic category. The Rotterdam report included all the technical recommendations provided by Balen et al. (2003) and the modified definition of PCO morphology developed by Jonard et al. (2003) as guidelines for the application of PCO morphology as a diagnostic criterion. In addition to the traditional NIH-defined or hyperandrogenic phenotype (marked by HA, oligo-ovulation and potential PCO morphology), the Rotterdam criteria introduced two new PCOS phenotypes:

- An ovulatory phenotype - whereby ovulation is present alongside HA and PCO morphology
- A non-hyperandrogenic phenotype - whereby PCO morphology and anovulation are present without HA

5.6.2. The construction of a contrast-case

The Rotterdam report employed a number of rhetorical devices that served to represent the new criteria it introduced as being in stark and favourable contrast to those introduced by the 1990 NIH-NICHD Conference. The report began by remarking on the absence of clinical trial evidence behind the criteria introduced at the NIH-NICHD Conference. In describing the 1990 NIH criteria, the Rotterdam report's authors explained that:

> *Based on the majority opinion rather than clinical trial evidence, the following diagnostic criteria were recommended: clinical or biochemical evidence of hyperandrogenism, chronic anovulation and exclusion of other known disorders (Zawadski and Dunaif, 1992).*
>
> ESHRE/ASRM, 2004: 41

This contained an implicit critique of the NIH criteria, appealing to the normative value placed by science on sound empirical evidence[56] as the basis for scientific decision-making and, in the case of consensus conferences, the basis on which consensus should be reached

[56] Clinicians typically use and assess evidence according to a clinical construct known as a 'hierarchy' or 'pyramid' of evidence (Desai et al. 2019: 11). This hierarchy or pyramid prioritises evidence generated by randomised controlled trials (RCTs) according to the extent to which it contains primary data and researcher bias. It prioritises evidence containing minimal researcher bias, and significant components of primary data (*ibid.*).

(Solomon, 2011). Appealing to science's norms of good practice and presenting an opponent as having breached those norms is a common rhetorical strategy employed by experts embroiled in a conflict or controversy (Mercer, 1996). In the above extract, the Rotterdam report also inaccurately described the diagnostic criteria developed at the NIH-NICHD Conference. In listing the criteria that the 1990 Conference put forth, the Rotterdam report intentionally omitted any mention of PCO morphology's inclusion as a *possible* diagnostic criterion for PCOS (Dunaif et al. 1992; ESHRE/ASRM, 2004). Overlooking this detail provided the Rotterdam report with a firm foundation on which to depict the NIH criteria as rigid and outdated and as having entirely overlooked evidence of PCO morphology as a valuable diagnostic indicator for PCOS.

Building on this foundation, the Rotterdam report's authors ascribed particular characteristics to the NIH criteria and to their own newly devised Rotterdam criteria. Referring to the 1990 NIH-NICHD Conference, the Rotterdam report described for example how:

> *Since that time and as outlined during a number of subsequent international conferences, there has been a gradually increasing awareness that the clinical expression of PCOS may be broader than that defined by the 1990 NIH criteria.*
>
> ESHRE/ASRM, 2004: 19

In describing the PCOS spectrum of symptoms as most likely much *'broader'* than the NIH criteria would suggest, the authors of the Rotterdam report were able to ascribe the opposite characteristic to the NIH criteria and depict them as narrow and restrictive. The Rotterdam report authors presented their new criteria for PCOS in the table below (Figure 7.) *alongside* the NIH-NICHD criteria for PCOS. This was an important strategy designed to emphasise a stark contrast between the two sets of criteria, namely in terms of Rotterdam's inclusion of PCO morphology as a diagnostic criterion. This strategy reinforced the Rotterdam report's earlier misrepresentation of the NIH-NICHD Conference as having entirely omitted PCO morphology as a diagnostic criterion for PCOS and contributed to the consolidation of a stark contrast-case between both sets of criteria (Gieryn, 1983). This was a strategy that would come to epitomise many of the future rhetorical positions employed by supporters of the Rotterdam criteria in their bid to defend and protect it.

Table I. Revised diagnostic criteria of PCOS

1999 criteria (both 1 and 2)
1. Chronic anovulation
2. Clinical and/or biochemical signs of hyperandrogenism, and exclusion of other aetiologies

Revised 2003 criteria (2 out of 3)
1. Oligo- and/or anovulation
2. Clinical and/or biochemical signs of hyperandrogenism
3. Polycystic ovaries
and exclusion of other aetiologies (congenital adrenal hyperplasias, androgen-secreting tumours, Cushing's syndrome)

Figure 7. The Rotterdam report's (ESHRE/ASRM, 2004: 20) summary of the differences between the 1990 NIH and 2003 Rotterdam criteria

The effectiveness of the Rotterdam report's employment of this contrast-case device was clearly evident from the post-2003 papers in my dataset; the NIH criteria's inclusion of polycystic ovaries on ultrasound as a possible additional criterion was mentioned in only one paper, which was published before the Rotterdam Conference was held (Kahsar-Miller et al. 2001). This demonstrates the extent to which the 1990 NIH-NICHD Conference's original consideration of PCO morphology as a PCOS diagnostic criterion was effectively written out of the PCOS diagnostic category's history. This was the result of the somewhat exaggerated emphasis that was placed by inclusivity focused OG-PCOS experts on the exclusionary nature of the NIH criteria. In contemporary OG-PCOS literature, PCO morphology as a diagnostic criterion for PCOS is now exclusively associated with the 2003 Rotterdam criteria.

Through its incorporation of PCO morphology as a PCOS diagnostic criterion and its reclassification of HA to a no longer compulsory criterion, the Rotterdam report represented a seismic change in OG's standardised approach for diagnosing PCOS. It embodied both the widespread acknowledgement within OG-PCOS research that ovulatory women *could* present with PCOS, as well as the robust guidelines and mechanisms that had been put in place by supporters of a more inclusive set of diagnostic criteria for the standardised and routinised use of ultrasound across the field. The Rotterdam report was not however without contention. The release of the Rotterdam report was followed by a surge in publications within OG-PCOS literature, many of which contained vociferous interactions between experts with opposing perspectives on the value and implications of the Rotterdam criteria. The 'contrast-case' presented within the Rotterdam report, between the *inclusive* Rotterdam criteria and the *outdated* and *rigid* NIH criteria, continued to be either mobilised or challenged by experts in the field. Given the intensification in the disagreement over the issue of diagnostic criteria in PCOS and the consolidation of a boundary between two

distinctive and opposing sides, I argue that the Rotterdam Conference represented an important turning point in the evolution of existing uncertainties and questions within the OG-PCOS research landscape into a full-blown controversy. In the next section of the chapter, I analyse the nature of this turning point, exploring the rhetorical strategies which were engaged in by both groups of experts and their role in sustaining and shaping the playing out of the controversy.

5.7. Navigating the Controversy: Rotterdam Opponents

In the aftermath of the Rotterdam Conference, traditionalist PCOS experts, who had resisted any revision to the PCOS diagnostic criteria in the first place, resurfaced within the literature and expressed their explicit opposition to the 2003 Rotterdam criteria. From hereon in the thesis, I refer to this group of experts as *Rotterdam opponents.* As well as committing themselves to challenging the validity and effectiveness of the Rotterdam criteria on the grounds that it incorporated women who may not have PCOS, Rotterdam opponents also strived to promote the value of the older 1990 NIH criteria and to present HA as a requisite feature of PCOS. They did this through a host of rhetorical strategies which included presenting alternative interpretations of, and explanations for, the evidence base behind the Rotterdam criteria, appealing to potential risks presented to OG-PCOS research by the widespread application of the Rotterdam criteria, and mobilising flexible repertoires and imagined communities in order to present the original 1990 NIH set of criteria for PCOS as the most useful and widely applied of the two.

5.7.1. An alternative interpretation of the Rotterdam evidence base

One particular PCOS expert, Azziz, resurfaced within my dataset as the scholar most actively and persistently opposed to the Rotterdam criteria in the immediate aftermath of its publication. Azziz (2004, 2005, 2006a, and 2006b) deployed various rhetorical strategies repeatedly in the opposition he expressed towards the 2003 Rotterdam criteria as a means of shifting the debate in favour of his own interpretations and ambitions for the PCOS diagnostic category. Citing the same study from Carmina and Lobo (2001) that was used as evidence in the Rotterdam report for the presence of ovulation in women with HA and/or PCO morphology, Azziz (2005) explained that the findings of this study reported no significant differences in the androgen levels and LH/FSH ratios between two groups of hyperandrogenemic ovulatory women with and without polycystic ovaries. Azziz (2005) argued on this basis that:

> *Taken together, these data suggest that hirsute hyperandrogenemic ovulatory women with polycystic ovaries, whether hirsute or not, tend to have mild insulin resistance and mild evidence of ovarian dysfunction, although significantly less than women with anovulatory PCOS….*
>
> *Overall, when the available data are critically reviewed it would appear that ovulatory women with hirsutism and/or hyperandrogenemia and polycystic ovaries may have a mild form of PCOS, although it should be recognized that differences from normal are modest at best and that additional studies are needed to confirm these findings.*
>
> Azziz, 2005: 1344

Considered in the context of the Rotterdam report's own mobilisation of this same evidence to support its assertion that '*it is now recognized that women with regular cycles and hyperandrogenism and/or polycystic ovaries (PCO) may have the syndrome*' (ESHRE/ASRM, 2004: 19), the extract from Azziz (2005) above offers us an example of two very different representations of the same body of data. Azziz emphasised the *mildness* of the ovulatory phenotype introduced by Rotterdam, enabling him to present it as a possible over-extension of the PCOS diagnostic category and as requiring further research. This was an interpretation that was in line with Azziz's own commitment towards reinstating the NIH criteria for PCOS, since it positioned NIH-defined PCOS (marked by HA, oligo-ovulation, and/or PCO morphology) as the most serious contingent of the disorder. The Rotterdam report on the other hand, deemed this same evidence from Carmina and Lobo (2001) justifiable grounds on which to introduce an ovulatory phenotype.

5.7.2. Identifying insufficiencies and offering alternative explanations

As well as emphasising evidence pointing to the mildness of the ovulatory phenotype, Azziz (2005) commented on the limited evidence there was to support the inclusion of a non-hyperandrogenic phenotype altogether. He described how:

> *There is considerably less evidence that women with polycystic ovaries and ovulatory dysfunction, but without clinical or biochemical evidence of hyperandrogenism, have features suggestive of PCOS.*
>
> Azziz, 2005: 1344

While the Rotterdam report (ESHRE/ASRM, 2004: 19) did not provide any citations to support its assertion that '*it has also been recognized that some women with the syndrome will have PCO without clinical evidence of androgen excess but will display evidence of*

ovarian dysfunction', Azziz (2005) instead mobilised this apparent paucity of evidence to provide a series of alternative explanations for the presence of PCO morphology in non-hyperandrogenic, ovulatory women. He outlined how:

> *Many patients with nonandrogenic disorders also demonstrate a polycystic ovarian morphology. For example, most patients with bulimia and other eating disorders demonstrate polycystic ovaries on ultrasound in addition to having menstrual and ovulatory abnormalities. At least 50% of patients with hyperprolactinemia or hypothalamic amenorrhea also demonstrate polycystic ovaries. Finally, many adolescents transiently demonstrate polycystic ovaries.*
>
> Azziz (2005: 1344)

In the above extract, Azziz addressed the limited body of evidence supporting the co-presence of PCO morphology and irregular menses in non-hyperandrogenic women as conclusively indicative of PCOS. He did this by identifying numerous other potential scenarios - eating disorders, hyperprolactinemia or hypothalamic amenorrhea, and adolescence - independent of the presence of PCOS, that could explain this combination of features. Here, Azziz (2005) strategically employed an alternative explanation to account for the presence of PCO morphology in non-hyperandrogenic, ovulatory women and as a means of undermining the argument presented by the Rotterdam report that this particular feature was indicative of PCOS. It was on this basis that, combined with what he had characterised as the *mildness* of ovulatory PCOS phenotypes, Azziz (2005) was able to offer the following conclusion regarding the 2003 Rotterdam criteria:

> *Consequently, while it is clear that polycystic ovaries are a frequent feature of PCOS, the widespread adoption of the diagnostic criteria proposed in the 2003 Rotterdam meeting proceedings should be considered premature, particularly considering available data. While undoubtedly additional research is needed to more clearly determine the entire spectrum of PCOS, the publication of these guidelines should not be interpreted as an indication that the data are already available to support the phenotypes proposed.*
>
> Azziz, 2005: 1345

In this instance, Azziz (2005) was able to employ his own interpretation of the evidence on which the Rotterdam criteria was based to support his conclusion that its introduction had been premature and to call for further evidence to illuminate the true spectrum of PCOS symptoms. Azziz (2006a) later strategically employed this same strategy again when

responding to a letter from Dewailly (2006), which had argued that the imprecision of prevailing measurements of HA meant that women defined in clinical research and practice as non-hyperandrogenic should not necessarily be excluded from a PCOS diagnosis. Azziz addressed this argument by suggesting that women who met Rotterdam's definition for non-hyperandrogenic PCOS essentially met the same criteria for functional hypothalamic amenorrhea (FHA)[57]. Azziz (2006a) argued that:

> *Finally, FHA is usually defined by a history of amenorrhea of at least six months' duration, a negative urinary pregnancy test, serum LH, FSH, TSH [thyroid stimulating hormone], PRL [prolactin], and androgen levels within the normal range, and an LH:FSH ratio less than 2. How is this different than the women with "nonhyperandrogenic PCOS" that Dr. Dewailly proposes to include?*
>
> Azziz, 2006a: 530

Azziz (2006a) argued in the above extract that the features he listed as emblematic of FHA should constitute an essential exclusion criterion for PCOS and that were this to be implemented, it would rule out the possibility that non-hyperandrogenic women might have PCOS. In other words, Azziz (2006a) considered that women who were being diagnosed with non-hyperandrogenic PCOS would, from his perspective, have a closer similarity to the pre-existing diagnosis of FHA rather than PCOS. Were this similarity to be accepted by the wider OG-PCOS research field, it would shift the network of signs and symptoms on which PCOS classification was based back towards a central focus on HA as a fundamental component of PCOS. As Quine (1963: 43) argues, 'any statement can be held to be true come what may if we make drastic enough adjustments elsewhere in the system'. By revising other parts of the network of classifications in which PCOS was situated and reclassifying the non-hyperandrogenic phenotype as FHA on account of the presence of normal levels of biochemical indicators for HA, amenorrhea, and PCO morphology, HA would automatically be reclassified as a requisite feature of PCOS.

5.7.3. Appealing to the issue of 'risk'

Azziz (2006a) concluded his reply to Dewailly (2006) by reiterating his belief that the application of the Rotterdam criteria was premature. He explained that:

[57] Functional hypothalamic amenorrhea (FHA) is a form of chronic anovulation which can result in infertility and is understood to be the result of weight loss, stress and/or excessive exercise (Meczekalski et al. 2014).

> *As I noted in my editorial, I believe the risks of prematurely expanding and assigning a name to a phenotype, which we are only now beginning to study, are greater than the benefits. It has the potential of negatively affecting research by making our study populations more heterogeneous and by creating the a priori impression that we understand the health implications of these newly proposed phenotypes when we do not. It also suggests to physicians and their patients (and their insurance providers) that women with these phenotypes are at increased risk for metabolic and cardiovascular consequences, despite the lack of data available to support this assertion.*
>
> Azziz, 2006a: 530

In his conclusion above, Azziz (2006a) invoked a particular social contingency that *could* arise through the premature application of the Rotterdam criteria. He drew attention to the issue of risk - particularly metabolic and cardiovascular risk - in women diagnosed with either of the two newer PCOS phenotypes. By suggesting that future research could be stifled or negatively impacted by the inclusion of overly heterogeneous research populations, Azziz (2006a) employed a particular rhetorical ploy designed to evoke concern among other OG-PCOS researchers and practitioners observing the controversy. Interlinked with this, was Azziz' (2006a) suggestion that the inclusion of ovulatory and non-hyperandrogenic women within the PCOS diagnostic category - whose symptoms he had already argued to be extremely mild - would create the impression of a raised cardiovascular and metabolic risk among these groups without any sufficient supporting evidence for this. This raised the possibility of an unnecessary or unsubstantiated use of medical and/or financial resources among these groups. It would also position non-hyperandrogenic and ovulatory PCOS as synonymous in severity with the traditional, NIH-defined PCOS. This was something Azziz considered to be a serious misconception and one to which he was explicitly opposed.

5.7.4. Mobilising flexible repertoires and imagined communities

Azziz and his fellow Rotterdam opponents offered alternative explanations for the evidence on which the Rotterdam criteria were based, identified a paucity of research behind some of the decisions made at the Rotterdam Conference, and appealed to the risks of what could happen were they widely implemented in practice. Rotterdam opponents were also committed to presenting their own decision making as, by contrast, entirely supported and

substantiated by evidence. In 2006, a meeting[58] held by the Androgen Excess Society (AES)[59] - composed primarily of Rotterdam opponents including Azziz - established a special Task Force, which aimed to develop '*an evidence-based definition for polycystic ovary syndrome (PCOS), whether already in use or not, to guide clinical diagnosis and future research*' (AES Task Force, 2006: 4237). The report (2006) explained that:

> *The task force considered all data published and summarized above, emphasizing larger epidemiological and phenotypic studies, in arriving to its conclusions and recommendations regarding the phenotype of PCOS.*
>
> AES Task Force, 2006: 4241

Although the Task Force (2006) acknowledged the importance of taking PCO morphology into account in diagnosing PCOS, it also argued that:

> *Consistent with the recommendation (PCOS is a hyperandrogenic disorder) above, the task force felt strongly that in those women with polycystic ovaries but no evidence of clinical or biochemical hyperandrogenism, the diagnosis of PCOS is less certain, regardless of the presence of concomitant ovulatory dysfunction.*
>
> AES Task Force, 2006: 4241

A number of words and phrases in the above extracts indicate the level of subjectivity that was in fact involved in the Task Force's decision-making process. These include references to how the panel '*felt strongly'* and how a diagnosis of PCOS in non-hyperandrogenic women was '*less certain'.* This, alongside the report's inability to offer any definitive evidence for its 'evidence-based' nature, demonstrates the rhetorical nature of the report's framing of its recommendations and decision-making in this way. It is testament to what Mercer (1996: 46-47) refers to as scientists' 'use of flexible vocabularies for describing their own work relative to their opponents' according to different social contexts and various social interests' when embroiled in a scientific controversy. The AES Task Force report (2006: 4237) presented the conclusion that '*PCOS should be first considered a disorder of androgen excess*

[58] This was the 3rd meeting of the Androgen Excess Society, held on 3rd June 2005. The Special Task Force report that was produced as a result of this meeting was published in November 2006.

[59] The AE-PCOS Society (originally known as the Androgen Excess or AE-Society) formed during a meeting of the well-established Endocrine Society in Toronto in June 2000, during which Dr Richard Legro, Dr John Nestler, and Dr Ricardo Azziz identified the need for a new society focusing explicitly on issues of androgen excess. The Society was later renamed as the Androgen Excess and PCOS Society (AE-PCOS Society) in 2007, after it was agreed that PCOS represented the main androgen excess disorder (*AE-PCOS Society*, 2021).

or hyperandrogenism', and that '*there should be acceptance of the original 1990 National Institutes of Health criteria with some modifications*'.

At the AES meeting, Azziz (2006b) presented a paper entitled *Diagnosis of Polycystic Ovarian Syndrome: The Rotterdam Criteria Are Premature.* It is important to note Azziz' redeployment of the concept of *prematurity* in this paper and his re-attribution of this to the Rotterdam criteria. As well as labelling the Rotterdam criteria as '*premature'* in light of existing evidence, Azziz (2006b) placed great emphasis on what he considered to be the robustness of the evidence on which the 1990 NIH criteria for PCOS had been based and also made several appeals to the wider imagined scientific community of OG researchers and practitioners as a means of depicting the NIH criteria as the more useful, practically applicable of the two. Regarding the NIH criteria, Azziz (2006b) argued that:

> *Ample evidence is available to support the association of the two phenotypes included in both the NIH 1990 and the Rotterdam 2003 criteria (i.e. oligoanovulation, and hirsutism and/or hyperandrogenemia, with or without polycystic ovaries) with an increased risk for type 2 DM.*
>
> Azziz, 2006b: 783

Azziz (2006b) made this argument in spite of earlier criticisms within the 2004 Rotterdam report of the limited evidence behind the NIH criteria. As well as emphasising the quantity and quality of the evidence on which the NIH criteria had been introduced, Azziz (2006b) also stressed the frequency with which the criteria was being applied in clinical research and practice. He described how:

> *Polycystic ovary syndrome (PCOS) is defined most commonly according to the proceedings of an expert conference sponsored by the National Institutes of Health (NIH) in April 1990, which noted the disorder as having 1) hyperandrogenism and/or hyperandrogenemia, 2) oligoovulation, and 3) exclusion of known disorders.*
>
> Azziz, 2006b: 781

Azziz (2006b) presented a similar claim in his depiction of the 2003 Rotterdam criteria as having constituted merely an *expansion*, rather than a replacement of the criteria introduced in 1990. Azziz (2006b) was explicit that:

> *We should note that the Rotterdam 2003 criteria did not replace the NIH 1990 criteria, because all women diagnosable by the NIH 1990 criteria would also meet the Rotterdam definition (Table 2). Rather, it expanded the definition of PCOS, adding two*

> *additional phenotypes as PCOS, including women with 1) polycystic ovaries and clinical and/or biochemical evidence of androgen excess, but without ovulatory dysfunction, and 2) polycystic ovaries and ovulatory dysfunction, but without hyperandrogenemia and/or hirsutism (i.e. no signs of androgen excess).*
>
> Azziz, 2006b: 782

In both the above extracts, Azziz (2006b) mobilised another common rhetorical ploy during a scientific controversy. By stressing the acceptance of the NIH criteria among the wider OG community and positioning the new Rotterdam phenotypes as having expanded an existing and entirely functional set of criteria, Azziz made a rhetorical claim that the OG community was behind him and that the NIH criteria remained the most useful tool for diagnosing PCOS. This was a strategy that could shape critics' perspectives on the criteria and draw onlookers on the controversy closer into Rotterdam opponents' point of view.

In this section of the chapter, I have analysed the various rhetorical ploys used by Rotterdam opponents in their bid to challenge the Rotterdam criteria and present the older NIH criteria as the most useful diagnostic device for PCOS. In the next section of the chapter, I analyse the rhetorical ploys and strategies deployed by supporters of the Rotterdam criteria, many of which constituted direct responses to the narratives presented by Rotterdam opponents outlined above.

5.8. Navigating the Controversy: Rotterdam Supporters

Emblematic of the principal features of a scientific controversy, the papers analysed above attracted critical attention from the supporters of the Rotterdam criteria (Gieryn, 1983; Rees, 2009). This group of experts committed themselves to defending the evidence on which the Rotterdam criteria were based and to highlighting the criteria's value in enabling the full breadth and spectrum of PCOS symptoms to be recognised. These experts are referred to as *Rotterdam supporters* from hereon in the thesis. Like Rotterdam opponents, Rotterdam supporters employed various rhetorical strategies in their efforts to navigate and attempt to close the controversy. Rotterdam supporters also made appeals to the wider imagined scientific community of OG, attributed the characteristics of *breadth* and *inclusivity* to the Rotterdam criteria, and engaged in the construction and mobilisation of a discourse around patient wellbeing, presenting this as a concern and priority exclusive to the Rotterdam criteria.

5.8.1. Attributing characteristics of 'breadth', 'inclusivity' and 'heterogeneity'

I begin this part of the analysis by considering Franks' (2006) paper, entitled, '*Diagnosis of Polycystic Ovarian Syndrome: In Defense of the Rotterdam Criteria'*. The title of this paper reflected its aim, which was to '*to review and justify the basis'* for the definition and criteria for PCOS introduced at the Rotterdam Conference (Franks, 2006: 786). Franks' paper was published around the same time as Azziz' (2006b) paper. It is difficult to determine which of these papers were written first, since the publication date for both is March 2006 and neither paper cites the other. Nonetheless, the timing is significant, since it provides an insight into just how active both Rotterdam opponents *and* supporters were at this stage of the controversy. Franks' (2006) paper placed persistent emphasis on the *breadth* and *inclusivity* in diagnosis facilitated by the Rotterdam criteria. He argued for example that:

> *The Rotterdam criteria take account of the broad spectrum of presenting features of PCOS, including women with hyperandrogenism but regular menses and, more controversially, those with menstrual disturbance without overt androgen excess. In my view, the Rotterdam definition is much more appropriate in this era in which the broader spectrum of clinical and biochemical presentation of women with polycystic ovaries has been widely acknowledged.*
>
> Franks, 2006: 786

By attributing these characteristics to the Rotterdam criteria, Franks (2006) was able to present the Rotterdam criteria as representing an apt embodiment of more recent findings on the heterogeneity of PCOS and to sustain the contrast-case laid out by the 2004 Rotterdam report between the timely Rotterdam criteria and the outdated 1990 NIH criteria. Franks (2006) also referred to the diagnostic category's broader history, using this as a rhetorical device to demonstrate heterogeneity as having constituted a longstanding characteristic of PCOS and to counter the claim that its recent incorporation had been hurried or ill-considered. Franks (2006) outlined how:

> *References to what we now recognize as PCOS can be found in scientific publications dating back to the 19th century, but in modern times, the syndrome was first clearly described in the classic paper by Stein and Leventhal in 1935 (7). In their series, the typical polycystic ovarian morphology was the common finding in a group of patients who had amenorrhea and clinical evidence of androgen excess. Nevertheless, even in this classic reference series, heterogeneity of presentation was apparent; not all patients were hirsute, and three showed evidence of recent ovulation (7).*
>
> Franks, 2006: 786

The above extract constituted a response to Azziz's (2005: 1345; 2006a; 2006b) representation of the Rotterdam criteria as having been a '*premature*' addition to the traditional NIH criteria. It suggested that the Rotterdam criteria's incorporation of a significantly broader spectrum of women with PCOS was not just timely, but long overdue. This reciprocal exchange between experts of alternative perspectives and viewpoints is emblematic of the continuous dialogue and alternative representations of scientific developments, history, and evidence, that are so common within scientific controversies (Collins, 1975; 1981; Rees, 2009).

5.8.2. Countering dismissals of evidence

Franks also referred to more recent evidence that he considered to support Rotterdam's inclusion of women with regular ovulation, PCO morphology and HA within the PCOS spectrum. Franks responded to Azziz's (2005; 2006) emphases on the apparent mildness of the ovulatory PCOS phenotype, as well as to his claims that the evidence base for their inclusion remained limited, by explaining that:

> *It was really the application of high definition ultrasound imaging of the ovaries in the 1980s that first highlighted the finding that polycystic ovaries were very commonly associated with hirsutism and hyperandrogenemia in women with regular, ovulatory cycles. The question that arose was are such women part of the same spectrum of presentation as classic PCOS, as defined by the NIH criteria? There is much evidence to suggest that the answer is yes (12). The results of more recently published data have confirmed that women with regular cycles and polycystic ovaries share many of the biochemical features of PCOS. Such evidence includes data from studies of familial PCOS in the search for the genetic basis of the syndrome. Probands presenting with classic features of PCOS, anovulation and hyperandrogenism, may have an affected sister who is equally hyperandrogenemic, but has regular cycles and polycystic ovaries.*
>
> Franks, 2006: 787

Franks' (2006) use of citation 12 was a reference to the same study by Carmina and Lobo (2001) employed in the Rotterdam report to justify their inclusion of an ovulatory phenotype *and* in Azziz' (2005) paper stressing the apparent mildness of this phenotype relative to its expression in women with traditional NIH-defined PCOS. While Azziz (2005) interpreted this evidence as indicative of the relative triviality of the issue of an ovulatory PCOS contingent, Franks (2006) emphasised the significant similarities between ovulatory and anovulatory women with PCOS; this undermined the implication that the apparent mildness of the

ovulatory PCOS contingent rendered it less important than, or unequal to, anovulatory PCOS. Azziz (2005) argued that further evidence was required to justify the inclusion of the ovulatory phenotype, while Franks (2006) considered the available evidence more than sufficient.

5.8.3. Countering alternative explanations

It was not just Franks (2006) who offered a rhetorical response to the strategies and claims presented by Azziz (2005) in a bid to defend the Rotterdam criteria and justify its continued use. Dewailly (2006) responded directly to Azziz's (2005) alternative hypotheses that the presence of PCO morphology in non-hyperandrogenic women could be the result of a number of other conditions independent of PCOS, with a letter which was published in the same journal. Dewailly's (2006: 529) letter[60] acknowledged the '*controversy*' that surrounded Rotterdam's introduction of a non-hyperandrogenic PCOS phenotype, but also argued that, given the continued difficulties the field was facing in developing a precise and measurable definition for HA, definitions of some women as non-hyperandrogenic were equally unlikely to be precise or reliable. On the surface, this might be interpreted as having supported Azziz' claims regarding the prematurity of the inclusion of this particular group in the PCOS diagnostic criteria. Dewailly however, mobilised it in a way that suggested that the exclusion of this group could be deemed equally premature and unsubstantiated by sufficient evidence and that the same applied to Azziz's (2005) alternative hypothesis for explaining the symptoms presenting in this group. It was on this basis that Dewailly's (2006) letter to Azziz (2005) presented the following question:

> *Even though some women with polycystic-like ovaries at ultrasound (U/S) were strictly normoandrogenic[61], should this phenotype be excluded from PCOS? Dr. Azziz seems to recommend this, arguing that polycystic ovaries (PCO) are not specific of PCOS because a multifollicular ovarian pattern, the cornerstone of the U/S definition of PCO is encountered in other situations such as functional hypothalamic amenorrhea (FHA) or hyperprolactinaemia (HPRL). This introduces the very disputable issue of whether multifollicular ovaries (MFO) are PCO or not. Most of the studies that Dr. Azziz quoted about this issue are outdated and did not use a consensual threshold for the number of small (2–9 mm) follicles at U/S to define the multifollicularity. As far as PCO are concerned, we set this threshold at 12/whole*

[60] Dewailly's (2006) letter to Azziz, which was response to Azziz's 2005 paper published in *Fertility and Sterility*, *Diagnostic criteria for polycystic ovary syndrome: a reappraisal*, was written in September 2005, but published in the February 2006 edition of *Fertility and Sterility.*

[61] 'Normoandrogenic' refers to women with normal levels of androgens, as opposed to excess levels which is referred to as hyperandrogenism (HA).

> *ovary because it was the one that discriminated the best between PCOS and normal women. Whether this threshold is appropriate to distinguish MFO from PCO has not been investigated so far. Therefore, there is still much confusion about the definition and significance of MFO in the literature. I agree that MFO may not always be PCO, but in the absence of histological data about MFO, it is not known whether all stages of follicular growth are involved, and thus, whether or not they represent a distinct entity from PCO.*
>
> Dewailly, 2006: 529

In the above extract, Dewailly (2006) applied the same rhetorical strategy applied by Azziz in his 2005 paper but to opposite effect. He pointed out the inadequacies of the evidence on which Azziz had based his recommendations, reinforcing his argument that if the inclusion of non-hyperandrogenic women in the PCOS diagnostic spectrum had been premature, then by extension, so too was the labelling of PCO morphology as non-specific to PCOS. As argued by Barnes, Bloor, and Henry (1996: 26), 'the gap between observation and interpretation is clear: both may observe the same thing, but the interpretation involves bringing to bear the resources of a tradition'. This is perfectly encapsulated in this instance, in which Dewailly (2006), like Azziz (2005), was able to invoke his own interpretation of Azziz's evidence in a way that was concordant with his own commitment towards maintaining a broader set of diagnostic criteria for PCOS. While Azziz (2005) was content with the thresholds applied in the studies he cited, Dewailly (2006) considered them insufficient for undermining the claim that PCO morphology in non-hyperandrogenic women should not be included. Dewailly identified a need for further evidence to be generated regarding the most appropriate threshold for distinguishing between MFO and PCO morphology.

In their study of non-hyperandrogenic women with PCO morphology and irregular menses, Dewailly et al. (2006) generated findings that pointed to the inconsequentiality of HA in some women with PCOS. This was in contrast to Azziz (2005), who had highlighted what he considered to be the disadvantages - both to future advancements in PCOS research and to the increased likelihood of misconceptions among women diagnosed with either of the two newly introduced PCOS phenotypes - generated from the inclusion of women with much milder symptoms of PCOS, including those with the ovulatory phenotype. Dewailly et al. (2006: 3925) on the other hand, declared that '*phenotype C, so-called ovulatory PCOS in the literature, does not suffer from controversy anymore'.* This is an example of the deployment of a rhetorical strategy by Dewailly et al. (2006), similar in nature to Azziz's (2006b) appeal to

the wider imagined community of OG but, motivated by an alternative interpretation of the same medical phenomenon and associated body of evidence. Dewailly et al. (2006) presented the existence of the ovulatory phenotype as established science. Azziz's alternative take on this issue demonstrates that the issue was not in fact established science, at least not among Rotterdam opponents; it also suggests Dewailly's representation of this issue to have been a rhetorical ploy, designed perhaps to draw in undecided or indifferent onlookers further in line with Rotterdam supporters' perspective. In reporting their findings, Dewailly et al. (2006) described how:

> *Our data indicate that patients with nonhyperandrogenic OA (phenotype D) had in fact slightly but significantly higher mean androgen levels than controls, although by definition all individual values were within the normal range. This raises the question about the validity of using an upper normal threshold for the androgen data as a yes or no answer to the question of whether this patient is normo- or hyperandrogenic?...*
>
> *For this reason, we think that the absence of overt HA might simply represent a false-negative finding in many of our patients with phenotype D and that it is not sufficient by itself to preclude the diagnosis of PCOS…*
>
> *Therefore, on condition that FHA is carefully excluded before applying the Rotterdam criteria, as we did in the present study, we and others think that the risk is low for the Rotterdam definition to include erroneously non-PCOS ovulatory disorders. Lastly, one should also consider the possibility that both FHA and PCOS could coexist in the same patient. It has been recently reported that some women with FHA caused by anorexia nervosa had genuine PCO at U/S that were previously associated with hyperandrogenic symptoms before the patients became amenorrheic and turned off their LH secretion because of food restriction.*
>
> Dewailly et al. 2006: 3925, 3926

In the above extract, Dewailly (2006) presented another challenge to Azziz (2006a), this time targeted at his hypothesis that a closer similarity existed between FHA and non-hyperandrogenic PCOS than between non-hyperandrogenic PCOS and the ovulatory and hyperandrogenic contingents of the condition. Here Dewailly (2006) presented his own alternative hypothesis, raising the possibility that FHA and non-hyperandrogenic PCOS could in fact co-exist. In doing so, Dewailly (2006) presented yet another theory that fit with the evidence being presented. At this point in the controversy therefore, four alternative explanations of the same body of evidence relating to the presence of PCO morphology in non-hyperandrogenic, anovulatory women had been presented. Dewailly et al. (2006) concluded their paper by reporting that:

> *In conclusion, our data indicate that OA with PCO but without overt HA constitutes a phenotype that has subtle PCOS endocrine and metabolic features and is presumably the mildest form of PCOS, with minimal insulin resistance. Whether this phenotype shares the same long-term risks as the classical PCOS remains to be elucidated to inform the patients appropriately.*
>
> Dewailly et al. 2006: 3926

In the above extract, another call was made, this time by a Rotterdam supporter, regarding the need for more evidence to be generated to illuminate the degree of long-term metabolic and cardiovascular risk faced by women with non-hyperandrogenic PCOS. These persistent calls for more evidence, presented by experts on both sides of the debate, were at odds with the trajectory through which the controversy had so far played out. Newly presented evidence was repeatedly met with competing interpretations and explanations, rendering it insufficient to generate consensus and resolve the controversy.

5.8.4. Appeals to 'scientific authority' and to 'patient care'

Franks continued his own defence of the Rotterdam criteria in a co-authored 2009 paper with Balen and Homburg (referred to hereon as Balen et al. 2009). In contradiction of Azziz's (2006) claim that the NIH criteria represented the most commonly applied definition for PCOS, Balen et al. (2009: 1) argued that '*the Rotterdam criteria have been accepted throughout the world and are now used in most studies and publications'.* Balen et al. (2009) used this rhetorical strategy in a bid to claim that the Rotterdam criteria have 'scientific authority' (Gieryn, 1983; Ramírez-i-Ollé, 2015: 384) internationally across the field of OG. Balen et al. (2009) also mobilised a specific appeal to patient care and depicted this as a focus and concern exclusive to the Rotterdam criteria. They argued that:

> *The Rotterdam consensus definition provides a helpful framework for the diagnosis and management of PCOS. A pragmatic approach is required in diagnosing the syndrome, and other causes of menstrual cycle disturbance and hyperandrogenism should be excluded. Too exclusive a definition would leave many women at the milder end of the spectrum without a diagnosis, even though they have equal rights for medical care and management of their symptoms. PCOS is associated with substantial psychological morbidity and a negative effect on quality of life, even in adolescence, whether related to the dermatological manifestations, disturbed menstrual cycle, subsequent infertility, or associated obesity and metabolic problems.*
>
> Balen et al. 2009: 2

This appeal to patient care came relatively late on in the controversy and related specifically to growing evidence within OG-PCOS literature of the profound psychosocial impact PCOS can have on women across the diagnostic spectrum. The growth in this kind of evidence within the OG-PCOS research landscape reflected a change taking place in medicine more broadly, through which medicine's increasing adherence to a patient-centred model of care brought with it a proliferation in the 'biopsychological perspective' on health (Scambler and Morgan, 2018: 59). This is a perspective that emphasises 'social and psychological as well as biomedical aspects of illness and the meanings for individuals' (Scambler and Morgan, 2018: 59). It signified that, during this time in medical research and practice, the social and psychological implications of physical illness and its potential to negatively impinge on quality of life were becoming increasingly recognised.

By drawing on a body of narratives that were becoming increasingly prevalent in medicine more broadly (Scambler and Morgan, 2018), Rotterdam supporters were able to strengthen their case for the importance of inclusivity and breadth within the PCOS diagnostic category. They presented the Rotterdam criteria as a resource more suited to accommodating for the '*equal rights*' of patients and for managing and eliminating the risks of missed diagnosis and the associations between PCOS, psychological issues, and impaired quality of life (Balen et al. 2009: 2). Drawing on these narratives provided Rotterdam supporters with a powerful new rhetoric through which concerns raised about the impact of a broad PCOS diagnostic category on research or in generating misconceptions about the condition, could be countered with an emphasis on the need to prioritise patient care and equal access to diagnosis and treatment. It also meant that Rotterdam opponents' mobilisation of a discourse of risk, which pointed to the apparently limited metabolic and cardiovascular risks presented in the newer, milder phenotypes of the condition, could be undermined by Rotterdam supporters' mobilisation of a discourse concerning the importance of patient care and quality of life across the entire PCOS diagnostic spectrum.

5.9. The Underdetermination of Evidence

Emblematic of the underdetermination of evidence by theory - whereby the evidence available is always insufficient for providing conclusive answers (Barnes, Bloor, and Henry, 1996; Duhem, 1954; MacKenzie, 1989) - Rotterdam opponents and supporters used rhetoric to demonstrate the consistency of each body of evidence with their own perspectives, traditions, and beliefs. This is a common feature of scientific controversies and in this section

of my chapter, I reflect on the ways in which evidence as underdetermined by theory and belief maintained and shaped the playing out of this controversy, so that by 2010, consensus within the field seemed far out of reach.

The influence of the underdetermined nature of evidence in the initial onset of the controversy was brought to the fore after the failure of the Rotterdam Conference - in spite of the consensus that was generated at the Conference itself - to produce a consensus which translated across the field as a whole. The proliferation in publication activity and the continuous dialogue that unfolded between experts with differing views on the diagnostic criteria was testament to this. The Conference's inability to bring about consensus stemmed from the fundamental differences that existed between the agreements reached at the Conference and Rotterdam opponents' interpretations of PCOS. As Barnes, Bloor, and Henry (1996: 37) argue, scientists see and understand scientific knowledge, evidence, and practice through the lens of 'local interpretive tradition'. It is when these traditions fundamentally differ between scientists, for instance divergent similarity relations for classification/diagnosis, that disputes unfold. For Rotterdam opponents, HA was an intrinsic feature of PCOS and any evidence of the presence of PCOS symptoms - such as PCO morphology or anovulation - without HA, was without question the result of scientific error or insufficient data or indicative of a physiological phenomenon distinct from PCOS. For Rotterdam supporters, the PCOS diagnostic spectrum existed beyond and without HA and any evidence suggesting that non-hyperandrogenic women could not present with PCOS was itself the product of scientific error or insufficient data.

The alternative traditions and conventions that framed Rotterdam opponents' and supporters' competing interpretations of evidence meant that each side was unable to accept the importance of one another's reading and representation of PCOS. This was epitomised in those instances in which each side interpreted the exact same body of PCOS-related evidence in very different ways. For instance, the Rotterdam report (ESHRE/ASRM, 2004) considered evidence by Carmina and Lobo (2001) suitable grounds on which to significantly expand the PCOS diagnostic criteria to include ovulatory women with PCOS. Azziz (2005) on the other hand, considered this premature and interpreted this exact same strand of evidence as indicative of the mildness of this combination of PCOS features and the need for more evidence to determine the extent to which it could be considered constitutive of PCOS. Similarly, the exchange of letters that took place between Azziz (2005) and

Dewailly (2006) was further testament to the endless potential for evidence to be interpreted differently by scientists of different perspectives and traditions. While Azziz (2005) drew on evidence that he considered to indicate a closer similarity between non-hyperandrogenic PCOS and FHA rather than to PCOS, for Dewailly, this similarity was in fact indicative of the co-presence of FHA and non-hyperandrogenic PCOS within the same patient.

The inherently underdetermined nature of scientific evidence also offered Rotterdam opponents and supporters considerable scope for dismissing or challenging evidence that did not conform with their own perspective. The identification of insufficiencies in an opponent's evidence base, or the deployment of alternative explanations for evidence which does not concord with an expert's own theoretical standpoint or beliefs, are common practices in controversies (Dietrich and Skipper, 2007; MacKenzie, 1989). The PCOS controversy was no exception. As argued by MacKenzie (1989: 412), 'a sufficiently determined critic can always find reasons to dispute any alleged "result"'. This was epitomised in Dewailly's (2006) inversion of Azziz's (2005) attribution of 'prematurity' to the Rotterdam criteria through his identification of insufficiencies in the thresholds used by Azziz (2005) between MFO and PCO morphology; this was something which, from Dewailly's viewpoint, rendered Azziz's evidence base equally premature. It was also epitomised in the range of alternative hypotheses Azziz (2005) invoked for explaining the presence of PCO morphology and irregular menses in non-hyperandrogenic women; this is an example which demonstrates the extent to which 'for any finite body of evidence, there are indefinitely many mutually contrary theories, each of which logically entails the evidence' (Laudan, 1990: 269).

It was as a result of the fundamental differences in viewpoint between Rotterdam supporters and opponents and the incapacity for evidence to resolve these differences, that the PCOS controversy ensued and that persistent calls for new evidence proved fruitless. Invariably, any newly produced evidence was met with opposing interpretations by Rotterdam supporters and opponents. As a result, Rotterdam supporters' and opponents' continual preoccupation with debating and generating new evidence not only epitomised this stage in the playing out of the controversy, but also maintained and prolonged it.

5.10. Chapter Summary

This chapter has traced the onset and playing out of a controversy within the field of OG-PCOS research and practice between 1990 and 2010. It outlined the increasing contention and divisions that developed in the OG-PCOS research field following the 1990 NIH-NICHD Conference and its decision to retain a more traditionalist definition and set of diagnostic criteria. These divisions became evident in experts' divergent interpretations of the broader significance of a newly identified similarity between ovulatory women with PCO morphology and HA and women presenting with traditionally defined PCOS. While more inclusivity focused experts favoured the expansion of the PCOS diagnostic criteria, more traditionally focused experts were opposed to this idea and committed themselves to defending the 1990 NIH criteria and its centralisation of HA as a requisite feature of PCOS. The increased routinisation of ultrasound technology however, laid down strong foundations for a new broader set of criteria for PCOS and these were introduced and devised at the 2003 Rotterdam Conference.

I identified the Rotterdam Conference and its newly devised diagnostic criteria for PCOS as having represented an important turning point in the evolution of disagreement and contention within the OG-PCOS research field into an outright controversy. This was on account of the tidal wave of disagreement that ensued within the field, as a stark division unfolded between OG-PCOS experts who supported the Rotterdam criteria and those who were opposed to it. These competing sides, Rotterdam opponents and supporters, became embroiled in an endless series of rhetorical exchanges and continuously and strategically deployed alternative explanations of evidence in a way that was concordant with their own interpretation of the PCOS diagnostic spectrum. It was both sides' preoccupation with evidence, and with generating more evidence, that prolonged and maintained the controversy. Rotterdam supporters' later appeal to the issue of patient care however, which depicted the Rotterdam criteria as a valuable resource for meeting the biomedical, psychological, and social needs of *all* women with PCOS and not just those with the most traditionally defined contingent of symptoms, represented an important shift in OG-PCOS discussions and in medicine more broadly. The psychological and social wellbeing of women with PCOS had, up to this point in the controversy, scarcely been mentioned. The mobilisation of these issues as a rhetorical strategy by Rotterdam supporters foreshadowed

what would become their centralisation within the controversy, as explored and presented in the next chapter of this thesis.

Chapter 6. 2011 - 2019: The Development of a 'Patchwork Agreement'

6.1. Introduction

This chapter examines the continued playing out of the controversy explored in the previous chapter, focusing this time on developments in OG-PCOS literature published between 2011 and 2019. The analysis pays attention to a notable shift in the dynamics and content of the controversy and in the exchanges that took place between Rotterdam supporters and opponents during this time. It argues that although the controversy was not closed or resolved, its intensity subsided significantly so that the field of OG-PCOS research was able to divert its focus to issues aside from the ontological intricacies of the PCOS diagnostic category. In this chapter, I highlight the emergence of patient voices within the controversy and the attention these drew to the pronounced physical and emotional implications of PCOS. I then go on to map the emergence of lifestyle factors as a source of treatment for PCOS and their role in the fundamental shift within the controversy during this time.

I argue that as a result of the incorporation of patient voices and the increasing invocation of lifestyle factors within the OG-PCOS research landscape, Rotterdam supporters and opponents became less concerned with demonstrating the flaws in one another's evidence base and with calling for new evidence to resolve the controversy. Instead, to keep pace with the changes occurring in the field, Rotterdam opponents and supporters actively contributed to the development of a functional definition for PCOS; this was a definition that would work for OG-PCOS clinical practice and research, but which also embodied as much of their own respective interpretation of the PCOS diagnostic category as possible. I consider this definition to have represented a state of 'patchwork agreement' in the field. I define this as a temporary acceptance by Rotterdam opponents and supporters of a definition for PCOS that did not adhere completely with their varying perspectives on the specific ontological components of PCOS, but which enabled both sides, and the field as a whole, to move on from these debates and to focus their research efforts on other aspects of PCOS, most notably those of patient treatment and care.

6.2. The Emergence of Patient Voices and a Change in the Diagnostic Landscape

Over the last two decades, the domains of health and medicine in western countries have sought increasingly to engage patients and consumers in biomedical research and in healthcare policy- and decision-making (Moreira, 2015; Rabeharisoa et al. 2014). Simultaneously, patient and consumer groups have expanded the scope and reach of their

activities; they have strived not only to represent and inform their members but also to contribute to guideline development and clinical research, not as 'passive subjects' but as 'active partners in research' (Carter et al. 2013: 308; Rabeharisoa et al. 2014). Clinical practitioners - whose knowledge is distinct from that of academic medical experts in that it is developed primarily within the clinic - have also become involved in these activities, co-producing knowledge alongside patients and academics and becoming increasingly receptive to patients' accounts of their experiences beyond the clinic (Carter et al. 2013). The ongoing controversy over PCOS diagnosis is embedded within the context of these broader changes. From 2011, a number of PCOS patient and consumer groups, as well as collaborative alliances between patients, academics and clinicians, became increasingly active and influential in OG-PCOS literature.

In this first section of my chapter, I explore the ways leading OG-PCOS experts who were not embroiled in the controversy, employed and incorporated patient voices within OG-PCOS literature as a mechanism for breaking the deadlock between Rotterdam opponents and supporters. By incorporating new and diverse patient voices and invoking a more active discussion of patient treatment and needs, these experts were able to facilitate a move within the field away from the internal conflicts over the 'correct' signs and symptoms of PCOS, which had consumed the field for more than two decades, and towards a subsequent dilution in the controversy's intensity. In exploring this distinctive change within the PCOS diagnostic landscape, I analyse the content and recommendations of two separate reports - the 2011 Australian Task Force report (Jean Hailes, 2011; Teede et al. 2011)[62] and the 2012 NIH report. Together, these reports played a pivotal role in generating new questions that were intended to alter the course of the controversy. The 2011 Australian Task Force report shed light on some of the ways through which the wide-ranging emotional and physiological implications of PCOS could be managed and treated, drawing particular attention to the importance of lifestyle management in PCOS. The report identified a host of new questions and issues relating to PCOS management and treatment in need of further research, many of which were acknowledged by, and fed into, a separate report by the NIH in 2012. On account of the power and authority held by the NIH as a medical research institution and a

[62] The 2011 Australian Task Force report was published in two different formats - a summary report by Teede et al. 2011, and a more detailed report by the Jean Hailes Foudation. I refer to and use both of these citations throughout my analysis of the report (Jean Hailes, 2011; Teede et al. 2011).

landmark proposal it presented for a phenotypical approach to the application of the Rotterdam criteria, the NIH's 2012 report brought about a pronounced shift in the direction and dynamic of the OG-PCOS controversy and required Rotterdam opponents and supporters to fundamentally reconsider their positions regarding PCOS diagnosis. The new questions raised by the 2011 Australian Task Force report, followed by their acknowledgement and widespread dissemination by the NIH (2012), significantly altered the PCOS diagnostic landscape.

6.2.1. A co-productive approach to PCOS guideline development

The 2011 Australian Task Force report stood out within the literature because of its co-productive approach towards evidence evaluation and knowledge production and its explicit focus on the management of lifestyle and emotional wellbeing in women with PCOS. These components of the report rendered it distinctive from the consensus reports and guideline recommendations that had been published previously in the controversy, which were primarily the work of leading OG-PCOS academic researchers whose central focus was on evaluating and establishing how best to define PCOS as a diagnostic category (NIH, 1990; ESHRE/ASRM, 2004; AES Task Force, 2006; ESHRE/ASRM, 2008). The Task Force report was co-produced by three different organisations - the Australian PCOS Alliance (an organisation of Australian PCOS academic experts), the Jean Hailes Foundation (a not-for profit organisation which researches Women's Health), and the Polycystic Ovary Syndrome Association of Australia (POSAA - Australia's national support group for PCOS) - and involved academic, clinical, and "consumer" representatives in every stage of its development.

The report's mobilisation of these three different types of expertise meant that it drew attention to an extensive range of issues in patients' PCOS experiences that were so far relatively underdeveloped within OG-PCOS literature and that carried the potential to generate new questions and research priorities that might alter the course of the controversy. These related to the role of ethnic variation and socio-economic factors in shaping PCOS experiences, the emotional and psychological features of PCOS, and the benefits of lifestyle change and of a more multidisciplinary approach to PCOS diagnosis and care. The Task Force also consulted seventeen different voluntary and professional expert organisations across a diverse range of professions and specialties - including the Royal Australian College of General Practitioners, the Dietetics Association of Australia, and the Australian Psychological Society - contributing to its mobilisation of a distinctly

multidisciplinary mode of expertise and allowing it to present a broad range of treatment recommendations for PCOS. The report's lead author and research director was Dr Helena Teede[63] who, despite a longstanding endocrinological research interest in PCOS and in engaging consumers and the wider community in healthcare research, was a relatively new voice within the controversy and unaffiliated with the Rotterdam opponents and supporters who had dominated the research discourse.

6.2.2. New voices and new questions

Reflective of the Task Force's commitment to exploring issues of emotional wellbeing in PCOS, an *Emotional wellbeing guideline development group* was established as part of the process of convening the report (Jean Hailes et al. 2011; Teede et al. 2011). In the Task Force's published report (Jean Hailes et al. 2011; Teede et al. 2011), the *Emotional wellbeing* group presented extensive recommendations around the issue of emotional wellbeing in PCOS. Although within OG-PCOS research, the implications of PCOS for quality of life and emotional wellbeing had been considered by a minority of papers (Balen et al. 2009; Coffey and Mason, 2003; Coffey et al. 2006; Deeks et al. 2010; Himelein and Thatcher, 2006; Teede et al. 2010), practical recommendations regarding how to treat and address these issues were scarce. The 2011 Australian Task Force began the process of addressing this gap; it recommended that practitioners screen all women with PCOS for a wide range of psychological issues, including anxiety and depression, negative body image, disordered eating and eating disorders, and psychosexual dysfunction. The report contained specific screening questions and detailed further assessment and referral procedures to be conducted in clinical practice (Jean Hailes et al. 2011; Teede et al. 2011). The report also identified the management and treatment of emotional wellbeing in PCOS, including '*across the different cultural and age groups affected by PCOS',* as an area requiring extensive additional research (Jean Hailes et al. 2011: 59). The report's authors subsequently drew attention to a host of unanswered questions regarding how best to optimise emotional wellbeing in PCOS through medical treatment and care. In shedding light on an otherwise underdiscussed element of PCOS experiences, the 2011 Australian Task Force report opened

[63] By this point in the controversy, Teede had published multiple papers on a wide range of PCOS-related issues but had not commented in depth on the contentious issue of PCOS diagnosis. From 2011 however, Teede was the lead author of three key publications which actively engaged PCOS consumers and patients in the development of guidelines aimed at improving the lives of women with PCOS, in part by creating greater clarity over the issue of diagnosis.

up an avenue of research and discussion distinct from those taking place between Rotterdam opponents and supporters over definitional issues in PCOS. However, this important and powerful example represents just one component in the foundations laid down by the incorporation of patient voices within OG-PCOS literature that facilitated a fundamental shift in the controversy's direction and intensity.

Alongside the proliferation in patient involvement in clinical research and guideline development over the last two decades (Moreira, 2015), concerns have been raised about the extent to which minority ethnic groups are adequately represented and engaged within these activities (Dawson et al. 2018). This has been particularly important in the context of PCOS clinical research and guideline development because of growing speculation and acknowledgment of the role of ethnic variation in influencing PCOS symptomology and expression (Kalra et al. 2009; Kauffman et al. 2008; Kauffman et al. 2011; Kim et al. 2010; Legro et al. 2006; Lobo, 2003; Teede et al. 2010; Zain et al. 2009; Zhao et al. 2010). It has also been important more generally, because of the widespread 'inequalities in care' and 'specific health and social care needs' commonly experienced by minority ethnic groups (Dawson et al. 2018: 4). The 2011 Australian Task Force report set about addressing this gap, actively seeking representation from Indigenous women with PCOS[64]. Indigenous people make up an estimated 3.3% of the Australian population (*AIHW*, 2021) and face heightened levels of social and material deprivation (Hunter, 2007; Jean Hailes, 2011; Redmond and Skattebol, 2019).

The 2011 Australian Task Force report identified Australia's Indigenous women as being at increased risk of developing PCOS and more severe PCOS symptomology. It also emphasised the impact of limited access to '*culturally appropriate care, services and programmes*' and '*socioeconomic factors such as poverty and overcrowding'* on Indigenous women's experiences of PCOS (Jean Hailes, 2011: 29). The report acknowledged that some of its recommendations could be more applicable to Australia's non-Indigenous population than to Indigenous women with PCOS and raised awareness of the need for this disparity to be addressed at an institutional level (Jean Hailes, 2011). The report's engagement with new

[64] The Task Force was clear that they used the term 'Indigenous' to refer to '*all Aboriginal or Torres Straight Islanders'* (Jean Hailes et al. 2011: 27).

and diverse voices in developing its guidelines, strengthened the quality and credibility of the experiential expertise it contained and made it more applicable and adaptable to the needs of the Australian population at large. It also raised a distinctive set of questions about the impact of structural inequalities in shaping PCOS experiences and access to adequate treatment and care. This enabled the report's authors to draw attention to the need for increased research regarding the optimisation of PCOS treatment and care for women from marginalised groups. It contributed further to the foundations laid down by the 2011 Australian Task Force report and its incorporation of patient voices in facilitating a fundamental shift in OG-PCOS discussions and debates.

6.2.3. Lifestyle treatment recommendations

In placing its focus firmly on women's PCOS experiences and on the most effective modes of treatment and care for different women with PCOS, the 2011 Australian Task Force report simultaneously drew attention to the role of individual life course factors in influencing experiences of the condition and the extent to which it progresses over time. In the introduction to the report, it explained for example that:

> *The clinical implications of PCOS are broad and vary across the lifespan. Whilst reproductive features are prominent, PCOS has potential for major metabolic consequences including obesity and related type 2 diabetes (DM2) and cardiovascular disease (CVD), all currently national health priority areas. It also has significant mental health and psychological impact, impairing quality of life (QoL). Overall PCOS has significant health and economic costs. With increasing obesity exacerbating incidence, prevalence and severity of PCOS and weight loss improving reproductive, metabolic and psychological features, lifestyle change should be first-line PCOS therapy. Currently 70% of Australian women with PCOS remain undiagnosed, clinical practice is inconsistent, psychological issues are neglected and there is little focus on lifestyle and prevention with most services targeting infertility and costly assisted reproductive technology.*
>
> Jean Hailes, 2011: 6

The above extract identified obesity as an exacerbator for PCOS prevalence and severity, highlighted the long-term health risks believed to present from PCOS, and the extensive economic costs associated with the condition. Despite recognition of the role played by structural inequalities in shaping PCOS experiences and severity in some parts of the report, the Australian Task Force ultimately laid out an individualised course of action for treating and managing PCOS and identified lifestyle change as representing 'first-line PCOS therapy'

(Jean Hailes, 2011: 6). In discussing lifestyle treatment in the context of its cost-effectiveness and efficacy in reducing the long-term health risks presented by PCOS, the report was engaged in the delivery of a process of 'lifestyle drift' (Williams and Fullagar, 2019). It recognised the wider structural factors that influence social inequalities in PCOS expression and prevalence but at the same time, and somewhat counterintuitively, identified individualised lifestyle change as the ultimate solution to this issue.

The Australian Task Force's individualised approach to managing and treating PCOS was also evident in the language it employed when referring to women with PCOS, consistently employing the term 'consumers' rather than 'patients'. This suggested that the Task Force viewed women with PCOS, not as 'passive recipient(s)' of patient care but instead, as 'active choice maker(s)' with the freedom and responsibility to decide which health services they pay for (Clarke, 2004: 39, brackets added; Williams and Fullagar, 2019). On one level, this facilitated the report's enhanced focus on the varying treatment options available to women with PCOS and on women's freedom and agency to choose, thus shifting attentions away from issues relating to PCOS diagnosis and definition. In emphasising individual decision-making as important in the management of PCOS however, it simultaneously invited a more explicit focus on the influence of individual lifestyle choices on PCOS. The report invited further discussion and consideration of the role of lifestyle in treating and managing PCOS by providing a multitude of wide-ranging lifestyle-orientated recommendations for necessary future research into PCOS. These included recommending research into:

- *The extent of the benefits of lifestyle management compared to no or minimal treatment for all clinically relevant outcomes*
- *The effect of lifestyle management for women who are both overweight and not overweight and specific reproductive outcomes such as menstrual regularity, ovulation and fertility and the relative efficacy of lifestyle management either compared to or in combination with pharmacological therapy*
- *The types, intensities and delivery methods of exercise strategies that are optimal for lean and overweight women for improved clinical outcomes*
- *A range of diet compositions including low GI [Glycaemic Index[65]] for both prevention of weight gain/weight maintenance and weight loss in women who are overweight and in women who are lean*

  Jean Hailes, 2011: 84

The research recommendations provided by the Australian Task Force presented lifestyle management as important for all women with PCOS and advocated more targeted and tailored lifestyle management in overweight or obese women with PCOS. Thus, lifestyle management interventions were identified as centrally important research priorities for OG-PCOS research. This strengthened the report's potential and capacity to instigate a fundamental shift in discussions taking place within OG-PCOS literature, moving the focus from its internal controversy about the ontological intricacies of PCOS as a diagnostic category towards a focus on issues of lifestyle treatment and on women with PCOS themselves. Alongside this though, providing that these research priorities were adopted and pursued and that the report's recommendations for lifestyle change were implemented in clinical practice, the report's lifestyle-orientated recommendations laid down foundations for the increasing formulation of PCOS as a lifestyle condition. This framing situates PCOS as a condition that is primarily driven by poor lifestyle choices, with obesity and excess weight as particular aggravators, and as a condition that is best managed and treated by positive lifestyle change. In and of itself however, the 2011 Australian Task Force report was unlikely to make little impact beyond Australia. The organisations involved in compiling the report were not internationally known or influential and the report was therefore relatively limited in its reach and impact. It was as a result of the report's endorsement by a much larger and

[65] A measurement system which ranks food items according to the rate at which it raises levels of blood glucose (*BDA*, 2023).

influential institution in 2012, the NIH, that the content and ideas it contained came to play an integral role in shifting the dynamics and direction of the PCOS controversy.

6.3. The 2012 NIH report

Shortly after the publication of the 2011 Australian Task Force report, the 2012 NIH report was published and presented a detailed evaluation of the three different sets of criteria that continued to be applied to varying degrees for PCOS (NIH, 1990; ESHRE/ASRM, 2004; AES Task Force, 2006). In its report, the NIH endorsed many of the recommendations presented by the Australian Task Force (2011); it cited it both as a source of evidence and a model to be emulated across OG-PCOS research as a whole. Unlike the Australian Task Force however, which was set up entirely for the purpose of producing the report outlined above, the NIH is an institution with extensive medical, financial, and legal authority (history.nih.gov; Wadman, 1998). Its endorsement of the 2011 report therefore, carried significantly more weight in influencing the field of OG-PCOS research than the 2011 report in and of itself (history.nih.gov). The United States' Government's National Institutes of Health Reform Act of 2006 substantially increased the financial resources available to the NIH, as well as its authority to make independent decisions regarding the attribution of these resources. As a result, the NIH carried significant institutional power and capacity to move the controversy beyond its focus on issues of definition and ontology. The authors of the (2012) NIH report endorsed and echoed multiple components of the (2011) Australian Task Force report, including: (i) its identification of obesity as an aggravator of PCOS; (ii) its emphasis on the cost implications of established PCOS treatment options; (iii) its positioning of treatment, including lifestyle treatment, as an area in need of immediate and focused academic and clinical attention. As well as this, the NIH (2012) report authors also proposed that the OG-PCOS research and practice fields adopt a phenotypical approach to the application of the 2003 Rotterdam criteria for PCOS.

6.3.1. An endorsement of the Australian Task Force report

The NIH's (2012) extensive endorsement of the 2011 Australian Task Force report had important implications for the research agenda on PCOS, expanding the international scope and reach of the 2011 recommendations. The foundations laid down by the Australian Task Force and their subsequent endorsement by the NIH, facilitated a shift in OG-PCOS research discussions and broke the deadlock between Rotterdam opponents and supporters engaged in the controversy over PCOS diagnostic criteria. The authors of the 2012 NIH report cited

the (2011) Australian Task Force report as evidence for the wide-ranging heterogeneity of PCOS, explaining that:

> *The PCOS Australian Alliance evaluated the quality of the published evidence on PCOS in 2011 and published a 1,100-page evidence appraisal document based on 22 separate systematic reviews and more than 38,000 articles from around the world.*
>
> NIH, 2012: 5

Like the 2011 report, the 2012 NIH report also presented PCOS heterogeneity in the context of the varying life course factors that can influence expression and progression in PCOS. It argued that:

> *The impact of the syndrome on an individual varies significantly based on several factors, such as the severity of the components, comorbidities, and life course considerations. In addition, each individual experiences the syndrome in the context of her own reproductive health, metabolic, and quality-of-life concerns. Hirsutism, obesity, and infertility are common complaints. This syndrome also is associated with metabolic dysfunction, including diabetes. However, it is unclear whether these abnormalities increase the incidence of cardiovascular events or other diabetic complications. The relationship between the syndrome and other metabolic abnormalities, sleep apnea, depression, anxiety, and quality of life remains to be defined by longitudinal studies. Given the prevalence of this syndrome worldwide, these important public health issues deserve more attention.*
>
> NIH, 2012: 4-5

In the above extract, the NIH (2012) amplified the focus placed by the 2011 Australian Task Force report on individual lifestyle factors in influencing PCOS expression and development. In doing so, the NIH report's authors ensured that discussions moved further in the direction of PCOS treatment and management and away from a consideration of its aetiological intricacies. They also explicitly endorsed the Australian Task Force's engagement of women with PCOS in clinical guideline development, presenting the argument that:

> *We believe that the involvement of consumers in the guideline development of the Australian task force and the engagement of primary care providers, multidisciplinary teams, and patients in education and programmatic roll-out is a model worthy of imitation.*
>
> NIH, 2012: 7

The NIH's (2012) endorsement of the Australian Task Force's co-productive and consumer-centred model paved the way for further incorporation of patient voices and perspectives within the PCOS controversy and OG-PCOS literature more broadly. It also laid down further foundations for a sustained change in the controversy's direction, away from the issue of diagnosis and towards that of PCOS treatment and care. In the extract above, the NIH (2012) employed the same language as that of the Australian Task Force (2011) by referring to women with PCOS not as 'patients' but 'consumers'. This was reflective of the shared principles and aims on which these reports were based and was emblematic of the increasing attention being paid within medicine more broadly, to the promotion of a more market-based model of health and of health care (Schrecker, 2016).

Like the 2011 Australian Task Force report, the NIH (2012: 2) placed extensive emphasis on the costs of treating PCOS. It explained that '*costs to the U.S. healthcare system to identify and manage PCOS are approximately $4 billion annually; however, this estimate does not include treatment of the serious conditions associated with PCOS'*. In highlighting the costs of treating PCOS, the NIH (2012) report strengthened its case for diverting attentions within OG-PCOS research away from Rotterdam supporters' and opponents' concerns over the diagnostic category's ontological components and towards establishing more cost-effective methods for treating PCOS. The NIH (2012: 5) identified lifestyle change as representing one such method of treatment, explaining that '*Lifestyle modification and weight reduction have been shown to decrease androgen effects, increase ovulation, and improve insulin sensitivity*'. The NIH's endorsement of the Australian Task Force report - its emphasis on consumers, treatment costs, individual life course factors, and the value of lifestyle treatment - represented a landmark moment in the changing dynamics and direction of the controversy. It strengthened the potential impact of the new co-productive voices introduced into the controversy by the 2011 Australian Task Force report and paved the way for the development of a PCOS definition focused more explicitly around patient needs, subsequently shifting the controversy's focus away from its earlier debates around evidence and ontology.

6.3.2. Proposal for a new diagnostic model for PCOS

In order to successfully facilitate this shift and lessening in the ongoing PCOS controversy, it was important for the NIH to also address the issue of PCOS diagnostic criteria explicitly and provide Rotterdam opponents and supporters with a certain level of appeasement that

would encourage them to leave the issue to one side. The 2012 NIH report outlined the three sets of criteria that existed for PCOS and argued that while each carried its own respective advantages and disadvantages, significant challenges had arisen through the co-existence of multiple sets of criteria:

> *Over the past 2 decades, the use of the NIH Criteria, the Rotterdam Criteria, and the AE-PCOS Society Criteria have been useful in understanding the syndrome. The individual components of these criteria are difficult to measure, and it is not clear how each contributes to the outcomes of concern…*
>
> *The use of multiple classification systems is confusing and delays progress in understanding the syndrome. It also hinders the ability of clinicians to partner with women to address and manage the health issues that concern them. Each of these diagnostic criteria has inherent strengths and weaknesses (see Table 3).*
>
> NIH, 2012: 1

The extract above employed similar language to that used by the 2011 Australian Task Force report, placing the concerns of women with PCOS and the capacity of medical practitioners to '*partner'* with women with PCOS at the centre of the issue of PCOS diagnosis (NIH, 2012: 1). The report continued to use this patient-centred language when listing the strengths and weaknesses of each respective set of criteria (Figure 8. and 9. below[66]):

Table 3. Strengths and Limitations of Diagnostic Criteria

Diagnostic Criteria	Strengths	Limitations
Androgen Excess	• Included as a component in all major classifications • A major clinical concern for patients • Animal models employing androgen excess resemble but do not fully mimic human disease	• Measurement is performed only in blood. • Concentrations differ during time of day. • Concentrations differ with age. • Normative data are not clearly defined. • Assays are not standardized across laboratories. • Clinical hyperandrogenism is difficult to quantify and may vary by ethnic group. • Tissue sensitivity is not assessed.

Figure 8. The NIH (2012: 2) report's summary of the strengths and limitations of diagnostic criteria for PCOS

[66] Please note that Table 3 (Figures 8 and 9) is presented within the NIH (2012: 2 -3) report across two separate pages and has therefore been presented as two separate figures here.

Table 3. Strengths and Limitations of Diagnostic Criteria (*continued*)

Diagnostic Criteria	Strengths	Limitations
Ovulatory Dysfunction	• Included as a component in all major classifications • A major clinical concern for patients • Infertility a common clinical complaint	• Normal ovulation is incompletely understood. • Normal ovulation varies over a woman's lifetime. • Ovulatory dysfunction is difficult to measure objectively.
Polycystic Ovarian Morphology	• Historically associated with syndrome • May be associated with hypersensitivity to ovarian stimulation	• Technique dependent • Difficult to obtain standardized measurement • Lack of normative standards across the menstrual cycle and lifespan (notably in adolescence) as ovarian morphology varies with age • Technology required to accurately image not universally available • Imaging possibly inappropriate in certain circumstances (e.g., adolescence)

Figure 9. Continuation of the NIH (2012: 3) report's summary of the strengths and limitations of diagnostic criteria for PCOS

Having laid out the respective strengths and weakness of each set of diagnostic criteria for PCOS, the 2012 NIH report's authors presented a proposal for the implementation of a new diagnostic model for PCOS. The model represented a very straightforward amalgamation of what appeared to have been the respective central demands of each side engaged in the controversy - Rotterdam supporters' ambition to oversee the universal application of the broad Rotterdam criteria for PCOS and Rotterdam opponents' commitment to the identification of the hyperandrogenic, or 1990 NIH-defined, PCOS contingent as a separate entity from the phenotypes introduced by the Rotterdam criteria in 2003. The report made the following recommendation regarding the issue of competing diagnostic criteria for PCOS:

> *We recommend maintaining the broad, inclusionary diagnostic criteria of Rotterdam (which includes the "classic NIH" and AE-PCOS criteria) while specifically identifying the phenotype:*
>
> - *Androgen Excess + Ovulatory Dysfunction*
> - *Androgen Excess + Polycystic Ovarian Morphology*

- *Ovulatory Dysfunction + Polycystic Ovarian Morphology*
- *Androgen Excess + Ovulatory Dysfunction + Polycystic Ovarian Morphology*

The specific phenotypes should be reported explicitly in all research studies and clinical care. This recommendation should be disseminated to journal editors, funding sources, and professional societies.

NIH, 2012: 6 - 7

Controversy closure occurs when a controversy is concluded or resolved through the emergence of consensus (Pinch and Leuenberger, 2006) or because of a waning of interest and subsequent abandonment of the controversy altogether (Engelhardt and Caplan, 1987). It is clear from the extract above that the 2012 NIH's proposal for diagnosing PCOS, even at this early stage in its introduction into the literature, was not designed to bring about the closure of the OG-PCOS controversy over diagnosis. Consensus within OG-PCOS research remained elusive and out-of-reach. Both Rotterdam opponents and supporters were still profusely at odds with one another in their respective definitions of PCOS and remained unwaveringly committed to promoting and applying these definitions in their own approaches to diagnosing PCOS. The NIH's newly proposed model did not represent a renewed effort towards instilling consensus. Instead, it offered Rotterdam opponents and supporters a pragmatic compromise that met the respective central demands of both sides simultaneously, and which carried the capacity to bring about a level of agreement between both Rotterdam opponents and supporters that could function for the field as a whole. This pragmatic development facilitated a move towards a focus on treatment and patients' needs and away from debates over the 'correct' signs and symptoms for diagnosing PCOS.

In this section of my chapter, I have outlined the content and panel recommendations of two separate reports - the 2011 Australian Task Force report and the 2012 NIH report. I have argued that thanks to its influence and authority as a key medical research institution, the NIH (2012) was able to amplify the focus placed by the 2011 Australian Task Force report on individual lifestyle factors in influencing PCOS expression and development and ensure that discussions moved away from a consideration of PCOS' ontological intricacies. This required Rotterdam opponents and supporters to reconsider their respective positions regarding PCOS diagnostic criteria in order to keep pace with the developments taking place in the field. In presenting a proposal for a phenotypical model for PCOS diagnosis, one which

amalgamated the respective central demands of Rotterdam opponents and supporters, the 2012 NIH report also contained the potential to bring about a level of agreement within the existing controversy in which a functional but negotiated definition for PCOS might be deemed acceptable by Rotterdam opponents and supporters alike.

6.4. Rotterdam Opponents and Supporters post-2012: Alternative Mobilisations of Risk

Rotterdam opponents and supporters had spent the nine years prior to the publication of the NIH's (2012) proposal arguing vehemently against one another's interpretations of PCOS as a diagnostic category. Although the NIH's proposed phenotypical approach for applying the Rotterdam criteria centred around the identification of differences in 'types' of PCOS, it nonetheless represented an important development in the fulfilment of Rotterdam supporters' ambition to oversee the universal application of the Rotterdam criteria and the expansiveness and breadth that it would bring to the PCOS diagnostic spectrum. Furthermore, despite the NIH's (2012) proposal having been at odds with Rotterdam opponents' longstanding opposition to the Rotterdam criteria, its phenotypical dimension corresponded with Rotterdam opponents' definition of the traditional hyperandrogenic, or 1990 NIH-defined, PCOS phenotype as a separate entity from the newer phenotypes introduced by the 2003 Rotterdam criteria. In the analysis below, I analyse Rotterdam opponents' and supporters' responses to the NIH's proposal and to the more patient- but also lifestyle-orientated focus that was emerging in OG-PCOS literature. I explore the more modified and measured stance on PCOS diagnostic criteria adopted by Rotterdam opponents and supporters, both of whom accepted the NIH's newly proposed diagnostic model, and the wider shift within OG-PCOS literature away from issues of evidence and ontology. I also pay attention to each side's mobilisation of alternative discourses of risk. I argue that it was through their construction and dissemination of risk-based discourses relating to PCOS that each side was able to continue to promote their own respective definitions of the diagnostic category, albeit in a more modified form, while amalgamating and keeping pace with the rest of the field in adopting a more explicit focus on issues of patient treatment and care.

6.4.1. Rotterdam opponents: Endorsement of a risk-based phenotypical approach

In his 2014 paper '*Polycystic Ovary Syndrome: What's in a Name?*', Azziz responded to recent calls within the field[67] for the PCOS diagnostic category to be renamed as a means of

[67] Calls for a name change to the diagnostic category were presented in both the 2012 NIH report and a 2013 paper by Dunaif and Fauser.

alleviating the confusion that continued to exist around the role played by PCO morphology in PCOS pathophysiology. In his 2014 paper, Azziz consented to the idea of changing the diagnostic category's name, but also presented a modified stance regarding PCOS pathophysiology and the 2003 Rotterdam criteria and endorsed a phenotypical approach to defining and diagnosing PCOS. In contrast to Azziz's earlier contributions when he had argued unwaveringly in favour of defining PCOS as a condition of HA (see Chapter 5), in this paper Azziz (2014: 1144) conceded that not *all* women with PCOS necessarily present with HA and that there is '*no uniform clinical feature'* within PCOS. In presenting this argument, Azziz accepted the changed diagnostic landscape within OG-PCOS research and practice, surrendered his previous commitment towards challenging and questioning the validity of the milder, non-hyperandrogenic PCOS phenotype, and accepted its definition as a PCOS contingent. This was made further apparent in his own proposal for renaming PCOS, which suggested that:

> *One option is to leverage what is already happening in the world of androgen excess research, where PCOS is being subdivided and considered according to its phenotypes (2, 5). In that case, using the broadest definition of the disorder, the Rotterdam 2003 criterion, the disorder could be subdivided naturally into three broad phenotypes: the classic form (oligo-anovulation + hyperandrogenism ± PCOM[68]), the ovulatory form (hyperandrogenism + PCOM), and the normoandrogenic form (oligoanovulation + PCOM). As previously noted, the classic form is most commonly associated with clinically significant metabolic dysfunction.*
>
> *So perhaps we should rename the classic form of PCOS, by far the most common type of the disorder seen clinically, as the "functional metabolic-hyperandrogenic syndrome," or better still, the "metabolic hyperandrogenic syndrome" (MHS or MH syndrome). The ovulatory forms could be called the "polycystic ovary-hyperandrogenic syndrome" (POHS or POH syndrome), and the normoandrogenic forms could be termed the "polycystic ovary-anovulatory syndrome" (POAS or POA syndrome). Although this scheme does not differ markedly from the Dunaif and Fauser proposal, the proposed nomenclature is based on clinical phenotype, not on discipline of the healthcare provider.*
>
> Azziz, 2014: 1444

Azziz (2014) accepted the NIH's (2012) proposal - referenced as citation 2 within the above extract - for dividing the Rotterdam criteria into different phenotypes, by suggesting that this could provide a route forward for the field and a solution to the question of renaming PCOS.

[68] Azziz's (2014) use of the acronym PCOM here is a reference to PCO morphology.

In accepting this proposal, Azziz also presented an implicit acceptance of the Rotterdam criteria for PCOS and the newer phenotypes it introduced, acknowledging these as legitimate contingents of the condition.

Although Azziz (2014) amended his position on these issues in order to keep pace with the changes taking place in the field, this development did not signify the emergence of a consensus within the field nor the imminent closure of the controversy. Unlike the 2012 NIH report, which did not signpost to differences between each phenotype aside from their respective diagnostic criteria, Azziz (2014: 1444) stressed the prevalence and severity of metabolic dysfunction in the '*classic form'* of PCOS. He also suggested that this particular PCOS contingent be renamed entirely separately from the other PCOS phenotypes, in a way which emphasised its distinctive metabolic and hyperandrogenic components. Despite having accepted a phenotypical approach to the application of the Rotterdam criteria, Azziz's (2014) continued commitment towards emphasising the unique severity and long-term risks associated with '*classic'* PCOS suggested that although Rotterdam opponents and supporters were moving closer towards the development of a functional definition which worked for both sides, important differences remained in their individual perspectives regarding how best to define PCOS.

Azziz's (2016) paper placed significant emphasis on the genetic determinants of PCOS and on the need for these to be investigated further in order to improve and develop strategies for managing and treating PCOS. This was a response to the increasing prevalence of lifestyle explanations for PCOS within OG-PCOS literature, which conflicted with Azziz's longstanding commitment to defining PCOS as a heritable hyperandrogenic disorder that was limited to a select group of women with a select combination of symptoms. Although Azziz (2016) acknowledged PCOS' environmental determinants, he stressed that there was limited evidence to suggest that they play an extensive role in PCOS pathogenesis and argued that:

> *Environmental determinants of PCOS and its phenotype are less well studied. Although we understand that obesity (and associated increased sedentary lifestyle, poor nutrition, and overeating) plays a role in worsening the metabolic complications of PCOS, there are limited data to suggest that obesity itself drives the development of the disorder, nor is there clear evidence of significant differences in diet between women with and without PCOS.*
>
> Azziz, 2016: 5

Azziz (2016) again signposted to the distinctive differences in long-term risks presented by the four different PCOS phenotypes, drawing attention to differences in both metabolic and reproductive risks:

> *The phenotype of PCOS can be subdivided into four different types. Phenotype A and B (hyperandrogenism + ovulatory dysfunction, with [A] and without [B] polycystic ovarian morphology [PCOM], respectively) can be considered to represent the ''classic'' form of the disorder. Phenotype C is the so-called ''ovulatory'' PCOS (hyperandrogenism + PCOM only). And phenotype D is often referred to as ''nonhyperandrogenic'' PCOS (ovulatory dysfunction + PCOM only). The different phenotypes vary in the degree to which they are associated with an increased risk for metabolic dysfunction and reproductive complications…*
>
> *Metabolically, phenotypes A and B (also called ''classic PCOS'') behave similarly, with approximately 75% to 85% demonstrating insulin resistance and some form of metabolic dysfunction. These individuals have an increased risk of glucose intolerance and diabetes. Alternatively, PCOS women with phenotype D (also called ''nonhyperandrogenic PCOS''), who do not demonstrate overt evidence of androgen excess, have little evidence of metabolic dysfunction and are at low risk of developing disorders of glucose intolerance. Patients with phenotype C (often referred to as ''ovulatory PCOS'') have levels of metabolic dysfunction and risk that are somewhat less than those with the classic forms of PCOS but still measurably higher than those of control subjects or nonhyperandrogenic PCOS women.*
>
> Azziz, 2016: 4

In the extract above, Azziz (2016: 4) presented the four different PCOS phenotypes in an almost hierarchic fashion, discussing each in terms of its diminishing level of long-term health risk. Lupton (1993: 425, 432) argues that the multiple meanings and often 'ideologically loaded' nature of risk means that depending on how risk is defined within a particular discourse, it can function as a 'hegemonic conceptual tool' with significant power to organise and order sociocultural patterns and relations. Risk in the above extract, was applied in a way which exemplified its organisational and ordering capabilities. It conveyed the idea that hyperandrogenic PCOS, defined by Rotterdam opponents as greatest in metabolic risk, was constitutive of the most classic, authentic, and serious PCOS contingent. This was strengthened further by Azziz's (2016: 4) use of the term "*classic PCOS"* to refer to the hyperandrogenic phenotype. Although the concept of a 'classic PCOS' had already made appearances within OG-PCOS literature and had been used on both sides of the controversy (Azziz, 2006b; Dewailly et al. 2006; Franks, 2006; NIH, 2012), its mobilisation in the context of the risk-based discourse above denoted a level of authenticity or validity to phenotypes A

and B. Ovulatory PCOS (phenotype C), higher in metabolic risk than non-hyperandrogenic PCOS (phenotype D) but lower in metabolic risk than hyperandrogenic PCOS (phenotypes A and B), was presented as a moderate PCOS contingent in terms of its long-term health risks. The risk level in non-hyperandrogenic PCOS was presented as minimal, denoting a lower level of clinical significance for this phenotype.

As well as highlighting PCOS' phenotypical differences, Azziz (2016: 4) repeated his endorsement of a phenotypical approach to diagnosis by arguing that '*although there are different criteria for defining the disorder, more important is the need to clearly define the phenotype of the patient being considered'.* Although throughout the papers explored in the previous chapter, Azziz (2005; 2006a; 2006b) repeatedly discussed the dangers of prematurely expanding the range and number of phenotypes considered representative of PCOS and argued persistently in favour of prioritising research into the hyperandrogenic phenotype, he nonetheless engaged in continuous and heated debate over the specificities of PCOS diagnostic criteria and the appropriateness of the Rotterdam criteria. It was significant then that Azziz (2016: 4) attributed greater importance to the issue of defining individual PCOS phenotypes than to the issue of PCOS diagnostic criteria. It indicated a change in Azziz's priorities, away from a focus on generating evidence aimed at discrediting the Rotterdam criteria, towards the development of a definition for PCOS that would function for both sides while retaining Rotterdam opponents' definition of hyperandrogenic PCOS as the most clinically severe PCOS phenotype. This was reflective of the wider changes taking place in the field, which had required experts like Azziz to reconsider their approach to navigating the controversy.

6.4.2. Rotterdam supporters: An emphasis on risk as universal, ubiquitous, and variable

A change was also evident in Rotterdam supporters' priorities at this stage in the controversy. Following the NIH's (2012) report, Rotterdam supporters endorsed the recent changes in the PCOS diagnostic landscape and were increasingly accepting of evidence identifying phenotypical differences in PCOS-associated long-term health risks. However, although this contrasted with Rotterdam supporters' earlier papers and their calls for further evidence to illuminate the potential health risks presented by the ovulatory and non-hyperandrogenic PCOS phenotypes, Rotterdam supporters remained committed to emphasising the importance and necessity of PCOS diagnosis amongst women with these milder PCOS contingents. In ensuring that this aim was adequately fulfilled in any realisation

of the NIH's (2012) proposed model for diagnosis, Rotterdam supporters placed significant emphasis on the potential for an individual's risk of developing other long-term health conditions to change over their life course and also presented psychological risk in PCOS as unaffected by individual phenotype. The result was that the lifestyle-orientated discourses that were becoming increasingly prevalent within OG-PCOS literature, including in the 2011 and 2012 reports analysed above, were endorsed and remobilised by Rotterdam supporters in a way which contributed to the definition of PCOS as a *lifestyle condition*. Mobilising and adapting these discourses simultaneously enabled Rotterdam supporters to maintain their case for the need for an inclusive, all-encompassing approach to diagnosis, which did not overlook or trivialise any individual phenotype.

A 2014 position statement from the ESE - of which both Franks and Dewailly were co-authors - described the advancements that had been made within the field regarding diagnostic criteria:

> *Since PCOS is a very common disorder (the prevalence ranges from 6 to 20% depending on the criteria used), it would be helpful to have unity about the diagnostic criteria. Some progress has been made towards that goal by the recommendations of the Expert Panel following the NIH (USA) Evidence-based Methodology Workshop on PCOS in December 2012, whose major results have been summarised and presented very recently. While supporting the Rotterdam definition as the most inclusive and appropriate in a global context, it was suggested that a more appropriate, less 'ovary-centric' name for the syndrome should be considered. It is therefore a timely opportunity for the European community of endocrinologists to discuss where future efforts in research and clinical management should be focused.*
>
> ESE, 2014: 2

The ESE's (2014) commendation of the progress made within the field following the NIH's (2012) report suggested that Rotterdam supporters did not consider the NIH's proposed phenotypical approach to diagnosing PCOS to be at odds, or in conflict with, an inclusive approach to PCOS diagnosis. In line with their acceptance of this phenotypical approach, the ESE (2014), and Rotterdam supporters more generally, acknowledged the wider evidence base indicative of significant phenotypical differences in the long-term health risks presented by PCOS. Jayasena and Franks (2014) recognised for example that:

> *Substantial evidence from cross-sectional studies indicates that the metabolic features of the syndrome differ by phenotype—patients with the NIH–NICHD phenotype are at the highest risk of developing insulin resistance, the metabolic syndrome and T2DM [type 2 diabetes mellitus]. These metabolic abnormalities are less severe or are absent in the other phenotypes, particularly in women with regular menses. Prospective studies are now needed to delineate and compare the long-term health risks of the various phenotypic subtypes of PCOS.*
>
> Jayasena and Franks, 2014: 626

Rotterdam supporters' alignment with Rotterdam opponents in acknowledging phenotypical differences in some of the long-term health risks presented by PCOS, represented an important advancement towards the development of a functional agreement in the field and the realisation of the NIH's (2012) proposed phenotypical approach. Important differences remained however, in Rotterdam supporters' and opponents' attitudes to the PCOS diagnostic category as a whole. Regarding the issue of psychological risk in PCOS - specifically, its potential to detrimentally impact on quality of life and emotional wellbeing - the ESE (2014) report cast doubt over the significance of phenotypical differences:

> *In addition to the signs and symptoms like hirsutism, acne, irregular menses, infertility and excessive body weight, psychological disorders may have a specific link with PCOS and they may have significant implications on the quality of life. Although there are very few available studies, it has been shown that similar psychological profiles exist in both NIH and non-NIH phenotypes of PCOS, which implies that the presence of psychological dysfunction occurs even in milder phenotypes of the syndrome, suggesting that psychological function and quality of life should be considered in all women with PCOS.*
>
> ESE, 2014: 10

In presenting the psychological risks of PCOS as likely to be equal across the entire PCOS diagnostic spectrum, Rotterdam supporters provided a strong case for maintaining an inclusive approach to diagnosis; this was an approach which sought to recognise and alleviate the potential effects of PCOS on the QoL and psychological wellbeing of all women with the condition. Rotterdam supporters' case for maintaining such an approach was strengthened further by the potential capacity they identified for PCOS - its phenotype, expression, and long-term health risks - to change over the course of an individual's life span. The ESE report (2014) explained that:

> *In addition, it is not known whether women transfer from one phenotype to another, and specifically from ovulatory to anovulatory PCOS, and how this transition affects their health status in the long term. If the answer to the above question is affirmative, then it can be postulated that women who have presented once with a mild phenotype may at a later stage of their life develop a worse and severe phenotype, with the known adverse sequelae.*
>
> ESE, 2014: 4

The possibility of a change in PCOS phenotypes over an individual's life course carried significant implications for the PCOS diagnostic landscape, heightening the importance of an early PCOS diagnosis and of the implementation of effective PCOS treatment and management techniques aimed at reducing the potential for progression in symptomology and clinical severity. Unlike Azziz (2014; 2015), who placed most emphasis on the genetic components behind PCOS pathogenesis and presented risk levels in PCOS as somewhat static and unchanging, Rotterdam supporters drew considerable attention to the role of environmental factors, in particular weight gain, poor diet, and obesity, in the development and aggravation of PCOS. Jayasena and Franks (2014) argued for instance that:

> *Obesity and poor diet are major environmental factors that exacerbate insulin resistance and many symptoms of PCOS. The chronic low-grade inflammation associated with obesity could contribute to these adverse effects.*
>
> Jayasena and Franks, 2014: 626

By stressing the possibility for obesity and poor diet to aggravate insulin resistance in PCOS, Jayasena and Franks (2014) presented risk in PCOS as a changeable entity which was linked in part to social environmental factors. In doing so, they positioned risk in PCOS as something that needed to be identified and appropriately managed through early diagnosis and intervention. This was made more explicit in Franks' (2015) extract below which, while identifying metabolic and cardiovascular risk as elevated in women with 'classic' PCOS, also signposted to the capacity for an individual's expression of PCOS to change due to lifestyle factors:

> *It is helpful to consider which patients with PCOS are at increased risk of metabolic and cardiovascular disease. Among the varied phenotypes defined by the Rotterdam diagnostic criteria, it is those women with the 'classic' presentation of PCOS as*

> *defined by the experts' meeting at the NIH in 1990, in other words, those with both oligomenorrhea and hyperandrogenism, who are most at risk. Insulin resistance and other metabolic abnormalities appear to be fewer in those women with androgen excess and regular cycles or those with anovulation and normal androgens. But it is important to bear in mind the clinical presentation may change within an individual. For example, weight gain in a woman with hyperandrogenism but regular menses may then lead to irregular periods and, at the same time, an increase in metabolic risk factors.*
>
> Franks, 2015: 434

While on one level, Rotterdam supporters' emphasis on the variability of PCOS expression and risk due to lifestyle factors strengthened their case for increasing accessibility to early diagnosis for women with any PCOS phenotype, it also placed considerable individual responsibility on women with PCOS. In situating much of their discussion of increased risk in PCOS in the context of issues of weight and diet, Rotterdam supporters built on and amplified the individualised, lifestyle- and risk-orientated epidemiological explanation (White, 2017) of PCOS mobilised by the 2011 and 2012 reports outlined above. This represented an explanation for disease that was becoming increasingly prevalent in western medicine more broadly, on account of its transition to an evidence-based, neoliberal model (Schrecker, 2016). The implication of this definition in a PCOS context was that women with PCOS were at least in part responsible for the management and alleviation of their condition through risk-reduction and lifestyle change. Consistent with this, all three of the Rotterdam supporters' papers analysed in this section of my chapter (ESE, 2014; Franks, 2015; Jayasena and Franks, 2014) identified lifestyle change as an important treatment method for PCOS. Jayasena and Franks (2014) argued for example that:

> *…weight loss and exercise remain the most effective means of lowering cardiovascular risk and reducing progression to diabetes mellitus, as well as regulating periods. If lifestyle interventions prove unsuccessful, metformin is an effective second-line treatment…even though its benefits… for the treatment of infertility in women with PCOS are not proven. The most important consideration of management is to tailor treatment choices to the specific needs of the patient.*
>
> Jayasena and Franks, 2014: 633

Having laid out the phenotypical differences in the long-term health risks associated with PCOS, but also having emphasised the capacity for PCOS expression to change due to

lifestyle factors, Franks (2015) concluded his paper by further highlighting the importance of early PCOS diagnosis:

> *PCOS is very common endocrine disorder with a well-known impact on ovarian function but it is not just a reproductive disorder. Women with PCOS are at increased risk of diabetes and, potentially, heart disease and so it is important to recognize, as early as possible (and that may be in the teenage years), those who are particularly prone to problems with long-term health.*
>
> Franks, 2015: 435

Rotterdam supporters' deployment of a lifestyle-orientated risk-based discourse reflected wider cultural trends towards an increased focus on individual responsibility for both mental and physical wellbeing (White, 2017). It also aligned Rotterdam supporters with the NIH's (2012) report and even more so with the risk-orientated discourse of the 2011 Australian Task Force report. Rotterdam supporters' deployment of this discourse was essential for ensuring that they were able to keep pace with advancements in the field and avoid ostracization. It simultaneously provided them with a strong case for the implementation of a flexible and inclusive approach to the identification of individual PCOS phenotypes. Rotterdam opponents' and supporters' mobilisations of two very different risk-based discourses offered important insight into the development, not of consensus but instead, a functional 'patchwork' agreement between Rotterdam opponents and supporters.

6.4.3. Collaborations in the field

Alongside Rotterdam opponents' and supporters' more modified stances towards PCOS diagnostic criteria and their respective mobilisation of alternative discourses of risk, another important change, which was further indicative of the emergent patchwork agreement in the field, took place in this period. This concerned the increasing formulation of cross-disciplinary partnerships between OG-PCOS experts with divergent perspectives and research interests in PCOS. Among those involved in the development of a co-authored paper by Azziz et al. (2016) for instance, were Dunaif, who had taken a lead role in developing the 1990 NIH criteria for PCOS, Carmina, who had challenged the concept of PCO morphology and whose papers had featured heavily earlier on in the controversy (Carmina et al. 1997; Carmina and Lobo, 2001), and Teede, who was responsible for spearheading the 2011 Australian Task Force report into PCOS. The paper's mobilisation of such a broad range of expertise reflected the change in the controversy's nature and dynamics, in that PCOS

academic experts with varying epistemological and research priorities were now collaborating with one another in a bid to create further unity and clarity within the field. While Azziz's (2014; 2016) sole-authored papers had focused heavily on the issue of phenotypical variation in the long-term health risks presented by PCOS, his co-authored 2016 paper refrained from using the concept of 'classic PCOS'. Although phenotypical variations in the severity of metabolic dysfunction were mentioned, the paper also acknowledged potential biases behind this evidence as well as the more universal risks that presented themselves across the PCOS diagnostic spectrum. Regarding hyperandrogenic PCOS, Azziz et al. (2016) identified the possibility that statistics depicting the prevalence of this phenotype were significantly distorted:

> *The characteristic features of PCOS lead to several different phenotypes. The phenotypic distribution of PCOS in epidemiological studies in unselected (unbiased) populations is 40–45% for phenotype A and phenotype B combined, ~35% for phenotype C and ~20% for phenotype D5. An important point to keep in mind is that only studies in unselected (medically unbiased) populations will enable us to clearly identify the true phenotype of PCOS. Compared with unselected patients, patients with PCOS in the clinical setting are more obese, more hirsute, more hyperandrogenaemic and show a greater proportion of phenotype A and phenotype B, reflecting substantial referral bias.*
>
> Azziz et al. 2016: 2

Azziz et al.'s (2016) paper was also significantly more patient-focused than either of Azziz's (2014; 2016) sole-authored papers. It emphasised for instance, the importance of amending diagnostic measures for PCOS to accommodate for ethnic variation in expressions of PCOS symptomology:

> *Hirsutism, acne and androgenic alopecia are clinical signs and symptoms of hyperandrogenism. In clinical studies, hirsutism affects ~65–75% of black and white patients with PCOS, which is dramatically higher than otherwise expected (0–2%). Acne affects 15–25% of patients with PCOS and varies with ethnicity; although it is unclear whether the prevalence of acne is significantly increased in these patients over that observed in the general population. Although hirsutism is frequently defined visually by a modified Ferriman–Gallwey[69] (mFG) score of ≥6, which corresponds to the 95th percentile of the population studied, other studies indicate that an mFG score of ≥3 should be considered abnormal in white or black, and*

[69] The Ferriman-Gallwey scoring system is used to evaluate levels of hirsutism as part of PCOS diagnostic practices.

> *probably even in Mongoloid or Asiatic, women. Indeed, in a study of 228 patients with minimal unwanted hair growth (with an mFG score of =5), >50% demonstrated an androgen excess disorder. Thus, many women have excessive or unwanted hair growth but may not be afforded appropriate evaluation because they are not deemed to be 'sufficiently' hirsute.*
>
> Azziz et al. 2016: 2

The relatively moderate stance presented in the above extracts regarding the possible overinflation of statistical representations of hyperandrogenic PCOS and the need for more inclusive diagnostic measures for some PCOS indicators, reflected the extent to which Rotterdam opponents like Azziz were willing to reconsider their stance on and approach to discussing PCOS. Considered in the context of the field's significant and continuing shift away from the issues Rotterdam supporters had, earlier on in the controversy, presented as being of paramount importance, these modified representations of the PCOS diagnostic landscape offered a means through which Rotterdam supporters could build functional collaborations and retain their status and influence in the field.

Azziz et al. (2016) also demonstrated extensive awareness of the psychological features of PCOS and its impact on QoL. Much of this discussion was however, underpinned by an identification of the importance of lifestyle change in alleviating the severity of these issues. Azziz et al. (2016: 13) reported for instance that, '*limited available data indicate that weight loss in overweight or obese women with PCOS achieved by dietary restriction alone or combined with exercise improves both depressive symptoms and PCOS-specific QOL scores, except for the scores in the body hair domain'.* In this sense, the paper endorsed large components of Rotterdam supporters' recent arguments regarding effective PCOS management. Given the involvement of committed Rotterdam opponents in the development of the paper, and despite remaining differences in experts' ontological perspectives and priorities, Azziz et al.'s (2016) publication further signified an advancement within the field towards a more collaborative and co-productive mode of working.

Alongside its in-depth focus on individual patient needs however, and on the importance of lifestyle change in managing PCOS symptomology and expression, Azziz et al.'s (2016) paper offered a more intermediary stance on the issue of obesity in PCOS pathogenesis. Unlike Rotterdam supporters, who had presented obesity and lifestyle factors as a likely definitive

cause in aggravations of PCOS symptomology and expression, Azziz et al. (2016) cast doubt over this argument and explained that:

> *The effect of obesity on PCOS and PCOS on obesity is complex, and strong evidence of an association is currently lacking. Although PCOS occurs in obese and lean women, a recent systematic review and meta-analysis concluded that obesity was more prevalent in women with PCOS than in women without PCOS. However, all but two of the studies reviewed recruited their patients from hospitals or clinics. By contrast, studies in unselected (medically unbiased) populations have suggested that BMI[70] distribution was more similar between patients with PCOS identified in unselected populations and controls and that BMI was higher than in patients with PCOS in referral (clinically biased) settings. These data indicate that much of the obesity in women with PCOS may be driven by self-referral, as obesity is one of the primary depressors of quality of life (QOL).*
>
> Azziz et al. 2016: 2 - 3

In this sense, the paper undermined Rotterdam supporters' emphasis on the changeability of the long-term health risks presented by PCOS. The paper also aligned itself further with Azziz's (2014; 2016) sole-authored papers in echoing his call for greater importance to be attributed to the definition of individual PCOS phenotypes, rather than to PCOS diagnostic criteria more generally. Azziz et al. (2016) argued that:

> *Regardless of the criteria used to define PCOS, greater emphasis should be given to defining the actual phenotypes of PCOS. Different diagnostic criteria take different phenotypes into account. Phenotypes A–C are considered hyperandrogenic, whereas phenotype D is non-hyperandrogenic. In addition, phenotype A and phenotype B and, to a somewhat lesser extent, phenotype C, are associated with a higher risk of concomitant metabolic dysfunction, which is less so for phenotype D. Overall, most investigators today use the broader 2003 Rotterdam criteria for PCOS, but stress that the specific phenotypes included must be clearly recognized and documented as they differ substantially.*
>
> .
>
> Azziz et al. 2016: 8

The extract above is further testament to the continued move within the OG-PCOS controversy away from generating evidence to determine the most effective diagnostic criteria for PCOS, and towards developing a functional definition for PCOS which identified individual phenotypes. Azziz et al.'s (2016) paper offers my analysis important insight into

[70] BMI stands for body mass index, which is the sum of a person's weight in kilograms, divided by their height in metres. BMI is often used as a test of whether a person is clinically overweight, underweight or of a healthy weight (Martin, 2010).

the increasingly collaborative nature of the research and epistemological activities of OG-PCOS experts with varying perspectives and priorities, but also helpfully encapsulated the extent to which Rotterdam opponents and supporters remained at odds with one another regarding defining PCOS as a diagnostic category. While Rotterdam supporters remained committed to emphasising the heterogeneity and changeability of PCOS symptomology and expression, and the subsequent importance of increasing the accessibility of early PCOS diagnosis, Rotterdam opponents viewed individual PCOS phenotypes as largely static and unchanging and relatively unaffected by environmental factors such as individual lifestyle choices and obesity. It was this continued divergence in each sides' perspectives on the precise physiological nature and components of PCOS, amidst a simultaneous willingness to make certain concessions and work with one another in focusing on PCOS treatment and care, that meant that this controversy was not resolved but had reached a patchwork state of agreement.

6.5. A Consolidation of the 'Patchwork Agreement'

In the years that followed the 2011 Australian Task Force and 2012 NIH reports, a small number of papers, including those of Dokras et al. (2017); Gibson-Helm et al. (2017); Teede et al. (2014), continued the trend towards actively engaging patient and practitioner perspectives on PCOS. These papers shed further light on elements of patient and practitioner experiences of PCOS diagnosis that remained underexplored in OG-PCOS literature, including widespread misconceptions and knowledge gaps among clinical practitioners and patients about PCOS (Teede et al. 2014) and significant inadequacies in women's access to timely PCOS diagnosis, PCOS-related information at the time of diagnosis, and emotional and psychological support (Gibson-Helm et al. 2017). By illuminating these aspects of the wider experience of the PCOS diagnostic category, this more patient-centred research approach highlighted significant gaps in existing clinical guidelines for PCOS. It also consolidated the shift within OG-PCOS literature towards a greater inclusion of patient voices and away from the issues which had been central to the PCOS controversy. In 2018, new guidance was published that ostensibly drew the controversy to a close. This guidance, of which Teede was again the lead author, was significantly more international in scope than the earlier 2011 Australian Task Force report and has been particularly influential for PCOS clinical practice, especially in western settings (Blackshaw et al. 2019; Jarrett et al. 2019; Lim et al. 2019). This guidance is referred to from hereon in the thesis as the international

evidence-based guideline for PCOS[71]. It provided a series of recommendations relating to the continued engagement of patient voices in PCOS clinical decision - and policymaking, the treatment of PCOS through lifestyle change, and the application of a phenotypical approach to the Rotterdam criteria.

Testament to the changed nature of the field of OG-PCOS research and the increasingly collaborative nature of efforts to focus on issues other than defining the PCOS diagnostic category, the report not only engaged expert panels from a wide range of medical specialties - ranging from paediatrics to exercise physiology - but also brought together a significant number of wide-ranging OG-PCOS research and practice organisations. Among these, and of most significance for the questions addressed in this chapter, were the *Androgen Excess and Polycystic Ovary Syndrome Society (AEPCOS)* - of which Azziz and many other Rotterdam opponents were members, and which was responsible for the 2006 AES Task Force diagnostic criteria which defined PCOS as a hyperandrogenic disorder - and the ESE - which was predominately the domain of Rotterdam supporters and which played an important role in negotiating the recently changed diagnostic landscape in favour of Rotterdam supporters' ontological interests.

Like the 2011 Australian Task Force report, Teede et al.'s (2018a; 2018b) international evidence-based guideline for PCOS was developed using a consumer centred and highly co-productive approach. Teede et al. (2018a; 2018b) represented patient involvement as having been particularly central to the guideline's development, explaining that '*the guideline and translation program were developed with full consumer participation at all stages, targeting areas and outcomes of priority for women with PCOS'* (Teede et al. 2018a: 1603). They also identified the historic absence of patient involvement in the development of PCOS guidelines as an important factor in their decision to compile the report. Teede et al.'s (2018a; 2018b) highly patient-centred approach to the development of their guidelines was reflected in the aims and content of the report. In line with the foundational principles of a patient-centred care model, Teede et al. (2018a) presented the individual needs and values of patients as having been central to their guideline recommendations. They explained that:

[71] The full title of the 2018 guidance is 'the international evidence-based guideline for the assessment and management of polycystic ovary syndrome'. The guidance has been published in two different reports - a shorter report which I refer to as Teede et al. (2018a) and a longer report I refer to as Teede et al. (2018b).

> *The aim is to support women and their healthcare providers to optimize diagnosis, assessment and management of PCOS. There is an emphasis on partnership in care and empowerment of women with PCOS. Personal characteristics, preferences, culture and values are considered. With effective translation, the guideline and health professional and consumer resources will address gaps and priorities identified by women with PCOS and will promote vital future research.*
>
> Teede et al. 2018a: 1603-1604

Regarding the issue of diagnostic criteria for PCOS, Teede et al. (2018a: 1063) were clear that '*the guideline development groups (GDG) unanimously supported the Rotterdam diagnostic criteria (Group, 2004) for adult women'.* In a longer and more detailed version of the report, Teede et al. (2018b) provided a more explicit endorsement of the 2012 NIH's proposal regarding a phenotypical application of the Rotterdam criteria, stating that:

> *We acknowledge the challenges in defining specific diagnostic features, including around menarche and menopause, where diagnostic features naturally evolve.*
>
> *The guideline aims to facilitate timely and appropriate diagnosis for women with PCOS, whilst avoiding over diagnosis, especially in adolescents…*
>
> *We endorse the recommendation of the National Institutes of Health (NIH) evidence-based methodology workshop of PCOS 2012 that specific phenotypes should be reported explicitly in all research. The natural history and clinical implications of the phenotypes remain unclear at this stage:*
>
> ● *Androgen excess + ovulatory dysfunction + polycystic ovarian morphology (Phenotype A)*
>
> ● *Androgen excess + ovulatory dysfunction (Phenotype B)*
>
> ● *Androgen excess + polycystic ovarian morphology (Phenotype C)*
>
> ● *Ovulatory dysfunction + polycystic ovarian morphology (Phenotype D)*
>
> Teede et al. 2018b: 13

Teede et al.'s (2018a; 2018b) focus on patient care and patient voices, alongside their endorsement of the 2012 NIH proposal for a phenotypical approach to the application of the Rotterdam criteria, consolidated the 'patchwork agreement' within the field; this is an agreement that appears to have provided a level of compromise sufficient to enable the OG community to move on to different questions (for instance those of treatment). The involvement of expertise from a wide range of OG-PCOS organisations in the development of the report signified a wider acceptance among the OG-PCOS research and practice

community of the NIH's (2012) proposal and the shift to a more explicit focus on issues of patient care and treatment. Lifestyle recommendations were also central to Teede et al.'s (2018a; 2018b) report which, given the report's international scope and reach, played a fundamental role in the consolidation of emergent definitions of PCOS as a *lifestyle disorder.* Throughout these recommendations, emphasis was placed on weight management and/or weight reduction as crucial in managing and reducing PCOS symptomology for all cases and particular recommendations were included for overweight or obese women with PCOS. In putting forward these recommendations, Teede et al. (2018a; 2018b) acknowledged the complex interrelations between weight, lifestyle choices, and psychological issues, as well as the role played by wider structural factors relating to socioeconomic and ethnic differences in shaping lifestyle choices and the capacity to implement lifestyle change. They also placed considerable emphasis on the responsibilities of medical practitioners and healthcare professionals in supporting women with PCOS to implement lifestyle change, referring to this as the '*joint responsibility of all health professionals, partnering with women with PCOS'* (Teede et al. 2018a: 1610).

Although this recommendation may, on the surface, appear to have been intended to counteract and challenge the increasingly neoliberal discourses surrounding discussions of excess weight and illness more generally, it placed extensive responsibility on individuals themselves for the management of their condition. It is also important to pay attention to Teede et al.'s (2018a; 2018b) encouragement of a significant level of self-surveillance in women with PCOS as a means of managing their condition. The report recommended for example that, '*self-monitoring including with fitness tracking devices and technologies for step count and exercise intensity, could be used as an adjunct to support and promote active lifestyles and minimize sedentary behaviors*', and that '*prevention of weight gain, monitoring of weight and encouraging evidence-based and socio-culturally appropriate healthy lifestyle is important in PCOS, particularly from adolescence*' (Teede et al. 2018a: 1611-1612). The report's persistent emphasis on 'self-monitoring' as a mechanism by which women with PCOS could manage and treat their condition, corresponded closely with wider neoliberal discourses presenting the individual as responsible for the management of ill health through self-led risk reduction strategies (Teede et al. 2018a: 1610; 1611; White, 2017).

6.6. Chapter Summary

This chapter has outlined the notable shift that took place in the dynamics and content of the controversy over PCOS diagnostic criteria within OG-PCOS research and practice during the final eight years of literature examined in this thesis. In this chapter, I have argued that the incorporation of new patient voices by experts not directly involved in the controversy generated a host of new questions around the most effective modes of treatment and management for PCOS. Among these questions, was the role played by lifestyle, and obesity in particular, in aggravating PCOS - its symptomology and progression over time - and the benefits of lifestyle change as a valuable method of treatment. Alongside these questions and the move they facilitated within the field away from its longstanding preoccupation with issues of definition and ontology, was a new proposal presented by the NIH (2012) for a phenotypical approach to diagnosing PCOS. This proposal offered Rotterdam opponents and supporters a compromise on the issue of PCOS diagnostic criteria which, while failing to bring about consensus within the field, contained within it the potential to create a level of agreement that could function for the field as a whole.

In analysing Rotterdam opponents' and supporters' responses to these changes, I identified that both sides exhibited a more modified stance on the issue of diagnostic criteria, with each side accepting the NIH's (2012) proposed definition for PCOS as a condition of different phenotypes. Although these developments were unprecedented when considered in the context of the impassioned exchanges that had epitomised the earlier stages of the controversy, Rotterdam opponents and supporters remained at odds in terms of their respective views on the aetiology of PCOS - with Rotterdam opponents emphasising the genetic components of the condition, and Rotterdam supporters placing greater emphasis on the importance of environmental factors - and the nature of the long-term health risks associated with it. Rotterdam supporters appealed to the increasingly prevalent discourses around lifestyle and PCOS to make a case for the changeability of these risks according to lifestyle factors and the subsequent need for early and inclusive diagnosis.

It was each side's willingness to compromise on the specificities of the criteria for diagnosing PCOS, while remaining at odds in terms of their understandings of the principal nature of the condition, that constituted a 'patchwork agreement' within the field. This agreement enabled the field to move beyond the debates and disputes that had consumed it for nearly two decades and was consolidated and reified within a new set of international guidelines

for PCOS published in 2018 (Teede et al. 2018a; 2018b). These guidelines endorsed the NIH's (2012) phenotypical model for diagnosing PCOS and provided an extensive set of lifestyle recommendations for its treatment and management, conclusively defining PCOS as a lifestyle condition. In the following chapter, I reflect on the implications of this definition for how PCOS is experienced in the context of societal expectations of women's bodies and health, as well as with respect to intersecting inequalities and identities. I also consider the importance of developments within medicine more broadly, alongside the disputes and uncertainties unique to the OG-PCOS research landscape and PCOS diagnostic category, in bringing about this definition.

Chapter 7. Discussion

7.1. Introduction

This thesis has explored the development and unfoldment of the controversy over PCOS diagnostic criteria within OG-PCOS research and practice over the course of four and a half decades. It has traced the evolution of the controversy from an impassioned contest between two competing sides into a temporary 'patchwork agreement' within the field. It has identified the NIH (2012) proposal and Teede et al.'s (2018a; 2018b) international evidence-based guideline for PCOS as having been integral to this shift. These developments were part of a strategy mobilised by OG-PCOS experts not directly involved in the controversy, to move discussions within the field away from the ontological debates which had dominated it for so long. Although the controversy remains unresolved, the field of OG-PCOS research and practice has largely accepted the definition of PCOS as a condition of different phenotypes, each characterised by varying levels of clinical severity and long-term health risk. The representation of long-term health risk as variable in PCOS, and as heavily dependent on lifestyle factors, has resulted in the increasing characterisation of PCOS as a *lifestyle condition* with the potential to result in a range of metabolic and cardiovascular disorders if improperly managed. Underpinned by a resurgence in neoliberal healthcare policies designed to persuade individuals to engage in lifestyle and health-related behavioural change (Baum and Fisher, 2014; Schrecker, 2016), the construction of this definition for PCOS has contributed to the condition's *individualisation* and attributes significant responsibility to individuals for its onset and management.

In this chapter I consider the implications of each of these developments for the process of PCOS diagnosis in clinical practice settings, as well as for women living with PCOS. In presenting this discussion, I first discuss the wider social, economic, and cultural factors, alongside the disputes and uncertainties internal to the field of OG-PCOS research, that have contributed to the individualisation of PCOS in OG-PCOS literature. Second, I explore the intersections between PCOS as a diagnostic category and wider gendered expectations of bodies and health. I reflect on the implications of these for women living with PCOS and frame this discussion in the context of the different challenges that are presented by PCOS to normative femininity and the intersecting and multiple forms of marginalisation in which women experience the condition. Finally, I discuss the ultimate inability of the field of OG-PCOS research to reach a 'scientific' conclusion regarding the aetiology of PCOS and identify

the integral role this played in consolidating the field's increasing movement towards the social construction and definition of PCOS as a lifestyle disorder.

7.2. The Individualisation of PCOS

Tolvhed and Hakola (2018: 190) define the *individualisation of health* as the increasing prevalence in late modernity of the notion that individual citizens are themselves responsible for the prevention of poor health, alongside the gradual replacement of 'traditional structural and economic explanations of public health concerns' with the concept of 'lifestyle management'. This same process has taken place within the boundaries of the PCOS diagnostic category, and I argue that the absence of any clear-cut aetiological and pathophysiological explanation for PCOS, alongside the financial costs of treating its individual symptomology and of drawing attention to the potential role played by large-scale corporations in fuelling increases in PCOS prevalence, acted as major driving forces behind this process. Although the 2018 international evidence-based guideline for PCOS, patient-centred in its content and in the process through which it was developed, presented the management of PCOS through lifestyle change as the *shared responsibility* of women with PCOS and their medical and healthcare practitioners, the neoliberal lifestyle discourses that pervade medicine and public culture in the western world are underpinned by a robust focus on *individual responsibility* (Baum and Fisher, 2014; Popay et al. 2010; Williams and Fullagar, 2019). A complete upheaval and deconstruction of these discourses would be needed in order to limit the significant personal and moral responsibility they attribute to women with PCOS.

Agreement over an adequate aetiological and pathophysiological explanation for PCOS has evaded OG-PCOS experts for the entire history of the diagnostic category. In order to compensate for the absence of definitive evidence of a physiological cause, increasing emphasis was placed by many experts in the field, on the potential role played by environmental and lifestyle factors in the pathogenesis of PCOS. Over the course of this controversy, substantial concerns have also been raised by many OG-PCOS experts regarding the extent of the financial burden placed on established healthcare systems by PCOS and its associated long-term health risks (Azziz et al. 2016; Teede et al. 2018a; Teede et al. 2018b). The Australian PCOS Alliance's Task Force report described for instance how, '*the burden and cost of PCOS complications, including infertility, DM2, CVD and emotional wellbeing issues are significant*' (Teede et al. 2011: S72), while Azziz et al. (2016: 1) noted that '*In 2004, the*

economic impact of PCOS exceeded US$4 billion in the United States alone, even without considering the cost of the increased risk of obstetrical complications, type 2 diabetes mellitus (T2DM) and other disorders'.

The delivery of medical and healthcare support in the form of 'lifestyle advice' presented OG-PCOS experts with an economical solution for treatment interventions for the condition that would otherwise have been financially burdensome. It placed responsibility on women themselves for the management of their condition through lifestyle change and relieved healthcare systems of the responsibility to provide costly cosmetic, psychosocial, and fertility treatments. Although the definition of PCOS as a 'lifestyle condition' threatened to draw attention to the wider structural factors and large-scale corporations widely evidenced to fuel increasing socioeconomic health disparities in neoliberal societies (Baum and Fisher, 2014), the articulation of this definition within an increasingly robust epidemiological framework ensured that responsibility for the development of PCOS was leveraged at individual women themselves. The costs of addressing the concerns of women with PCOS, alongside the continued absence of any conclusive aetiological explanation for PCOS, has contributed to the condition's *individualisation*. The widespread implementation of Teede et al.'s (2018) guidelines internationally (Blackshaw et al. 2019; Jarrett et al. 2019; Moran et al. 2022; Pirotta et al. 2021; Tay et al. 2021), has made them integral to the translation and dissemination of definitions of PCOS as a lifestyle condition within clinical practice settings, with important implications for women receiving or seeking medical advice for this diagnosis.

7.3. Intersections between PCOS as a Diagnostic Category and Gendered Expectations of Bodies and Health

Issues with hirsutism, fertility, body weight, and difficulty losing weight, are widely experienced as distressing by many women with PCOS and as presenting major compromises to women's body image and adherence with normative feminine ideals (Hadjiconstantinou et al. 2017; Ismayilova and Yaya, 2022; Kitzinger and Willmott, 2002; Pfister and Rømer, 2017; Soucie et al. 2022; Williams et al. 2015). These PCOS symptoms are among the main reasons women with PCOS seek medical advice in clinical settings. In this section of my chapter, I discuss the intersections between wider cultural expectations of the body, and of women's bodies specifically, and the contemporary definition of PCOS that has developed in OG literature as primarily a lifestyle disorder. I reflect on wider societal norms around weight

and health and what I consider to be the reification of these norms within the 2018 international evidence-based guideline for PCOS (Teede et al. 2018a; Teede et al. 2018b). I explore the implications of this definition in the context of the intersecting and wider structural inequalities in which different women experience PCOS and the increased representation of patient voices within OG-PCOS literature. I use the concepts of normative femininity and intersectionality to inform this discussion.

7.3.1. Obesity, PCOS and gendered expectations of body weight

Obesity became increasingly central to discussions of PCOS in the last eight years of literature examined in this study. Discussed predominately as an aggravator of PCOS symptomology, and a factor which can alter an individual's PCOS phenotype across the lifespan, obesity was integral to many of Rotterdam supporters' more recent arguments in favour of retaining an expansive PCOS diagnostic category inclusive of a broad spectrum of women. It was subsequently constructed as a key problematic in PCOS. It also formed a central component of Teede et al.'s (2018a; 2018b) clinical guidelines, which recommended extensive screening and encouragement of weight loss in obese and overweight women with PCOS and presented the risks of cardiovascular disease (CVD), type II diabetes, and psychosocial issues as significantly increased among this group. In line with these recommendations, in clinical practice settings, women with PCOS are frequently advised to engage with immediate and long-term behavioural change, including adopting a restrictive and/or more balanced diet, alongside regular physical activity (Lim et al. 2019).

Many of these recommendations contain significant parallels with those that are widely disseminated by healthcare authorities in developed countries for treating and advising on the issue of obesity more generally (Webb, 2009). They are reflective of the expansive medicalisation, and more recent biomedicalization, of obesity in contemporary society, through which excess body weight has been constructed as indicative of poor health and shortened life span and the necessary focus of an abundance of medical tools and sub-specialisms aimed at monitoring and minimising risk in obese people (Kwan and Graves, 2013). They also reflect the wider societal idealisation of the 'thin' and 'slender' body (Webb, 2009: 855), ideals which are central to contemporary constructions of normative femininity and the fashion-beauty complex (Bartky, 2003). Together, constructions of obesity and fatness as harmful medical and aesthetic phenomena contribute to widespread experiences of 'felt stigma', or what Barlösius and Phillips (2015: 9) refer to as 'fat stigma',

among people who are overweight or obese. They also frame these issues as a matter of 'moral responsibility', through which citizens in general are considered morally obliged to make 'good' decisions regarding diet, physical activity, and general lifestyle (Grønning et al. 2013: 267).

In recent social scientific scholarship, women with PCOS report experiencing 'weight bias' (Ismayilova and Yaya, 2022: 8) and feeling blamed and shamed for weight gain in their interactions with medical practitioners (Ismayilova and Yaya, 2022; Soucie et al., 2022). Given what much of this literature reveals to be the significant challenges presented by PCOS to normative femininity (Hadjiconstantinou et al. 2017; Kitzinger and Willmott, 2002; Pfister and Rømer, 2017; Soucie et al. 2022), and what feminist literature highlights as society's construction of fatness as equivalent to undesirability and unfemininity (Kwan and Graves, 2013), excessive emphasis on obesity in clinical interactions about PCOS may further contribute to the limited self-esteem and daily self-disciplinary practices reported to be widespread among women with PCOS (Kitzinger and Willmott, 2002; Pfister and Rømer, 2017). The discussion of obesity in OG-PCOS literature in the context of increased long-term health risks in PCOS, and its subsequent translation into clinical practice settings, can be considered to both reflect and reinforce the wider societal construction of an association between obesity and poor health and to frame the management of weight in women with PCOS as a distinctly moral issue. It attributes moral and personal responsibility for obese women with PCOS to engage in lifestyle change and for lean women with PCOS to maintain awareness of the risks posed by obesity to an escalation in their condition and the development of other long-term health issues.

7.3.2. Obesity, PCOS and intersectional inequalities

As well as its intrinsic links with gendered expectations of the body, there are also important classed and racialised elements to obesity and obesity stigma. This means that the incorporation of obesity within the PCOS diagnostic category carries important ramifications for experiences of PCOS at the intersections of multiple and overlapping social inequalities. Significant socioeconomic and sociocultural disparities influence how, and among whom, obesity in PCOS is most likely to present (Broom and Warin, 2011). Women from lower socioeconomic backgrounds in western countries are more likely to be overweight or obese (Christensen and Carpiano, 2014; Hargrove, 2018; Veenstra, 2013). Evidence also exists for significant 'gendered racial/ethnic disparities in BMI' (Ciciurkaite, 2021: 1754), with women

from some racial/ethnic minority groups more likely to be overweight or obese (Ciciurkaite, 2021; Hargrove, 2018). In the context of PCOS specifically, there is evidence to suggest that women of lower socio-economic status (SES) are at increased risk of developing PCOS in the first place and that women with PCOS who are of lower SES and/or who belong to ethnic minority groups are more likely to be overweight or obese (Di Fede et al. 2009; Rubin et al. 2019).

In part the result of the structural inequalities that influence which women with PCOS are most likely to present with being overweight or obese, overweight or obese women with PCOS frequently face a host of psychosocial and socioeconomic barriers in implementing the lifestyle recommendations presented by Teede et al. (2018a; 2018b) and delivered in clinical practice settings. Some of the participants in Lim et al.'s (2019: 5) study report that 'logistical issues such as the prohibitive cost of personal training, meal delivery services or seeing a dietitian regularly' can represent barriers to long-term weight loss and lifestyle change among women with PCOS, while other barriers linked more explicitly to PCOS, such as tiredness, body dissatisfaction, and lower overall quality of life were also identified. Among overweight and obese women with PCOS, weight-related 'embarrassment' was also identified as an inhibiting factor in engaging in lifestyle change such as increased physical activity (Lim et al. 2019: 7). Existing social, gender, and ethnic inequalities in obesity rates, combined with the additional challenges many overweight and obese women with PCOS face in implementing the long-term lifestyle change advocated by Teede et al. (2018a; 2018b), contributes to an almost impenetrable cycle by which moral and personal responsibility are continually attributed to this group.

Teede et al. (2018a; 2018b) acknowledged some of the structural and socioeconomic factors that can lead to a propensity to gain weight, or to experience difficulty losing weight, among women with PCOS and encouraged clinical practitioners to take these factors into account during clinical interactions. However, little space was left within their guidelines to account for women's individual concerns and values relating to body weight and size. Significant sociocultural differences exist in normative expectations of weight and body size. As Lupton (2018: 28) notes, 'concepts of "fat", "overweight" or "obesity" are all arbitrary social categories, defined in different ways in different historical, social and cultural settings'. These concepts are also defined in different terms for men and women (Monaghan and Malson, 2013). In their study of perspectives on 'fatness' among Black and White men and

women in Canada, Ristovski-Slijepcevic et al. (2010: 317) report significant 'resistance to dominant western cultural values around health, obesity and beauty' among many of the Black women in their study. They explain that such resistance was considered to signify 'belonging to the Black community for Black women' and an act of defiance against oppressive 'White ideals' relating to body size and weight (*ibid*.). Resistance to these same norms around bodily femininity was also evident among some of the White women in the study, but this was considered more a means of distancing oneself from dominant gendered expectations, rather than a source of belonging. In failing to acknowledge sociocultural and individual differences regarding experiences and perspectives on body weight, Teede et al.'s (2018a; 2018b) guidelines were to some extent based on an assumption that weight loss is a desirable goal for all overweight or obese women with PCOS. The guidelines exemplified what Lupton (2018: 34) identifies as a common feature of public health discourses aimed at encouraging individual behavioural change - the relative absence of 'an awareness of the complexity of individuals' health-related behaviours and their embeddedness in historical, economic, cultural and social contexts'.

7.3.3. Hirsutism in PCOS and gendered expectations of body hair

Hirsutism is defined within the contemporary PCOS diagnostic category in highly pragmatic terms, as a useful signifier of HA rather than a symptom requiring considered medical attention. Unlike obesity, which was so central to Teede et al.'s (2018a; 2018b) clinical guideline recommendations, hirsutism assumed a more subsidiary focus. Hirsutism's role as a potential factor in contributing to 'depressive and anxiety symptoms' in women with PCOS, and in negatively impacting on body image, psychosexual functioning, and relationships, *was* acknowledged by Teede et al. (2018a: 1609). Their recommendations for treating hirsutism however, related solely to the use of pharmaceutical drugs such as contraceptive and antiandrogen medication. Pharmaceutical treatment for hirsutism is widely considered ineffective by medical practitioners and patients alike; it is also unsuitable for many women with PCOS due to physiological incompatibility and side-effects, or to individual or sociocultural preferences (Copp et al. 2022; Hadjiconstantinou et al. 2017). Contraceptive medication in particular, is considered taboo in some cultures (Copp et al. 2022; Hadjiconstantinou et al. 2017).

Teede et al.'s (2018a; 2018b) failure to identify effective and tailored treatment for hirsutism in PCOS was in spite of the widespread evidence from within social scientific scholarship,

that many women with PCOS experience hirsutism as a major cause of emotional and psychological distress (Ekbäck et al. 2009; Ekbäck et al. 2011; Kitzinger and Willmott, 2002; Pfister and Rømer, 2017). Like obesity, much of the distress caused by hirsutism stems from the challenges it presents to normative expectations of femininity. Toerien et al. (2005) identify the strong 'symbolic association' that exists between hairlessness and gender and explain that 'to have a hairy body is a sign of masculinity; to have a hairless one, a sign of femininity' (Toerien et al. 2005: 399). Women with hirsutism frequently describe feeling ashamed of their bodies, unwomanly and unfeminine, and experiencing significant levels of depression and anxiety as a result (Lipton et al. 2006; Pfister and Rømer, 2017; Williams et al. 2016). This is particularly true of facial hair, which is generally harder to conceal and manage than hair in other areas of the body, and which carries historic associations with Victorian freak shows in which women with facial hair were presented as spectacles on account of their unusual signs of 'masculinity' (Braun et al. 2013).

The difficulties faced by women with PCOS in accessing practical and effective medical treatment for hirsutism results in widespread social and economic disparity in the extents to which women with PCOS are able to manage this symptom. This corresponds with what Skeggs (2001: 295; 1997: 1) draws attention to as the 'appearance of femininity as a form of cultural capital', and how, 'the sign of femininity is always classed'. Taking advantage of both the enhanced financial resources of middle-class women in North American countries (Rice, 2014), alongside an awareness of society's historical reading of social class and status on the basis of appearance (Skeggs, 2001), early hair removal adverts targeted middle-class women specifically. They did this by framing female hairlessness as tantamount to 'femininity, whiteness, and beauty', and by constructing an association which linked 'women's body hair with dirtiness, ugliness, and disease' (Rice, 2014: 254-255). It remains the case in contemporary western societies, that those with the greatest financial resources are most likely to be able to afford permanent or semi-permanent treatment for hirsutism in the form of laser hair removal or electrolysis. For women without access to either of these expensive treatment options, daily hair removal techniques are widely described as exhausting, time intensive, and hugely expensive over a longer time period (Ekbäck et al. 2009; Ekbäck et al. 2011; Lipton et al. 2006; Pfister and Rømer, 2017). Considered at the intersections between gender, ethnicity, and social class, Teede et al.'s (2018a; 2018b) relegation of hirsutism to a relatively trivial issue, alongside their advocation of treatment methods widely deemed

ineffective, means women with PCOS of lower SES are most vulnerable to the significant psychological repercussions incurred by the challenges PCOS presents to normative femininity.

7.3.4. Implications of the PCOS diagnostic category for patient representation

In the context of the intersections between the PCOS diagnostic category, societal understandings of gendered bodies, and women's experiences of PCOS, it can be argued that despite the increased representation of the voices of women with PCOS within the last eight years of OG-PCOS literature examined in this study, the contemporary PCOS diagnostic category and its associated guidelines fall short in incorporating individual women's voices, values, experiences, and concerns. Teede et al. (2018a; 2018b) fail to acknowledge women's divergent experiences of or attitudes towards obesity and advocate tackling obesity in all women with PCOS through rigorous lifestyle change. In a context in which neoliberal public health discourses prevail and in which obesity is constructed as an individualised problem associated with extensive long-term health risk, what Teede et al. (2018a; 2018b) attempted to present as the *shared* responsibility of patients and medical professionals is in fact placed firmly in the hands of obese and overweight women with PCOS. The mobilisation of hirsutism on the other hand as a useful diagnostic indicator for PCOS, and the limited availability of effective treatment for hirsutism which is affordable and accessible to all women with PCOS, signifies a failure within the field of OG-PCOS research and practice to address the lived realities of PCOS; this relates in particular, to the challenges it presents to normative femininity and the significant emotional, psychological, and financial difficulties these create for many women.

However, it is also important to reflect on these recommendations and the definition of PCOS as a lifestyle disorder in the context of women's agency and their ability to independently decide how or whether to manage their PCOS symptomology. It could be argued that Teede et al.'s (2018a; 2018b) highly individualised recommendations for treating PCOS actually offer a way of de-professionalising responses to PCOS, rendering women's choices regarding their condition less reliant on expert clinical knowledge. While it is possible that this has constituted a source of empowerment for some women with PCOS, the extent to which women with PCOS are able to make informed and active choices about the management of their condition depends heavily on the social and financial resources they have available to them. Given that the implications of the definition of PCOS as a

lifestyle condition vary extensively for women with PCOS depending on the intersectional context in which they experience the condition, and that the definition raises particular challenges for women facing social and financial disadvantages, this thesis demonstrates that the increased representation of patient voices in medical literature does not necessarily translate into a fairer or more inclusive approach to diagnosis and treatment. Instead, it carries the potential to empower *some* women with PCOS by placing responsibility for the management of their condition largely in their hands. For other women though, without the social and financial resources necessary to generate meaningful options from which to select how they manage their condition, it increases their vulnerability to the psychosocial implications that can result from the challenges PCOS symptoms frequently present to dominant understandings of normative femininity.

7.4. An Absence in Aetiological Explanation

Medical theories and explanations continue to abound over the likely aetiology of PCOS; they discuss to varying degrees, the role of genetics, diet, metabolism, and environmental factors in the onset of the condition (Kshetrimayum et al. 2019). Foetal exposure to excess androgens, the role of the ovary in generating abnormal levels of hormones, and the importance of genetics in the manifestations of the disease, are among the explanations that continue to circulate in OG-PCOS literature. What my thesis has revealed to be the increasing dominance of lifestyle definitions for PCOS is not only a reflection of the wider neoliberal context in which individualised explanations of illness have become increasingly prevalent; it also reflects the continued uncertainty over the aetiology of PCOS which has for so long, epitomised research into the condition. The OG-PCOS research community's inability to conclusively explain this aetiology, and the necessity to move beyond aetiological questions as they were paralysing the OG-PCOS community, meant that turning to women with PCOS themselves in order to explain the condition offered a convenient and convincing solution. As the continued disagreements between Rotterdam supporters and opponents demonstrate, evidence for the definition of PCOS as a lifestyle condition remains open to debate. It is not therefore, the increased scientific validity of this explanation, but a change in the priorities of the field, which has led to its proliferation in OG-PCOS literature and practice.

7.5. Chapter Summary

The construction of PCOS as a 'lifestyle condition' within OG-PCOS literature fits in line with increasingly dominant neoliberal public health discourses and their representation of chronic health issues as the 'cumulative result of individual choice… paving the way for policies that exhort individuals to change their behaviour' (Baum and Fisher, 2014: 217; Lupton, 1993; Tolvhed and Hakola, 2018; White, 2017). In this discussion chapter, I have argued that the significant personal and moral responsibility attributed to women for the onset and subsequent management of their condition has varying implications for women with PCOS depending on their individual symptomology, sociocultural values and preferences, and the socioeconomic resources they have available to them. The result is that in spite of the increasing incorporation of diverse patient voices within OG-PCOS literature, existing socioeconomic and sociocultural inequalities in the experience and prevalence of PCOS have been exacerbated and reinforced. The individual concerns, values, and preferences of women with PCOS are increasingly lost and subsumed within a robust and ever-strengthening epidemiological framework, which explains PCOS in terms of excess weight and poor lifestyle choices and which presents self-directed weight loss and lifestyle change as a critical and desirable course of treatment.

Chapter 8. Conclusion

8.1. Introduction

This thesis demonstrates that the contemporary definition of PCOS as a lifestyle disorder has been the outcome of almost three decades of controversy over PCOS diagnostic criteria. Though still not resolved, it was as a result of the underdetermination of PCOS-related evidence by theory, and a wider ambition within OG-PCOS research to move the controversy away from the ontological debate which had long consumed it, that the field reached a unique state of 'patchwork agreement'. This agreement has been embodied within a definition for PCOS that adheres to elements of both sides' interpretations of the condition, but which was reached not on the basis of consensus but through a reversion to women's lifestyle choices as a way of explaining and responding to PCOS. In this chapter, I provide the closing comments of the thesis, reflecting on the broader significance of its findings for sociological understandings of diagnosis and scientific knowledge construction beyond the boundaries of the PCOS diagnostic category.

I begin by summarising the findings of my research, paying particular attention to the ways in which the study's three key objectives have been met, regarding 1) its illumination of the role played by socially informed processes of image production in shaping the PCOS diagnostic category; 2) the light shed on the importance of the underdetermination of evidence by theory in the onset and playing out of the PCOS controversy; 3) its examination of the processes by which a unique 'patchwork agreement' developed in the field of OG-PCOS research. I follow this by outlining the contributions my research makes to existing sociological understandings of diagnosis and its social construction, shedding light on a plethora of social factors which have contributed to the definition of PCOS as a lifestyle disorder. I demonstrate the value of SSK concepts when applied to a genealogical study of diagnosis and their illumination of important trends in medical knowledge construction that show that diagnostic categories are endlessly revisable and increasingly fluid in their nature. I conclude by arguing that a more integrated approach to the study of diagnosis has particular sociological value in enabling the impact of individual diagnostic categories on experiences of illness to be more fully understood. Ultimately, by incorporating a more nuanced and complex focus on the social construction of diagnostic categories the wider acknowledgment of their implications for society as a whole is made more visible.

8.2. Summary of Findings

This thesis began by analysing the transformative role played by ultrasound technology and its socially-informed processes of image production in shaping the evolving PCOS diagnostic category in 1970s and 1980s OG-PCOS research and practice. The development of specific visual markers aimed at directing visual attention towards cysts and follicles on the ovaries, and the mathematisation of these entities in graphic space through the development of specific measurements, facilitated the enhanced visualisation of PCO morphology. Rather than strengthening its position as a potential signifier for PCOS, the increased visualisation of PCO morphology drew attention to its prevalence in women presenting without one, or both, of the features traditionally considered definitive of PCOS - HA and anovulation. This was at odds with what was, at the time, the established definition for PCOS as a disorder of HA, anovulation, and PCO morphology. The implications of this for the PCOS diagnostic category were interpreted differently by different OG-PCOS experts, resulting in significant divergence in OG-PCOS experts' perspectives regarding which combinations of physiologic features should be considered indicative of PCOS. This widespread difference in opinion was emblematic of the new complexities and uncertainties that can be provoked by technological advancements in medicine and, in this instance, their potential to act as a catalyst for scientific controversy.

These differences in opinion greatly intensified following the convening of two international consensus conferences - the 1990 NIH-NICHD Conference and the 2003 Rotterdam Conference - and their introduction of two different sets of diagnostic criteria for PCOS. Two distinctive and opposing sides of experts emerged - Rotterdam opponents and Rotterdam supporters - who became embroiled in a longstanding series of rhetorical exchanges aimed at undermining one another's evidence base. While principally centred around a debate about PCOS' diagnostic signifiers, it was evidence, and alternative interpretations of evidence, which were at the heart of the onset and playing out of the PCOS controversy. Both Rotterdam opponents and supporters continuously discredited one another's evidence base. This meant that rather than enabling one side to acquire credence over the other and thus close the controversy on evidence-based terms, the controversy was actually fuelled and sustained by the continuous development and subsequent dismissal of new evidence. It was because of the underdetermination of evidence, that despite continued calls from both sides for further evidence to be generated, the PCOS controversy remained unresolved.

Significant changes were evident in the field of OG-PCOS research and practice within the last decade of OG-PCOS literature examined in this thesis. The voices of women with PCOS became increasingly present and a proposal for a new diagnostic model for PCOS presented Rotterdam opponents and supporters with a compromise, addressing some of the central concerns of both sides. One result of these developments was an increase in more nuanced discussions of individual PCOS phenotypes and a diversion of attentions away from the use of evidence for validating existing diagnostic criteria. While Rotterdam opponents emphasised PCOS' genetic basis and its associated long-term risks, Rotterdam supporters presented a case for the variability of these health risks over an individual's life course. The NIH's proposed model for understanding PCOS focused on treatment and coproduction with patients, and this was more consistent with Rotterdam supporters' claims. It was also consistent with the 2018 international evidence-based guideline for PCOS, which consolidated the definition of PCOS as a lifestyle condition and presented an extensive series of recommendations regarding necessary lifestyle interventions for women with PCOS (Teede et al. 2018). This definition, and the patchwork agreement it embodied, was the accumulative result of the incorporation of patient voices within OG-PCOS literature, an ambition within the field to move beyond the existing controversy, and Rotterdam supporters' endeavours to maintain the flexibility of the PCOS diagnostic category while endorsing a phenotypical approach.

8.3. The Value of a Genealogical Study of Diagnosis

In this section of my chapter, I reflect on the significance of the findings outlined above in the context of contemporary sociological understandings of diagnosis and of the social construction of scientific knowledge. I argue that the developments that have unfolded over the course of the literature examined in this study, are testament to what SSK identifies as the endless revisability of scientific knowledge and the value of scientific controversies in providing a hermeneutic device for the exploration and analysis of the ways that scientific and medical knowledge is constructed. The relevance of these findings for broader sociological understandings of diagnosis stems from the insights they offer into broader trends of medicalisation and the more nuanced examination they enable of the flexible and socially and historically contingent nature of diagnostic categories. These insights are of crucial sociological significance because they underline the sociality of diagnostic categories - a classificatory label with the potential to shape and influence multiple aspects of an

individual's everyday life and identity, but one which is highly contingent on a host of social and historical factors.

8.3.1. The revisability and expansion of the PCOS diagnostic category

Finitism tells us that every act of classification is 'defeasible and revisable' and that a single definition can only ever be based on a finite number of examples of cases (Barnes, Bloor, and Henry, 1996: ix). Through tracing the genealogy of the PCOS diagnostic category from the initial refinements and specificity facilitated by ultrasound imaging in the assessment of PCO morphology, to the expansions and revisions to the category that were generated by newly identified similarities among women presenting with this morphology, this study has generated findings that sit in line with SSK conceptualisations of the endless revisability of scientific and medical classifications. Adams et al.'s (1985) visualisation of an expansive variation in the possible sizes of cysts on the ovaries, significantly greater than that visualised in previous studies, constituted an early example in the history of the PCOS diagnostic category in which it was considered necessary to revise and expand the PCOS classificatory system. This was testament to what finitism understands to be the equivalence of a particular body of scientific knowledge to the finite set of cases that have been encountered within a given scientific field (Sturdy, 2007). It drew attention to the importance of resemblance in enabling scientific communities to expand existing classifications on the grounds of their similarity with newly encountered entities (Bloor, 1982).

The evidence base relating to PCO morphology continued to grow in line with advancements in, and the increasing availability of, ultrasound technology. Franks (1995) identified the presence of PCO morphology in both ovulatory and anovulatory women with HA as indicative of a need for a substantial revision in the PCOS classification system, which would incorporate PCO morphology as a diagnostic criterion and re-evaluate existing definitions of HA as a unifying feature. This raised important questions about the stability of the recently introduced NIH-NICHD recommendations and its continued classification of HA and oligo-ovulation as the central features of PCOS. It was also in line with SSK understandings of the revisability and open-ended nature of classification (Bloor, 1982). The years of disagreement and controversy that followed as a result of some experts' alternative interpretation of this data, brought into heightened focus the extent to which evidence is underdetermined by

theory and the complex social processes this can generate in overseeing the classification of a previously unclassifiable entity.

8.3.2. The medicalisation of distress and the development of a diagnostic 'continuum'

As these debates unfolded and three different sets of diagnostic criteria were introduced for PCOS, some experts focused increasingly on the psychological risks presented by PCOS. This was particularly true of Rotterdam supporters who presented these risks as unaffected by individual PCOS phenotype, supporting their case for a more inclusive approach to PCOS diagnosis. The psychological features of PCOS were mentioned repeatedly in Teede et al.'s (2018a; 2018b) international evidence-based guideline for PCOS, and professionals and organisations from psychiatry and psychology were involved in the development of this guideline. The 2018 international evidence-based guideline report consolidated and embodied what can be interpreted as the process by which distress associated with PCOS became increasingly medicalised. This contributed further to the expansion of the PCOS diagnostic category and the acknowledgment in OG-PCOS literature of its entanglement with a wide range of physical and emotional issues and experiences, which transcend far beyond the category's core diagnostic criteria. The medicalisation of distress can be defined in the broadest terms as, the 'process by which behaviours and emotions such as intense fear or sadness, that could be an expectable response to stressful life events and social circumstances, come to be treated as mental disorders' (Doblytė, 2022: 363-364). Although in the context of the PCOS diagnostic category, the medicalisation of distress resulted from Rotterdam supporters' mobilisation of risk as a tool for negotiating the category's boundaries, the degree to which Rotterdam supporters were able to apply this tool effectively reflects the societal and medical value that has come to be placed on the medicalisation of 'non-disordered mental distress' more widely (Doblytė, 2022: 375).

Although still nominally a category, these significant expansions in the boundaries of PCOS diagnosis over the course of this controversy have contributed to its evolution into a diagnostic 'continuum' or 'spectrum'. PCOS was discussed in OG-PCOS literature according to its degree of 'mildness' and 'severity', so that phenotypical variation has come to be defined as an inherent aspect of the condition. The terminology of 'PCOS' has itself evolved into a more flexible diagnostic label that encompasses a number of different types of conditions, rather than representing an absolute condition in its own right. This evolution in the concept of PCOS diagnosis in itself, is evidence of the fluidity and changeability of the

boundaries of diagnostic categories and of their evolution into less absolutist entities as a result of increasing processes of medicalisation. It is by analysing an individual diagnostic category through the lens of an ongoing scientific controversy, and by paying detailed attention to experts' alternative interpretations of that category, that this study has been able to shed new light on wider processes of medicalisation. It reveals the increasing trend towards the medicalisation of distress to be one that not only contributes to the development of new diagnostic categories, but which also expands the boundaries of existing ones. It also points to a potential new trend through which these boundary expansions, and their subjection to a continual process of medicalisation, may be resulting in the construction of a new type or structure of diagnostic category altogether.

8.3.3. The value of boundary work in sociological studies of diagnosis

As well as drawing attention to the possible implications of the fluidity and socially and historically contingent nature of the boundaries of diagnostic categories, in tracing the processes and strategies by which OG-PCOS experts navigated the controversy surrounding the PCOS diagnostic category, I have demonstrated the applicability of boundary work as a useful concept in the sociological exploration of contentious diagnostic categories. I analysed for example, the rhetorical strategies that were used by more traditionalist OG-PCOS experts, like Chang (2002) and Azziz (2003), to convey the argument that the NIH criteria, and in particular its classification of HA as central and essential to any diagnosis of PCOS, remained valid and useful for PCOS diagnostic practices. Chang (2002) presented the reticence among some PCOS experts regarding ultrasound technology as having been the result of a limited understanding within OG of the origins of PCO morphology, but I have argued that this in itself constituted a rhetorical device designed to preserve the diagnostic criteria in their most traditionalist form and to retain and protect the existing boundaries of the PCOS diagnostic category. I also explored the counter response to this traditionalist approach employed by experts who supported a revised and more inclusive PCOS diagnostic strategy. Their active efforts to bring about the increased standardisation and routinisation of ultrasound technology through the development of stringent tools and guidelines designed to optimise its value within OG-PCOS research, were intended to facilitate PCOS diagnosis among a broader spectrum of women including those without clinically or biochemically detectable HA.

As well as illuminating the reciprocal nature of attempts to influence the boundaries of the PCOS diagnostic category, applying the concept of boundary work to an uncertain and evolving diagnostic category shed important light on the role played by the underdetermination of evidence by theory in shaping the strategies experts use to navigate scientific and medical controversies. The Duhem-Quine thesis argues that scientific evidence is never sufficient to inhibit the development of alternative and contradictory theories, both of which may offer adequate explanations of that evidence (Quine, 1963). This means that it is always possible for scientific evidence to be disputed, dismissed, or for alternative explanations to be developed which contradict rival perspectives (Dietrich and Skipper, 2007). This is particularly so during controversies and, as the controversy explored in this thesis attests, there are a multitude of ways and rhetorical strategies through which the experts embroiled in such a conflict can undermine evidence as a means of navigating the controversy and challenging their opponent (MacKenzie, 1989).

In analysing these strategies, I focused in particular on Rotterdam opponents' criticisms of the quantity and quality of the evidence on which components of the Rotterdam criteria were based and also on their development of alternative explanations for other aspects of the Rotterdam evidence base that did not adhere with their own similarity relations for a diagnosis of PCOS. I argued that these represented strategies deployed by Rotterdam opponents as part of their efforts to challenge the Rotterdam criteria, reinstate the NIH criteria for PCOS, and attempt to close the controversy along more traditionalist lines. Rotterdam supporters countered many of these challenges by presenting their own alternative explanations of evidence and through emphasising the inadequacies of Rotterdam opponents' evidence base. It was Rotterdam opponents though, who placed greatest emphasis on their own arguments and claims as rooted in a strong scientific evidence base. The exaggeration of existing evidence, and persistent emphasis on its 'collective robustness', is a common rhetorical strategy employed by scientific experts or authorities embroiled in a controversy (Ramírez-i-Ollé, 2015: 391). While stressing the paucity of research behind some of the decisions made at the Rotterdam Conference in order to represent them as having been premature in light of available findings, Azziz and his fellow Rotterdam opponents placed significant emphasis on the evidence-based nature of the NIH criteria and of their own decision-making behind proposals for new criteria for PCOS.

It is interesting that Rotterdam opponents were more than willing to mobilise the underdetermined nature of the Rotterdam evidence base, but to overlook the same inherent nature of their own supporting evidence. It sits firmly in line with what Collins (1981) argues to be the credence and weight attributed to experiential and empirical evidence, regardless of the validity of that evidence in and of itself, in delivering and legitimating scientific claims making within a scientific dispute. It is also testament to what SSK identifies as the perpetual limitations of scientific evidence and the endless scope it offers for alternative hypotheses and explanations to be developed in line with an expert's own theoretical standpoint (Dietrich and Skipper, 2007; Quine, 1963). In this particular controversy, many of the exchanges between Rotterdam opponents and supporters involved calls for *more* evidence to be generated in order for lingering uncertainties and questions in the field to be answered and for the controversy to be closed. After the convening of the Rotterdam Conference in 2003 though, countless papers were published which provided new evidence on the issue of PCO morphology as a diagnostic indicator for PCOS; yet by 2010, the controversy was still far from resolved. It is in this sense that through using the concept of boundary work to examine the reciprocal exchanges that took place between Rotterdam opponents and supporters during the PCOS controversy, my study sheds light on the role that the underdetermination of evidence by theory can play in sustaining and fuelling controversies. The result in this instance, was that institutions and experts invested in the field of OG-PCOS research, but not directly embroiled within the controversy, sought alternative ways of closing the controversy and moving it away from a focus on evidence and the ontological intricacies of the PCOS diagnostic category.

8.3.4. How patient voice can alter a controversy - the development of a patchwork agreement

As a result of the incorporation of patient voices, the PCOS controversy moved away from its focus on evidence and definition and towards an ostensive agreement between Rotterdam opponents and supporters. The co-productive and patient-centred recommendations of the 2011 Australian Task Force report instigated the controversy's change in direction towards a focus on previously unconsidered dimensions of the PCOS diagnostic category, as experienced by patients. Alongside the report's incorporation of patient, academic, and practitioner expertise across a wide range of fields, the position of Teede, the lead author of the report, outwith the primary positions within the controversy, contributed to the report's status as a new body of voices within the controversy. It meant that the report carried a

certain detachment from the discursive exchanges taking place between Rotterdam opponents and supporters, allowing for an interpretation of its guideline recommendations as distinct from the rhetorical strategies that had by that point pervaded and maintained the controversy. The NIH (2012) report endorsed many of the Australian Task Force's (2011) patient-centred values and recommendations and presented a unique proposal for a new diagnostic model for the field. I argued that this proposal constituted a straightforward amalgamation of Rotterdam opponents' and supporters' respective central priorities for the PCOS diagnostic category and offered both sides a compromise that would function for the field as a whole.

In examining Rotterdam opponents' and supporters' responses to these developments, I highlighted their increasing alignment on the issue of phenotypical differences in *some* of the long-term health risks associated with PCOS and their mutual consent to the NIH's (2012) proposal for a phenotypical approach to the Rotterdam criteria. This was indicative of the extent of the shift that had been facilitated within the OG-PCOS literature as a result of the incorporation of new and diverse patient voices. The incorporation of patient voices required Rotterdam opponents and supporters alike, to reconsider and adapt their approach towards promoting and securing their own definitions of PCOS within the diagnostic category to avoid being left behind and marginalised by the rest of the contributors in the field. This unprecedented development, given each side's vociferous opposition to one another regarding these same issues earlier in the controversy, draws attention to Rotterdam opponents' and supporters' continued divergence in their interpretations of other aspects of the diagnostic category. At this stage in the controversy, Rotterdam opponents and supporters each mobilised a distinctive and competing risk-based discourse; they engaged in this as a means of working towards the fulfilment of as many of their own aims for the PCOS diagnostic category as possible within any realisation of the NIH's (2012) proposal.

Controversy closure amounts to the emergence of consensus within a field or a loss of interest in the issues which were once the source of conflict and disagreement (Engelhardt and Caplan, 1987; Pinch and Leuenberger, 2006). In the instance of Rotterdam opponents' and supporters' responses to recent changes within the field of OG-PCOS research - the NIH's (2012) proposal and the increased presence of patient voices and of patient-centred recommendations within the field - neither of these features of controversy closure took

place. It was the simultaneous willingness on both sides to concede on many of their previous demands for the PCOS diagnostic category, combined with a continued divergence in their fundamental definitions of PCOS, that was testament to the development, not of consensus, but of a functional 'patchwork' agreement in the field. A compromise had been reached on the issue of PCOS diagnostic criteria, enabling both Rotterdam supporters and opponents to focus their research efforts elsewhere. This compromise however, given the distinctive differences which remained in Rotterdam opponents' and supporters' respective perspectives on PCOS' ontological intricacies, contained, and continues to contain, a certain level of fragility.

Through applying controversy as method as a lens for exploring the social construction of a contentious diagnostic category, this study has identified a state of affairs in which a controversy became diluted in its intensity without necessarily being resolved. This offers a unique contribution to existing controversy literature, which at present discusses controversies as being either ongoing, or closed. In the case of the PCOS controversy, it is neither actively ongoing, nor decisively resolved. By providing insight into an alternative course through which controversies can change and develop over time, this thesis has also offered an important contribution to existing sociological understandings of diagnosis. It reveals the role that controversies themselves can play in shaping diagnostic categories and brings to the fore their sociality and complexity as an amalgamative combination of competing scientific interpretations and social interests. In this instance, the contemporary definition of PCOS as a lifestyle disorder is both a product of a once vociferous scientific controversy and a means of deterring any reignition of the impassioned debates that used to dominate the field of OG-PCOS research.

8.4. Directions for Future Research

I identified in the early stages of this project, a significant conceptual gap within existing social scientific scholarship focused on PCOS. This related to the role of diagnosis in shaping women's experiences of PCOS, as well as wider societal understandings of the condition. In order to advance this existing body of scholarship, and to develop a more nuanced appreciation of its implications for individuals and society as a whole, it seemed essential to first address this gap through a genealogical exploration of the PCOS diagnostic category. The conceptual tools SSK offers for a refined study of the social construction of scientific knowledge, alongside an awareness of the wide-reaching influence of individual diagnostic

categories, has enabled this thesis to shed light on the PCOS diagnostic category's complexity and its significance as a powerful classificatory tool. It reveals PCOS diagnosis to be a product, not just of scientific findings and straightforward associations between a set of symptoms and a cause but, of a plethora of historically situated social contingencies. More integrated analyses of this kind will help to shed further light on the complex sociality of diagnostic categories and the importance of competing social, cultural, and professional values and interests in shaping their development, as well as the frequent ambiguity and underdetermination of the evidence on which they are based.

Using SSK concepts within an applied study of diagnosis will also optimise the value of individual diagnostic categories as hermeneutic devices for illuminating broader trends in medicalisation and its societal implications. It will provide a more nuanced understanding of the role that diagnosis plays in shaping societal definitions of normativity, and deviations from it, while drawing attention to trends in medicalisation and medical knowledge formation that are currently underdeveloped in sociological literature. It is also important that future research explores the relations between the diagnostic category and the lived realities of being diagnosed and of living with PCOS and that this research represents women and people with PCOS from diverse social and cultural backgrounds. A more integrated application of concepts from within SSK and the sociology of diagnosis in framing and informing this research, will shed further light on the role that the processes of medical knowledge construction explored in this thesis play in shaping experiences of PCOS.

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Varanasi, L.C., Subasinghe, A., Jayasinghe, Y.L., Callegari, E.T., Garland, S.M., Gorelik, A. and Wark, J.D. (2018) 'Polycystic ovarian syndrome: Prevalence and impact on the wellbeing of Australian women aged 16–29 years', *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 58, 2: 222-233.

Veenstra, G. (2013) 'Race, gender, class, sexuality (RGCS) and hypertension', *Social science & medicine*, 89, 16-24.

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Appendices

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- Appendix E: Graph depicting total number of PCOS-related medical journal articles published between 1935 and 2019
- Appendix F: Graph depicting differences in amount of PCOS-related papers published in different medical specialties between 1935 and 2019
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Appendix A: Earliest PCOS-related medical journal articles identified using Google Scholar

Year of publication	**Author**	**Article title**	**Journal Title**	**Profession**
1935	I.F. Stein	'A 9-Year-Old Girl Presenting Central Precocious Puberty with Polycystic Ovary Syndrome'	*Am J Obstet Gynecol*	Obstetrics and Gynaecology
1935	I.F. Stein and M.L. Leventhal	'[CITATION] Amenorrhea associated with polycystic ovary syndrome'	*Am J Obstet Gynecol*	Obstetrics and Gynaecology
1936	H.C. Taylor	Symptoms and treatment of follicle cysts of ovary	*The American Journal of Surgery*	General surgery

Appendix B: PCOS-related medical journal articles published between 1941 and 1950 identified using Google Scholar

Year of publication	Article Title	Authors	Journal	Medical specialty
1941	Amenorrhea and sterility caused by bilateral polycystic ovaries	M.L. Leventhal	*American Journal of Obstetrics & Gynecology*	Obstetrics and gynaecology
1943	Bilateral Microcystic Degeneration of the Ovaries and Masculinizing Syndrome	S.J. Turner	*American Journal of Obstetrics and Gynecology*	Obstetrics and gynaecology
1947	THREE UNUSUAL ENDOCRINOPATHIES WITH ASSOCIATED OVARIAN PATHOLOGY: I. OVARIAN AGENESIS. II. PRECOCIOUS PUBERTY. III. VIRILISM	M.B. Goldberg, A.F. Maxwell, P.M. Smith	*The Journal of Clinical Endocrinology & Metabolism*	Clinical endocrinology
1948	Polycystic ovaries in a fetus	P. Bianchi	*Riv. Ital. di Ginec.*	Unknown
1949	Genesis of endometrial carcinoma. II. Cases 19 to 35 years old	S.C. Sommers, A.T. Hertig, H. Bengloff	*Cancer*	Oncology
1949	Results of bilateral ovarian wedge resection in 47 cases of sterility: Twenty-year end results: 75 cases of bilateral polycystic ovaries	I.F. Stein, M.R. Cohen, R. Elson	*American Journal of Obstetrics & Gynecology*	Obstetrics and gynaecology
1949	Sterility and endometriosis	L.S. McCoogan	*Archives of Surgery*	General surgery
1950	Ovarian resection for the relief of sterility	S.R. Meaker	*Fertility and sterility*	Obstetrics and gynaecology; Reproductive endocrinology; Urology

Appendix C: Screenshots of tables displaying PCOS-related articles generated per database

Scopus database

1951 – 1960

A search for polycystic ovary syndrome yields... 129 results

(note – this search engine seems to equate polycystic ovary syndrome *with* stein and Leventhal syndrome)

A search for stein and leventhal syndrome yields... 154 results

A search for stein and Leventhal yields...

A search for PCOS yields... 6 results (none of these results are relevant)

A search for polycystic ovaries yields... 163 results

Exclusions

When searching for polycystic ovary syndrome... I excluded anything that came under 'Energy' or 'Biochemistry, Genetics and Molecular Biology', as these are not relevant the area I am looking at. I also excluded all languages other than English – this left me with 50 articles, an already more manageable number.

I then applied these same rules to each of the other searches, leaving me with... 54 articles after searching for 'stein and Leventhal syndrome' ; 62 results for Stein and Leventhal; 64 results for polycystic ovaries

*Please note, due to numbers, I have not recorded overlaps/ or results that have already appeared, in the table below

Year of publication	Article Title	Author	Journal	Profession	Search term
1960	The polycystic ovary syndrome.	GREENBLATT, R.B., MORENO MARTINEZ, O.	Arizona medicine 17, pp. 519-524	General Medicine	Polycystic ovary syndrome
1960	"In vitro" production of androgenic steroids by human normal and "Stein-Leventhal type" ovarian slices.	LANTHIER, A., SANDOR, T.	Metabolism: clinical and experimental 9, pp. 861-864	Endocrinology, diabetes and metabolism; Medicine: Biochemistry (medical)	Polycystic ovary syndrome
1960	Is there a Stein-Leventhal Syndrome?	Roberts, D.W.T., Haines, M.	British Medical Journal 1(5187), pp. 1709-1711	General Medicine	Polycystic ovary syndrome
1960	Bilateral polycystic ovaries-Stein-Leventhal syndrome-enigma or dogma.	YONEDA, Y.	Canadian Medical Association journal 82, pp. 1117-1121	General Medicine	Polycystic ovary syndrome
1960	Amenorrheas of endocrine nature and celioscopy	VIGNALOU, J., PLOUIN, S.	Revue médicale de France 41, pp. 279-282	(Not sure, information is in French).	Polycystic ovary syndrome
1960	Acute hemoperitoneum caused by rupture of a polycystic ovary.	LAUDERDALE, J.M., RUSSELL, S.C.	Medical bulletin of the U. S. Army, Europe. United States. Army, Europe. Medical Division 17, pp. 47-50	Military Medicine	Polycystic ovary syndrome
1960	The syndrome of polycystic ovaries and hyperthecosis. A clinical eval uation.	LANTHIER, A., LAUZE, S., GRIGNON, C.E.	The American journal of the medical sciences 239, pp. 585-593	General Medicine	Polycystic ovary syndrome
1960	Urinary 17-ketosteroids in the syndrome of polycystic ovaries and hyperthecosis.	LANTHIER, A.	The Journal of clinical endocrinology and metabolism 20, pp. 1587-1600	Endocrinology, diabetes and metabolism; Medicine: Biochemistry (medical)	Polycystic ovary syndrome
1960	An investigation of ovarian tissue and urinary 17-ketosteroids in patients with bilateral polycystic ovaries	Trace, R.J., Keaty, E.C., McCall, M.L.	American Journal of Obstetrics and Gynecology 79(2), pp. 310-315	Obstetrics and Gynaecology	Polycystic ovary syndrome

Web of Science database

1971 – 1980

A search for polycystic ovary syndrome yielded... 9

A search for stein and Leventhal syndrome yielded... 12

A search for Stein and Leventhal yielded... 14

A search for PCOS yielded... None

A search for polycystic ovaries yielded... 13

Year of publication	Article Title	Author/(s)	Journal	Profession	Search term
1980	Prolactin Release in Polycystic Ovary.[Article]	FALASCHI, P. MD; POZO, E. DEL MD; ROCCO, A. MD; TOSCANO, V. MD; PETRANGELI, E. MD; POMPEI, P. MD; FRAJESE, G. MD	Obstetrics & Gynecology. 55(5):579-582, May 1980.	Obstetrics and Gynaecology	Polycystic ovary syndrome
1979	Use of Bromocriptine in Hyperprolactinaemic Anovulation and Related Disorders.[Miscellaneous]	Franks, S.	Drugs. 17(5):337-348, May 1979.	Clinical Medicine	Polycystic ovary syndrome
1976	CHARACTERIZATION OF THE INAPPROPRIATE GONADOTROPIN SECRETION IN POLYCYSTIC OVARY SYNDROME.[Miscellaneous]	REBAR, R.; JUDD, H. L.; YEN, S. S. C.; RAKOFF, J.; VANDENBERG, G.; NAFTOLIN, F.	Obstetrical & Gynecological Survey. 31(9):681-683, September 1976.	Obstetrics and Gynaecology	Polycystic ovary syndrome
1974	Etiology and Treatment of Dysfunctional Uterine Bleeding.[Article]	AKSEL, SEZER MD; JONES, GEORGEANNA SEEGAR MD	Obstetrics & Gynecology. 44(1):1-13, July 1974.	Obstetrics and Gynaecology	Stein and Leventhal syndrome
1973	Laparoscopy in Infants and Adolescents.[Miscellaneous]	COGNAT, MICHEL MD; ROSENBERG, DANIEL MD; DAVID, LOUIS MD; PAPATHANASSIOU, ZISSIS MD	Obstetrics & Gynecology. 42(4):515-521, October 1973.	Obstetrics and Gynaecology	Stein and Leventhal syndrome
1973	Inappropriate Secretion of LH in the Stein-Leventhal Syndrome.[Article]	GAMBRELL, RICHARD D. JR MD, FACOG; GREENBLATT, ROBERT B. MD, FACOG; MAHESH, VIRENDRA B. PhD	Obstetrics & Gynecology. 42(3):429-440, September 1973.	Obstetrics and Gynaecology	Stein and Leventhal syndrome
1971	Serum Gonadotropin Levels and Ancillary Studies in Stein-Leventhal Syndrome Treated with Clomiphene Citrate.[Article]	GAMBRELL, RICHARD D. JR, LT COL USAF, MC, FACOG; GREENBLATT, ROBERT B. MD, FACOG; MAHESH, VIRENDRA B. PHD, DPHIL	Obstetrics & Gynecology. 38(6):850-862, December 1971.	Obstetrics and Gynaecology	Stein and Leventhal syndrome
~~1971~~	~~TREATMENT OF ANOVULATION IN THE STEIN-LEVENTHAL SYNDROME. ANALYSIS OF 90 CASES.[Miscellaneous]~~	~~ZARATE, A.; HERNANDEZ-AYUP, S.; RIOS-MONTIEL, A.~~	~~Obstetrical & Gynecological Survey. 26(8):595-596, August 1971.~~	~~Obstetrics and Gynaecology~~	~~Stein and Leventhal syndrome~~
					Stein and Leventhal

Medline database

1971 – 1980

A search for polycystic ovary syndrome yielded... 47 (refined to only include English)

A search for stein and Leventhal syndrome yielded... 32 results (ONLY ENGLISH)

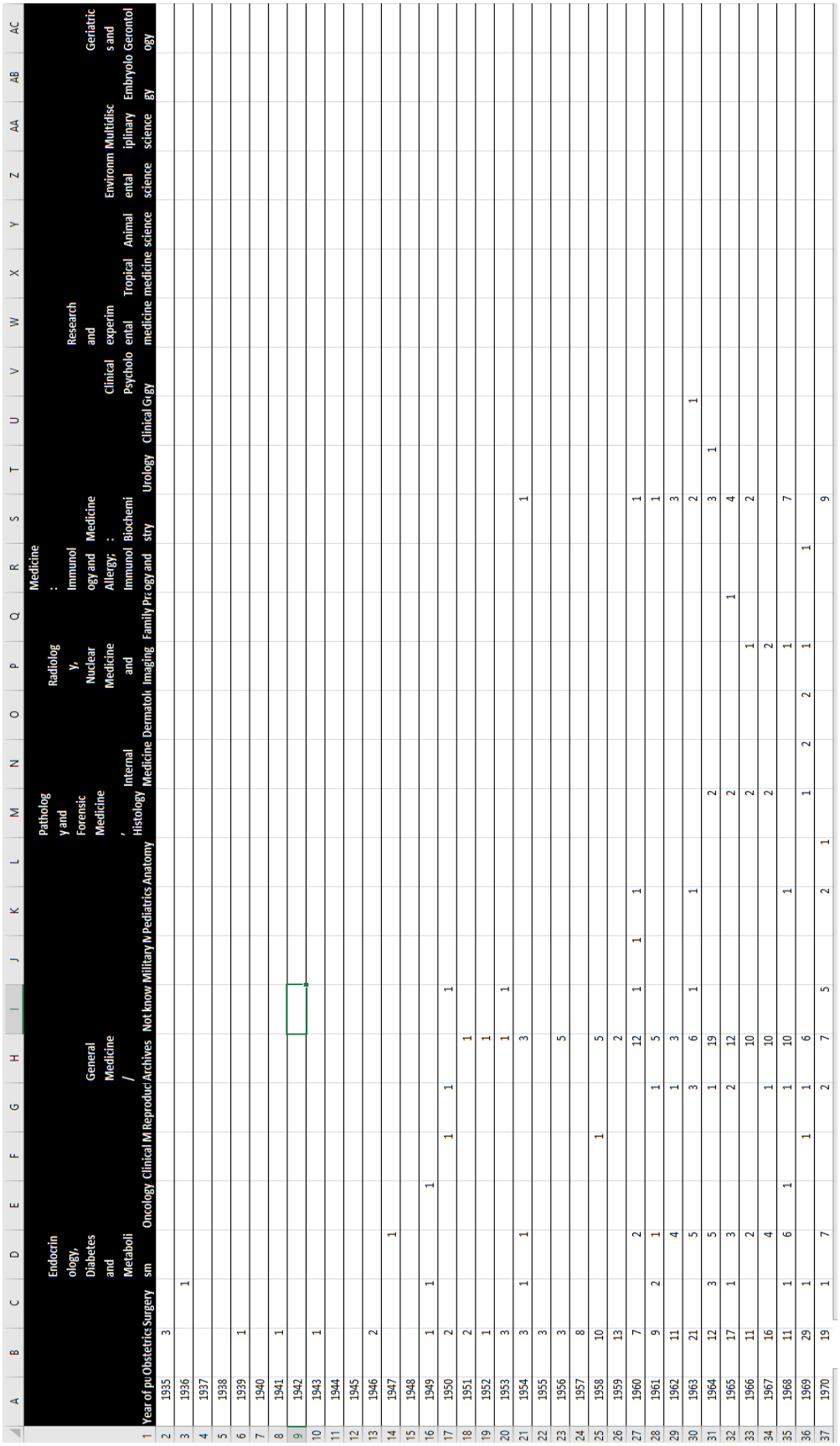
A search for Stein and Leventhal yielded... 32 results (ONLY ENGLISH) (all repeats of above bar 1)

A search for PCOS yielded... (2 that were relevant to this topic) (ONLY ENGLISH)

A search for polycystic ovaries yielded... 91 (ONLY ENGLISH)

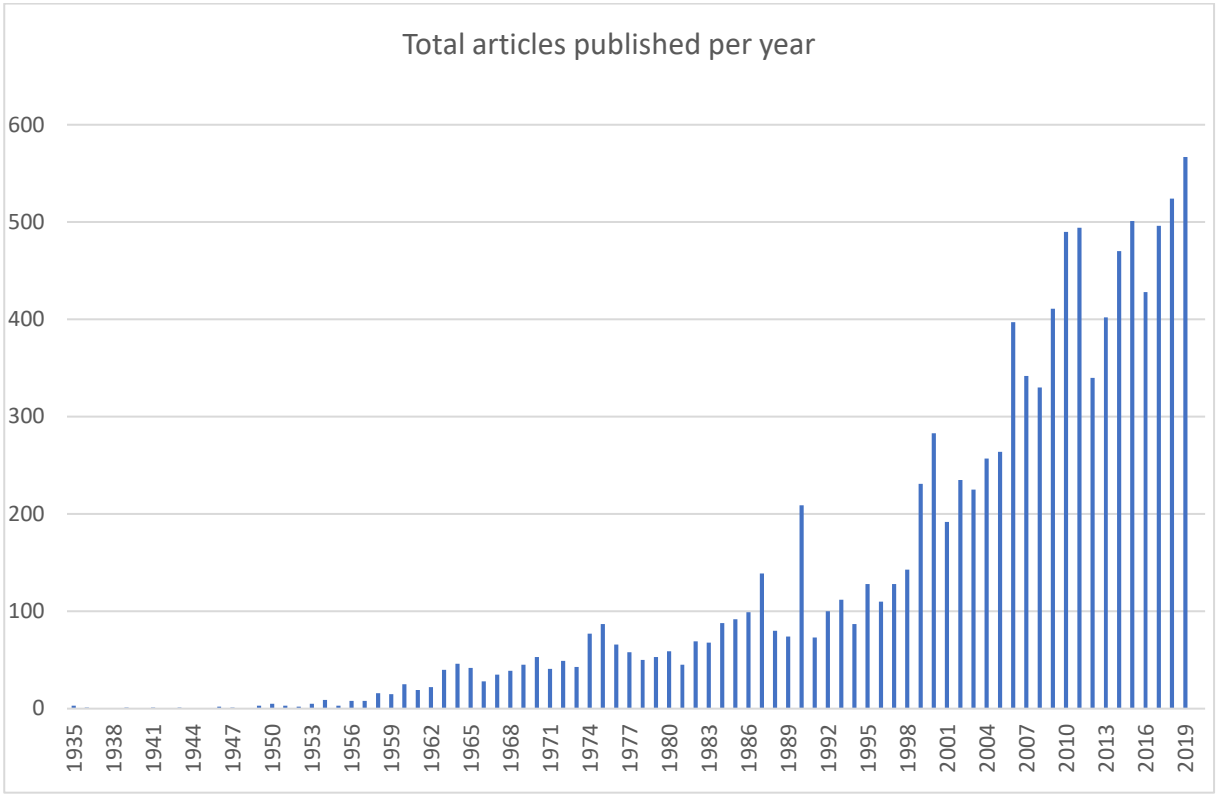
Year	Author	Article title	Journal Title	Profession	Search term
1980	YEN, SSC	POLYCYSTIC OVARY SYNDROME	CLINICAL ENDOCRINOLOGY Volume: 12 Issue: 2 Pages: 177-207 Published: 1980	Endocrinology & Metabolism	Polycystic ovary syndrome
1980	KASUGA, Y	OVARIAN STEROIDOGENESIS IN JAPANESE PATIENTS WITH POLYCYSTIC OVARY SYNDROME	ENDOCRINOLOGIA JAPONICA Volume: 27 Issue: 5 Pages: 541-550 Published: 1980	Endocrinology & Metabolism	Polycystic ovary syndrome
1980	WORTSMAN, J; HIRSCHOWITZ, JS	GALACTORRHEA AND HYPERPROLACTINEMIA DURING TREATMENT OF POLYCYSTIC OVARY SYNDROME	OBSTETRICS AND GYNECOLOGY Volume: 55 Issue: 4 Pages: 460-463 Published: 1980	Obstetrics & Gynecology	Polycystic ovary syndrome
1980	DELPOZO, E; FALASCHI, P	ROLE OF PROLACTIN IN THE POLYCYSTIC OVARY SYNDROME	SCOTTISH MEDICAL JOURNAL Volume: 25 Supplement: S Pages: S89-S93 Published: 1980	General & Internal Medicine	Polycystic ovary syndrome
1979	KANDEEL, FR; LONDON, DR; BUTT, WR; et al.	ADRENAL ABNORMALITIES IN SUBGROUPS OF THE POLYCYSTIC OVARY SYNDROME	ACTA ENDOCRINOLOGICA Volume: 91 Supplement: 225 Pages: 113-113 Published: 1979	Endocrinology & Metabolism	Polycystic ovary syndrome
1979	MCBEE, A; STACHURA, I	OVARIAN HILAR CELL TUMOR WITH COEXISTENT POLYCYSTIC OVARY SYNDROME AND MYOMETRIAL HYPERTROPHY	GYNECOLOGIC ONCOLOGY Volume: 8 Issue: 3 Pages: 370-375 Published: 1979	Oncology; Obstetrics & Gynecology	Polycystic ovary syndrome
1979	LACHELIN, GCL; BARNETT, M; HOPPER, BR; et al.	ADRENAL-FUNCTION IN NORMAL WOMEN AND WOMEN WITH THE POLYCYSTIC OVARY SYNDROME	JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM Volume: 49 Issue: 6 Pages: 892-898	Endocrinology & Metabolism	Polycystic ovary syndrome
1979	FALASCHI, P; ROCCO, A; POMPEI, P; et al.	HYPER-PROLACTINEMIA IN POLYCYSTIC OVARY SYNDROME AND IN PITUITARY-ADENOMA - PROLACTIN RESPONSE TO PHARMACOLOGICAL STIMULI	JOURNAL OF STEROID BIOCHEMISTRY AND MOLECULAR BIOLOGY Volume: 11 Issue: 5-6 Pages: R19-R19	Biochemistry & Molecular Biology; Endocrinology & Metabolism	Polycystic ovary syndrome
1979	HALPERIN, G; MASCHLER, I	ISOLATION OF URINARY C-20-ALPHA-HYDROXY-C21-STEROID AND C-20-BETA-HYDROXY-C21-STEROID METABOLITES IN CASES OF CONGENITAL ADRENAL-HYPERPLASIA, POST-PUBERTAL VIRILIZING SYNDROME AND POLYCYSTIC OVARY SYNDROME	STEROIDS Volume: 33 Issue: 1 Pages: 33-44 Published: 1979	Biochemistry & Molecular Biology; Endocrinology & Metabolism	Polycystic ovary syndrome
1978	KANDEEL, FR; BUTT, WR; LONDON, DR; et al.	ESTROGEN AMPLIFICATION OF LH-RH RESPONSE IN POLYCYSTIC OVARY SYNDROME AND RESPONSE TO CLOMIPHENE	CLINICAL ENDOCRINOLOGY Volume: 9 Issue: 5 Pages: 429-441 Published: 1978	Endocrinology & Metabolism	Polycystic ovary syndrome

Appendix D: Screenshot of Excel sheet recording the number of PCOS-related publications per year according to their specialty

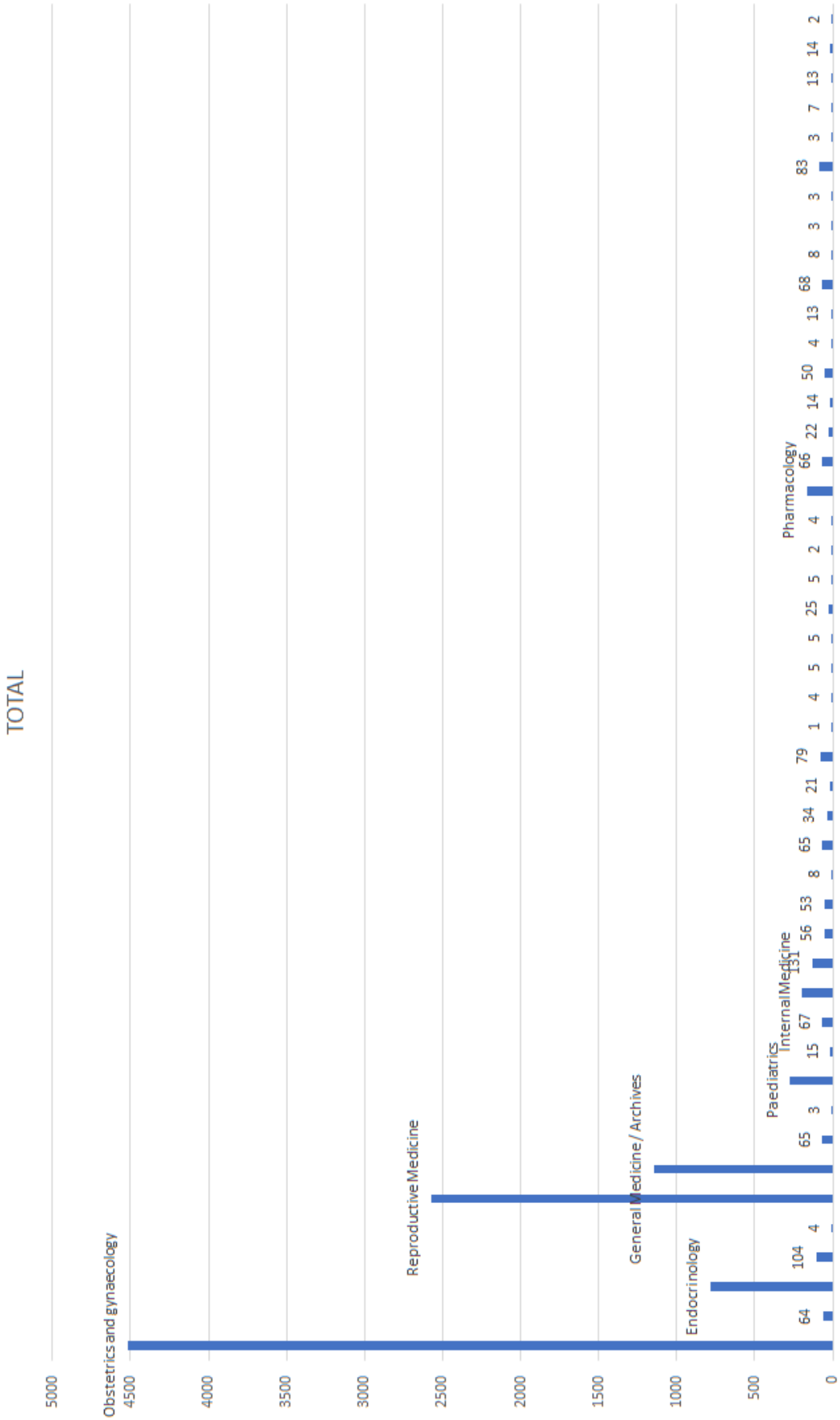


Year of pu	Obstetrics	Surgery	Endocrinology, Diabetes and Metabolism	Oncology	Clinical	Reproduct	General Medicine / Archives	Not know	Military N	Pediatrics	Anatomy	Pathology and Forensic Medicine, Histology	Internal Medicine	Dermatol	Radiology, Nuclear Medicine and Imaging	Family Pr	Immunology and Allergy; Immunol	Medicine : Biochemistry	Urology	Clinical Gy	Clinical Psycholo gy	Research and experim ental medicine	Tropical medicine	Animal science	Environm ental science	Multidisc iplinary science	Embryolo gy	Geriatrics and Gerontology
1935		3																									
1936			1																								
1937																											
1938																											
1939		1																									
1940																											
1941		1																									
1942																											
1943		1																									
1944																											
1945																											
1946		2																									
1947				1																							
1948																											
1949		1	1		1																						
1950		2				1	1		1				2			1												
1951		2						1																			
1952		1						1																			
1953		3						1	1																		
1954		3	1	1				3										1									
1955		3																									
1956		3						5																			
1957		8																									
1958		10				1		5																			
1959		13						2																			
1960		7		2				12	1	1	1								1								
1961		9	2	1			1	5											1								
1962		11		4			1	3											3								
1963		21		5			3	6	1		1								2		1						
1964		12	3	5			1	19					2						3	1							
1965		17	1	3			2	12					2				1		4								
1966		11		2				10					2		1				2								
1967		16		4			1	10			1		2		2												
1968		11	1	6	1		1	10							1				7								
1969		29	1			1	1	6					1	2	1			1									
1970		19	1	7			2	7	5		2	1							9								

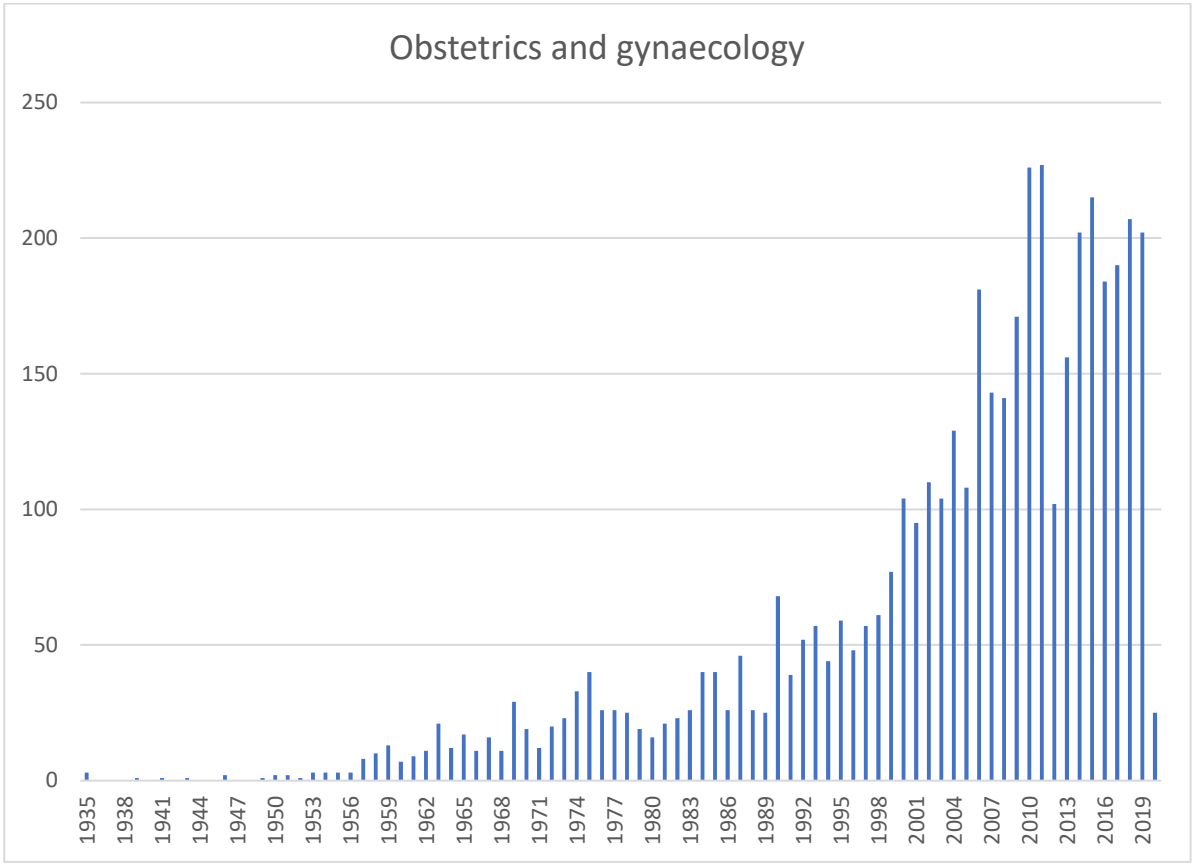
Appendix E: Graph depicting total number of PCOS-related medical journal articles published between 1935 and 2019



Appendix F: Graph depicting differences in amount of PCOS-related papers published in different medical specialties between 1935 and 2019



Appendix G: Graph depicting rate of PCOS-related publication activity within obstetrics and gynaecology between 1935 and 2019



Appendix H: Target quotas for document sample

	Number of OG articles published	Percentage of the OG articles published between 2001 and 2019 (%)	Quotas per year (number of articles)
2001	95	3.046824887748557	4
2002	110	3.527902501603592	5
2003	104	3.3354714560615775	5
2004	129	4.137267479153303	6
2005	108	3.463758819756254	5
2006	181	5.805003207184092	9
2007	143	4.58627325208467	7
2008	141	4.522129570237332	7
2009	171	5.484284797947402	8
2010	226	7.248236048749199	11
2011	227	7.2803078896728675	11
2012	102	3.27132777421424	5
2013	156	5.003207184092367	8
2014	202	6.478511866581142	10
2015	215	6.89544579858884	10
2016	184	5.9012187299551	9
2017	190	6.093649775497114	9
2018	207	6.638871071199487	10
2019	202	6.478511866581142	10

Appendix I: Sample list

2001

Kahsar-Miller, M.D., Nixon, C., Boots, L.R., Go, R.C. and Azziz, R. (2001) 'Prevalence of polycystic ovary syndrome (PCOS) in first-degree relatives of patients with PCOS', *Fertility and sterility*, 75, 1: 53-58.

El-Sheikh, M.M., Hussein, M., Fouad, S., El-Sheikh, R., Bauer, O. and Al-Hasani, S. (2001) 'Limited ovarian stimulation (LOS), prevents the recurrence of severe forms of ovarian hyperstimulation syndrome in polycystic ovarian disease', *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 94, 2: 245-249.

Lewis, V. (2001) 'Polycystic ovary syndrome: a diagnostic challenge', *Obstetrics and Gynecology Clinics*, 28, 1: 1-20.

Vandermolen, D.T., Ratts, V.S., Evans, W.S., Stovall, D.W., Kauma, S.W. and Nestler, J.E., (2001) 'Metformin increases the ovulatory rate and pregnancy rate from clomiphene citrate in patients with polycystic ovary syndrome who are resistant to clomiphene citrate alone', *Fertility and sterility*, 75, 2: 310-315.

2002

Awartani, K.A. and Cheung, A.P. (2002) 'Metformin and polycystic ovary syndrome: a literature review', *Journal of Obstetrics and Gynaecology Canada*, 24, 5: 393-401.

Glueck, C.J., Wang, P., Kobayashi, S., Phillips, H. and Sieve-Smith, L. (2002) 'Metformin therapy throughout pregnancy reduces the development of gestational diabetes in women with polycystic ovary syndrome', *Fertility and sterility*, 77, 3: 520-525.

Heard, M.J., Pierce, A., Carson, S.A. and Buster, J.E. (2002) 'Pregnancies following use of metformin for ovulation induction in patients with polycystic ovary syndrome', *Fertility and sterility*, 77, 4: 669-673.

Stadtmauer, L.A., Wong, B.C. and Oehninger, S. (2002) 'Should patients with polycystic ovary syndrome be treated with metformin? Benefits of insulin sensitizing drugs in polycystic ovary syndrome—beyond ovulation induction', *Human Reproduction*, 17, 12: 3016-3026.

2003

Azziz, R. (2003) 'Androgen Excess Is the Key Element in Polycystic Ovary Syndrome'*, Fertility and Sterility,* 80.2: 252-54.

Balen, A.H, Laven, J.S., Tan, S.L. and Dewailly, D. (2003) 'Ultrasound Assessment of the Polycystic Ovary: International Consensus Definitions', *Human Reproduction Update*, 9.6: 505-14.

Jonard, S., Robert, Y., Cortet-Rudelli, C., Pigny, P., Decanter, C. and Dewailly, D. (2003) 'Ultrasound examination of polycystic ovaries: is it worth counting the follicles?', *Human reproduction*, 18, 3: 598-603.

Korhonen, S., Romppanen, E.L., Hiltunen, M., Helisalmi, S., Punnonen, K., Hippeläinen, M. and Heinonen, S. (2003) 'Two exonic single nucleotide polymorphisms in the microsomal epoxide hydrolase gene are associated with polycystic ovary syndrome', *Fertility and sterility*, 79, 6: 1353-1357.

Lobo, R.A. (2003) 'What are the key features of importance in polycystic ovary syndrome?', *Fertility and sterility*, 80, 2: 259-261

2004

ESHRE/ASRM (2004) The Rotterdam ESHRE/ASRM-Sponsored PCOS consensus workshop group, 'Revised 2003 consensus on diagnostic criteria and long-term health risks related to polycystic ovary syndrome (PCOS)', *Human reproduction*, 19, 1: 41-47.

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Appendix J: Articles added to sample to achieve sample saturation

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Appendix K: Screenshot of thematic matrix

	A	B	C	D	E	F	G
1	**Authors of Article**	**Article title**	**Year: 2001**	**Sub theme 1.1-Adherence to NIH criteria**	**Sub theme 1.2-Adherence to Rotterdam criteria**	**Sub theme 1.3- Androgen Excess 2006 criteria**	**Sub theme 1.4. Inconsistencies**
2	David T. Vandermolen, M.D.,a Valerie S. Ratts, M.D.,b William S. Evans, M.D.,c Dale W. Stovall, M.D.,a Scott W. Kauma, M.D.,a and John E. Nestler, M.D.d	*Metformin increases the ovulatory rate and pregnancy rate from clomiphene citrate in patients with polycystic ovary syndrome who are resistant to clomiphene citrate alone*					
3	Melissa D. Kaltsas-Miller, Ph.D.,a Christa Nixon, B.S.,b Larry R. Boots, Ph.D.,b Rodney C. Go, Ph.D.,c and Ricardo Azziz, M.D., M.P.H.b,d	*Prevalence of polycystic ovary syndrome (PCOS) in first-degree relatives of patients with PCOS*		Design: Clinical and biochemical evaluation of the mothers and sisters of 93 patients with PCOS. The diagnosis of PCOS was established by: [1] a history of oligomenorrhea, [2] clinical evidence (i.e., hirsutism) or biochemical evidence (i.e., elevated total or free T) of hyperandrogenism, and [3] the exclusion of related disorders (p538)	In addition, many family studies have used the presence of "polycystic ovaries" as the principal or sole diagnostic criterion for the disorder (13, 18–20), even though the prevalence of this feature may exceed 20% in the general population (21–23). (p538-s4)		Previous family studies often had one or more important deficiencies, including: incomplete or uncorroborated family-member data and inconsistent or unclear diagnostic criteria for the disorder.
4				Inclusion criteria were consistent with recommendations of the 1990 National Institute of Child Health and Human Development conference (24) and included the following: [1] evidence of ovulatory dysfunction in conjunction with [2] hirsutism and/or hyperandrogenemia and [3] exclusion of other disorders, such as nonclassic adrenal hyperplasia, Cushing syndrome, hyperprolactinemia, and hypothyroidism (p54)	Furthermore, a preliminary consensus conference sponsored by the National Institute of Child Health and Human Development in 1990 concluded that although the presence of "polycystic ovaries" on ultrasound was a possible inclusion criterion, this sign was "particularly controversial" (24). (p54)		Furthermore, a preliminary consensus conference sponsored by the National Institute of Child Health and Human Development in 1990 concluded that although the presence of "polycystic ovaries" on ultrasound was a possible inclusion criterion, this sign was "particularly controversial" (24). (p54)
5							The diagnostic criteria for PCOS among the female relatives were similar to those of the probands. However, when studying relatives, we could not select only those who were untreated because the presence of PCOS itself may bias toward treatment. (p54)
6							In addition, because androgens are suppressed in the presence of hormonal therapy, menopause, or oophorectomy, we did not evaluate androgen levels in postmenopausal or hormonally treated relatives. These postmenopausal or treated women were deemed affected only if they had both a history of oligomenorrhea and clinical evidence of hirsutism. (p54-55)
7							Our data differ somewhat from those reported recently by Legro et a . (36). In that report, 115 untreated sisters of patients with PCOS were studies and only 22% were found to be affected by PCOS. Furthermore, those investigators noted that another 24% of sisters had hyperandrogenemia with regular menstrual cycles, whereas we observed this phenotype in only 2 of 35 (6%) premenopausal untreated sisters. These disagreements may reflect differences in the definition of PCOS, although differences in patient ethnicity or environment (e.g., diet) cannot be excluded. For example, white patients in Alabama are predominantly of Scottish-English descent, while many such women in Pennsylvania are of Dutch-German descent (p537)
8							In contrast to our criteria for PCOS, which included either hyperandrogenemia or hirsutism as evidence of androgen excess, Legro et al. (36) define the disorder solely by the presence of oligomenorrhea in combination with hyperandrogenemia, without regard to the presence of hirsutism (p537)