### The Australian Women's Midlife Years (AMY) study

Monash University Women's Health Research Program
Chief Investigator: Prof Susan Davis

### The most comprehensive study of midlife women's health this decade

The Women's Health Research Program recognised the compelling and urgent need to conduct a study of a *nationally representative study of Australian women aged 40 to 69 years,* to understand the contemporary menopausal experience, what women are taking in relation to menopause and mood changes, the prevalence of sexual concerns using a questionnaire applicable to all women and whether menopause adversely affects work engagement, independent other factors such as mood, education, work type and financial security. Additionally, the changes in testosterone and other hormones at midlife by age and menopausal status need to be established.

### Data collection for 8222 women across Australia is complete.

**Funding:** no specific grant support; support to expedite the analysis of this major study for Australian women would be most welcome.

### The Study:

Our 2014 study revealed 28% of Australian women experience moderate to severely bothersome menopausal symptoms, but only 11% were then using menopausal hormone therapy (MHT).

The attitude towards MHT has changed, but as most formulations are on private prescription we have no idea what women are taking to manage their symptoms today.

While menopausal symptoms have been implicated as adversely affecting work ability, the studies in this field have major limitations, notably selection bias, and being limited to women in paid employment- women have not been asked about the effects of menopause on their volunteer roles or carers for others.

Although testosterone has been recognised as an important female hormone, blood levels in women aged 40 to 69 years have not been documented with precision by age and menopausal status. Hence the associations between testosterone and an array of symptoms such as low mood, sexual function and so forth in women of this age remains unknown.

# The AMY Study will report on the following outcomes in the 8222 UNSELECTED participants across Australia who have completed the study.

- The prevalence and severity of menopausal symptoms
- The prevalence of use of prescription therapy for alleviation of menopausal symptoms, =
- The association between menopause symptoms and work performance in women in paid and unpaid work roles, & shift work, taking into account other major sociodemographic factors
- Whether menopause symptoms are an independent barrier to work engagement
- Prevalence of low mood, depression and antidepressant use
- Prevalence of low sexual wellbeing
- Reference ranges, by menopause status, for hormones measured precisely in women without factors influencing endogenous concentrations.

### Other outcomes include documenting:

- contraceptive use, use of assisted reproduction, prevalence of pregnancy/breast feeding
- antidepressant therapy

### MenoPROMPT:

A co-designed, comprehensive, evidence-based program to improve menopause care NHMRC grant 2015514

- Australian GPs and specialists lack skills and confidence in managing menopause, and often recommend unproven and mostly ineffective complementary and alternative medicines (CAMs) before prescribing menopausal hormone therapy (MHT) or effective non-hormonal therapy<sup>1</sup>.
- Australian women rely on self-help and CAMs to manage menopausal symptoms, as they view MHT negatively, with concerns about cancer risk and over prescription<sup>2,3</sup>.
- Most women are unaware that menopause is associated with bone loss and that menopause affects their cardiometabolic health<sup>2</sup>.

### COMPLETED STEPS:

- i. **Review of the literature: to update the** Practitioner Toolkit for Managing menopause; Review and updated Toolkit review published.<sup>4,5</sup>
- ii. **Co-design of confluent algorithms aligned with 'real world' consultations** to guide relevant medical history taking, investigations and life style recommendations
- iii. Algorithms for bone health screening and intervention
- iv. End-user review

The draft versions will undergo RACGP advisory group review to ensure MenoPROMPT meets practitioner needs, as well as review by our other Partner Organisations, and be modified as indicated to ensure acceptability when the educational product is disseminated.

### **UNDERWAY**

- II. Make MenoPROMPT accessible in primary care using the following steps:
- i. Integration of MenoPROMPT into general practice workflows
- ii. **Integrate MenoPROMPT into** the three most commonly used primary care EMR systems (Medical Director, Best Practice and ZedMed) using the Future Health Today platform.
- iii. Develop a simple pre-consultation menopause-health assessment to identify and address physical, emotional and mental health, with the goal of improving health outcomes and delivery of patient centred care. Women will receive access to consumer resources on completion of the tool, and the results will be sent to their GPs via Telstra Argus secure messaging and will be stored in their EMR. The PROMs results sent to GPs will incorporate links to the MenoPROMPT tool and Jean Hailes and International Menopause Society resources to guide shared decision making when a woman attends for her appointment.
- iv. Provide opportunity for practitioners to increase their knowledge of menopause
  We will embed links to online educational resources to enable health care professionals to
  advance their knowledge in the field of midlife women's health

**Project partners:** Monash University Women's Health Research Program, University of Melbourne Div of General Practice, Royal Australian College of General Practitioners Jean Hailes and the Australasian Menopause Society.

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#### ORIGINAL ARTICLE

# Health-care providers' views of menopause and its management: a qualitative study

S. R. Davis (6), D. Herbert, M. Reading and R. J. Bell (6)

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#### ABSTRACT

**Objective:** This study aimed to explore Australian health-care providers' knowledge of menopause and its consequences, and their views about menopause-related health care.

**Methods:** This was a cross-sectional qualitative study of Australian general practitioners (GPs), gynecologists (GYs) and pharmacists (PHs). Recruitment was ultimately achieved through professional networks and cold calling.

**Results:** There were equal numbers of GPs, GYs and PHs, and equal numbers of males and females in each group. All participants demonstrated sound understanding of menopause and its consequences. A strong theme was recognition of high usage of complementary and alternative medicines (CAMs) by women for menopausal symptoms. Most participants highlighted lack of efficacy evidence for most CAMs, but the majority of GPs and PHs considered CAMs to 'have a role'. Most supported menopausal hormone therapy (MHT) when symptoms impaired quality of life. Limitations to comprehensive care included knowledge gaps and lack of time.

**Conclusions:** Australian health-care providers appeared knowledgeable about menopause, but uncertain about its management. MHT prescription appeared limited to women with severe symptoms despite lifestyle modification and a trial of CAMs. The upskilling of clinicians providing care for women at midlife, with respect to the indications for and prescribing of MHT, urgently needs to be addressed.

#### ARTICLE HISTORY

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#### KEYWORDS

Menopause; menopause management; menopausal hormone therapy

### Introduction

Between 2001 and 2003 there was a dramatic decline in the prescribing of menopausal hormone therapy (MHT) globally following the first publication of findings from the Women's Health Initiative (WHI) estrogen-progestin study linking MHT use to an increase in breast cancer risk [1]. The use of MHT fell by approximately 40% in Australia [2], with even greater declines in Canada [3] and the USA [4]. Concomitantly, a hiatus developed in training of medical trainees and clinicians, and allied health professionals, in the management of menopause. A 2017 survey of trainees in family medicine, internal medicine, and obstetrics and gynecology in the USA reported that 20% had not had lectures on menopause in their residency and only 6.8% felt 'adequately prepared to manage women experiencing menopause' [5,p.242].

While approximately one-third of postmenopausal Australian women under the age of 55 years experience moderate to severe vasomotor symptoms [6], only 11% of women in this age group use MHT [7]. Our recent qualitative study revealed that although most Australian women understand what happens at menopause, few were aware of the long-term health consequences such as bone loss and increased risk of cardiovascular disease [8]. Furthermore,

women generally viewed MHT in a negative light, particularly in relation to breast cancer risk.

The aim of the current study was to explore the understanding and views of Australian health-care providers, specifically general practitioners (GPs), gynecologists (GYs) and pharmacists (PHs), about menopause and its management. We were also interested in how confident health practitioners were in managing menopause with respect to immediate symptoms as well as their role in reducing the risks of osteoporosis and cardiovascular disease.

### Methods

### Study design, participants and recruitment

This was a cross-sectional, qualitative thematic analysis that used semi-structured telephone interviews. Sampling was purposive to achieve diversity in terms of gender, age and geographical location of the practitioners. Although we had originally aimed to recruit until thematic saturation had been achieved, as recruitment to this study was so challenging we made a pragmatic decision to cease recruitment once we had 10 participants in each practitioner group.

Participant recruitment involved three sequential approaches: advertising, use of professional contacts and

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Supplemental data for this article can be accessed here.

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# Health-care providers' views of menopause and its management: a qualitative study

S. R. Davis, D. Herbert, M. Reading & R. J. Bell

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'cold calling'. Advertisements inviting participation were placed in e-newsletters specific for each professional group, anticipating these would be seen by large numbers of practitioners. Additionally, a slide was used to advertise the study at the end of a presentation at a national GP conference and we had a booth for the study at a national obstetrics and gynecology conference. Unsuccessful recruitment prompted members of the study team to approach GPs and GYs who were professional, but not personal, contacts. Members of the research team also visited pharmacies in person to recruit PHs face to face. Finally, in order to recruit nonmetropolitan GPs, GYs and PHs, for PHs we utilized 'cold calling' using a remoteness map issued by the Australian Bureau of Statistics

Participants were provided with an information sheet and a consent form by email and consent was recorded at interview and stored separately from the interview file. The study was approved by the Monash University Human Research Ethics Committee, Melbourne (Project ID 16590).

### **Data collection**

Each interview was completed in one session. The interviews were digitally recorded, transcribed and anonymized. Interviews lasted on average 20 min, ranging from 14 to 32 min. Transcripts were not returned to participants for comment or correction. All interviews were undertaken by the same researcher (D.H.).

The interviews were conducted using a standard set of questions (Supplementary Table 1) that covered general knowledge of the menopause and associated health effects, treatment options for menopausal symptoms and the nature of comprehensive menopause care. Factors enabling or limiting the capacity of the practitioner to provide optimal care were addressed. Demographic details collected included the participant's gender, age, year of graduation, location of practice and whether they had undertaken any specific training in women's health in the previous 3 years.

### Data analysis

A reflexive thematic analysis broadly based on the principles outlined by Braun and Clarke [9] was used, similar to our study of the understanding of menopause by women in the community [8]. This 'theoretically flexible' approach was well suited to our research question. The first step was data familiarization, whereby two members of the research team (D.H. and M.R.) read and re-read each transcript to explore the depth and breadth of the experiences and attitudes of each health-care practitioner. In generating the initial codes, the focus was 'theory-driven' due to the specific areas of interest. The anonymized transcripts were then manually coded independently by D.H. and M.R. The coded data were entered into an Excel spreadsheet according to participant ID and interview question, and, where applicable, a quote was included. Reviewing, defining and naming the themes occurred concurrently and consensus was reached after discussion within the research team.

The reporting of the methods and results of this study are in line with the Consolidated Criteria for Reporting Qualitative Research (COREQ) (https://www.equator-network. org/reporting-guidelines/coreq/). The study findings are presented in relation to specific topics covered, with quotes identified by practitioner group (GP, GY, PH), gender (male/ female) and participant ID number (1-10 for each group).

### Results

No participants were recruited through e-newsletter advertisements or invitation to participate at a large GP conference. The majority of GPs were recruited via professional networks (Figure 1), and GYs through professional networks and face-to-face engagement at a national conference. Recruitment of PHs required 'cold calling' and 'cold visits' to pharmacies. As indicated by the participant characteristics (Table 1), participant diversity - in terms of gender, age and practice location - was achieved.

### Menopause symptoms, effects and long-term health implications

All practitioners were aware of the most common menopausal symptoms. Hot flushes and disturbed sleep were considered the most troublesome of all symptoms (9/10 GPs, 9/ 10 GYs and 7/10 PHs). There was variation in the estimation of the proportion of women who experience bothersome symptoms, although 8/10 GPs, 7/10 GYs and 6/10 PHs included 50% in their estimate. Although a range of estimates was provided for the duration of menopausal symptoms, the most commonly reported upper limit specified for duration was 10 years. After prompting, vaginal symptoms were mentioned by 7/10 GPs, 9/10 GYs and 3/10 PHs.

There was general awareness of the long-term effects of menopause with respect to bone loss (9/10 GPs, 9/10 GYs and 9/10 PHs), increased cardiovascular disease risk (7/10 GYs, 5/10 GPs and 4/10 PHs) and adverse mood and cognitive effects (4/10 GYs, 5/10 GPs and 7/10 PHs):

... the things that they can't cope with at that time, can be the constant sweating and unable to sleep ... Those symptoms as they become less, tend to become less of a problem but it is the longer term ones that happen over a number of years when all of a sudden you look back over 10 years and it's the extra layers of body fat that wasn't there before, and a simple trip leading to a bone fracture. They are the longer-term problems that persist for a considerable length of time. (PH2, male)

### MHT use

MHT use was specifically mentioned by 8/10 GPs and 8/10 GYs, although lifestyle changes were mentioned as the first line of treatment by four GPs and four GYs. Asked at what stage women should be offered MHT, a common response was at the point when symptoms were severely impairing quality of life (five GPs, three GYs and five PHs). Three of 10 GPs and 5/10 GYs mentioned the need for an 'absence of contraindications to MHT use' and some practitioners used

Table 1. Characteristics of participants.

	General practitioners		Gyneco	Gynecologists		Pharmacists	
	Female (n = 5)	<i>Male</i> (n = 5)	Female (n = 5)	<i>Male</i> (n = 5)	Female (n = 5)	<i>Male</i> (n = 5	
Age (years)							
<30	0	0	0	0	2	1	
30-39	1	1	1	2	2	1	
40-49	2	1	2	1	1	1	
50-59	1	3	1	1	0	2	
60+	1	0	1	1	0	0	
Average (range) time since graduation (years)	28 (13–47)	23 (8–36)	25 (14–36)	21 (10–36)	10 (3–24)	23 (3–38)	
Geographic location	(13 4/)	(0 30)	(14-50)	(10-30)	(3-24)	(3-30)	
Metropolitan	3	4	4	2	1	3	
Non-metropolitan	2	1	1	3	4	2	
Employment type							
Sessional practitioner	4	3			1	3	
Partner or owner	1	2			4	2	
Any women's midlife training							
Yes	3	2	3	3	1	1	

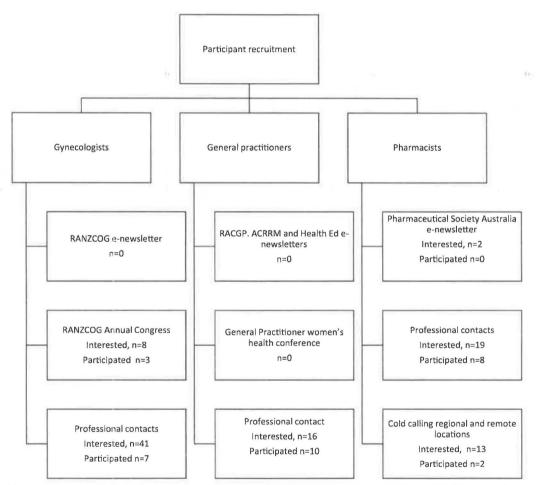


Figure 1. Participant recruitment. 'Interested' indicates they accepted a copy of the patient information and consent form. ACRRM, Australian College of Rural and Remote Medicine; RACGP, Royal Australian College of General Practitioners; RANZCOG, Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

the phrase 'when the benefits outweigh the risks'. Six of the PHs supported MHT use on the advice of a doctor. Generally, there were no concerns raised about the use of MHT when used for 'short periods', there were 'no contraindications'

and there was regular 'follow up' or 'monitoring' (seven GPs, six GYs and seven PHs):

And I suppose a measured, balanced conversation about menopause therapy, MHT or HRT. About the risks and benefits

and the general principle now is lower dose for the shortest period of time, annual review. Some people are homicidal and need to have it in which case there may be risks and benefits. (GY4, male)

Several clinicians said they would not prescribe MHT for the prevention of osteoporosis (six GPs and six GYs). Four GYs said they would refer the management of osteoporosis to an endocrinologist:

I think part of the problem is that you get varying advice, if that the right word, about how effective it is for preventing osteoporosis. So, when I started off life as a young doctor this was one of the big selling points, including decreasing cardiovascular disease. Then the women's study came out which stopped all of that and I think, since that time it is beginning to re-emerge that perhaps it is useful treatment for osteoporosis. (GP4, male)

### Use of complementary and alternative medicines

All practitioners acknowledged that complementary and alternative medicine (CAM) use by midlife women is common, and some expressed concern about the lack of, or limited availability of, evidence about efficacy (four GPs, seven GYs and eight PHs). Six GYs said that women were likely to suggest CAMs in the short term and for mild symptoms. Despite acknowledging the placebo effects of CAMS, seven GPs said 'it has a role' or a similar phrase:

fit has A role, Evidence scant, Based on 'best fit' for the patient, 'Certainly, I don't discourage it'. (GP10, male)

Being a scientist, I struggle with any agent that doesn't have good scientific data to support it. I think in the medical profession we have to be careful not to get caught up in the advertising and the hype and the glossy pictures that goes with these. I don't have an issue with people using agents that they feel comfortable to use that have demonstrated no harm, but find it difficult to recommend agents that I consider to have either poor evidence or no evidence. (GP2, male)

Seven of the PHs mentioned CAMs as a treatment to manage women's symptoms, including six who said they recommend CAMs to their clients for menopausal symptoms. One of these was amongst the five PHs who said the effects of CAMs were placebo effects. PHs also identified the power of branding and advertising of CAM products marketed for use during menopause.

### Providing comprehensive care and its limitations

Practitioners reported that establishing rapport with a woman facilitated discussion about menopause (six GPs, five GYs and three PHs). Six GPs reported that being 'younger' and 'male' were limiting factors when dealing with menopause in new patients. Doctors also reported that women were less likely to volunteer information about sexual health, so that this might require specific 'probing' in a consultation. Five PHs reported several barriers including lack of privacy for conversations in a pharmacy, that some women prefer to talk to a female PH and that some women prefer to speak to a doctor:

I think there are some things that women don't want to discuss with me being a male doctor, a younger, male doctor. So, there is probably, a little bit of a barrier there I would say. I certainly would say that I would see less women complaining of symptoms than my female colleagues would, having spoken to them. From the comfortability point of view, most women are happy to talk about it, but it's the occasional women who I know. (GP1, male)

On the whole I would have to say; look some people yes, but on the whole I would have to say no and I think it is more to do with the fact I don't think in most cases retail pharmacies are well enough set up to have those conversations in a private manner, (PH4, male)

The words used by doctors when asked about comprehensive midlife care included 'screening', 'comorbidities', 'mental health', 'family history' and 'lifestyle' (eight GPs and five GYs):

Comprehensive care entails all aspects of general practice, meaning their physical health, their emotional health and their psychological wellbeing. As part of that we have all our screening in terms of cervical screening, blood pressure monitoring and bowel screening in terms of general health. Comprehensive would mean that it would need to touch on other aspects of their health which would include, if they are being bothered by symptoms of menopause how that is being addressed, any concerns with their sexual function, relationships and psychological wellbeing. So I suppose comprehensive care would mean that all of those aspects are being covered. (GP5, female)

Six PHs talked about 'holistic care' and mentioned the importance of a woman having an interested GP at midlife:

Looking not just at menopause but the mental issues that might go along with it ... More access to those or GP's that might be more specialised in women's health. A GP can be helpful, but if they don't have an interest in the area. So having access to doctors who have an interest in this area. (PH1, female)

Most practitioners felt there were limitations to providing comprehensive care in their practices, with time limitation common to all groups (nine GPs, eight GYs and six PHs). Lack of privacy for confidential conversations was noted by three PHs. Five GPs and six PHs tended to feel women were uncomfortable discussing menopause related topics, whereas GYs did not see this as an issue. When asked whether they would raise the topic of menopause if a woman presented with an unrelated problem, four GPs said it would depend on the nature of the presenting complaint and time availability. Six GYs felt menopause would emerge as a topic in history taking. PHs said they would be unlikely to raise the topic:

Sometimes they have no idea whether they have gone through menopause. Other times they are experiencing symptoms which they have never thought there was an option in treatment. So certainly it is an opportunistic screening tool to improve their lifestyle. (GY10, male)

Regarding training and education in menopausal management, 4/10 GPs and 5/10 PHs noted few opportunities for menopause-specific education. There was general support for further training in comprehensive midlife women's health care (two GPs, six GYs and two PHs):

I have some comfort in being able to manage women at this stage of their life, however, I will be the first to admit, and I have said this already, I do not see women with it all the time. So I am not 100 per cent au fait with all the forms of HRT for example, and when you might choose one over another. It has also been a while since I've thought about complementary therapies and what exactly they help symptoms with. So I'm fairly happy assessing women going through it and am aware of the symptoms and health factors, I think. However, in terms of specifically commencing HRT or alternative therapies, I must admit I need to ask a little bit of advice, or refer sometimes, unless the lady has any ideas herself. (GP1, male)

### Discussion

The Australian GPs, GYs and PHs who participated in our study generally had a good understanding of menopause and its consequences, and were aware that symptoms can be severe and long lasting. Although the use of MHT was supported by GYs and GPs, most indicated it should be limited to women experiencing significantly impaired quality of life and not to prevent osteoporosis. While the lack of evidence to support the efficacy of CAMs was acknowledged, the majority of each practitioner group supported women trialing CAMs for their menopausal symptoms.

The description of menopausal symptoms was consistent across all groups, although doctors were more likely to include vaginal symptoms. There was general recognition that women tend to try CAMs when they first experience menopausal symptoms. Most participants indicated that CAMs have a role in the management of menopause, which conflicted with the simultaneous recognition that much of the perceived benefits of CAMs were placebo effects. Concomitantly, while the efficacy of MHT was widely accepted, there was a general reticence about MHT use. Most practitioners felt MHT should be reserved for women with severe symptoms.

The indications for approved estrogen therapies by the Australian regulatory body, the Therapeutic Goods Administration, include 'for the prevention of postmenopausal bone mineral density loss'. However, there was little support for MHT for the prevention of osteoporosis, suggesting a knowledge gap as to the indications for MHT prescribing that needs to be addressed. Consistent with this, several health-care providers in each group said they lacked knowledge about MHT use, with some doctors declaring they did not feel confident prescribing MHT, and that this limited their capacity to provide care for postmenopausal women. Added to this, most identified paucity of time further impaired holistic menopausal management.

The information shared by the practitioners in this study was consistent with the findings of our quantitative and qualitative studies of midlife Australian women. Australian women are more likely to use CAMs to manage vasomotor symptoms than MHT, with less than 5% of women using topical vaginal estrogen [7, 10], even though most postmenopausal women experience vulvo-vaginal atrophy symptoms [11]. Women are reticent to take MHT, primarily due to their concern that MHT might increase the risk of breast cancer, whereas CAMs are considered to be potentially effective and

safe [8]. Together, these studies suggest that uncertainty about the use of MHT amongst GPs and GYs and the tendency for GPs, GYs and PHs to support the use of CAMs reinforce women's negative attitudes to MHT, resulting in a significant proportion of highly symptomatic women, and women at high risk of postmenopausal bone loss, not being treated [7].

Recruitment to this study was challenging and highlights the lack of interest amongst health practitioners in participating in studies of this nature. This is not a new finding, with Bonevski et al. reporting that GP response rates to surveys are not only lower than seen in the general population, but that they have also declined [12]. Successful strategies to increase response rates have been found to be provision of incentives, notably monetary incentives, and pre-contact by a peer [13]. Consistent with this, recruitment to this study was only achieved by personal contact through professional networks, face-to-face discussions at a gynecological conference, and both visiting and 'cold calling' pharmacies. Factors contributing to non-participation of health-care providers in research have included time poverty, lack of interest and concern as to how the collected data might be used [12, 14].

Strengths of our study included interviews with specialist GYs and GPs as well as PHs, equal numbers of female and male practitioners across a broad age range and practitioners in metropolitan, rural and remote locations. Although our findings cannot be assumed to generalizable, we aimed to achieve the diversity in our study sample to enable a cross-section of views to be heard. A potential limitation of this work is that it was conducted in Australia and our findings may not apply to health-care delivery in other countries.

In conclusion, while health practitioners recognize the short-term and long-term effects of menopause, knowledge and confidence about menopausal care remains lacking, to the detriment of midlife women's health. The upskilling of clinicians providing care for women at midlife, with respect to the indications for and prescribing of MHT, urgently needs to be addressed.

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Potential conflict of interest S.R.D. reports having received honoraria from Besins Healthcare and Pfizer Australia, and has been a consultant to Roche Pharmaceuticals, Mayne Pharmaceuticals, Lawley Pharmaceuticals and Que Oncology. No other potential conflicts of interest, relevant to this article, are reported.

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The supporting notes for the Practitioner's Toolkit for Managing Menopause are published, with free access, in Climacteric, the journal of the International Menopause Society.

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### Endorsed by:















# Message from the research lead

I'm pleased to share this updated version of the Practitioner's Toolkit for Managing Menopause, the major update since the first iteration was launched in 2014.

The Toolkit, again published with open access in Climacteric, in which it was first published, meets the needs of clinicians by providing clear, evidence-based advice as to how to address and manage symptoms of, or concerns about menopause during clinical consultations.

It includes pragmatic algorithms to assess menopausal status, including that of women with a past hysterectomy or endometrial ablation, and users of hormonal contraception; along with treatment options and symptom management algorithms.

This updated version – relevant for clinicians around the world – builds on the 2014 publication, incorporating updated advice based on new knowledge around the physiological basis of menopause and new therapeutics, as well as expanding into guidance on issues of bone health. It also cuts through many years of misinformation and confusion, to provide clear evidence-based guidance on the appropriate use of menopause hormone therapies (MHT) and non-hormonal therapies for women with menopause-associated symptoms.

For many years the discomfort, poor health and reduced quality of life often caused by menopause has been viewed as an unavoidable consequence of ageing, one that lacked a sense of urgency with many in society and the medical community. It's been heartening to see a change in the seriousness with which menopause has been viewed over the last decade. This has been backed up by increased research funding, greater international collaboration, and louder women's voices sharing their experiences and demanding positive action in the media. This document can serve as a comprehensive guide for shared decision-making with patients, and thus provide patient-informed care.

I hope the Toolkit will help health practitioners around the world deliver informed care that genuinely responds to the needs of all the women who have or will inevitably experience menopause.

I'd like to thank the team of dedicated researchers who assisted in this update: Dr Sasha Taylor, Dr Chandima Hemachandra, Dr Karen Magraith, Professor Peter R Ebeling, Dr Fiona Jane, and Dr Rakibul Islam, and Professor Rodney Baber for his advice.

PROFESSOR SUSAN DAVIS AO

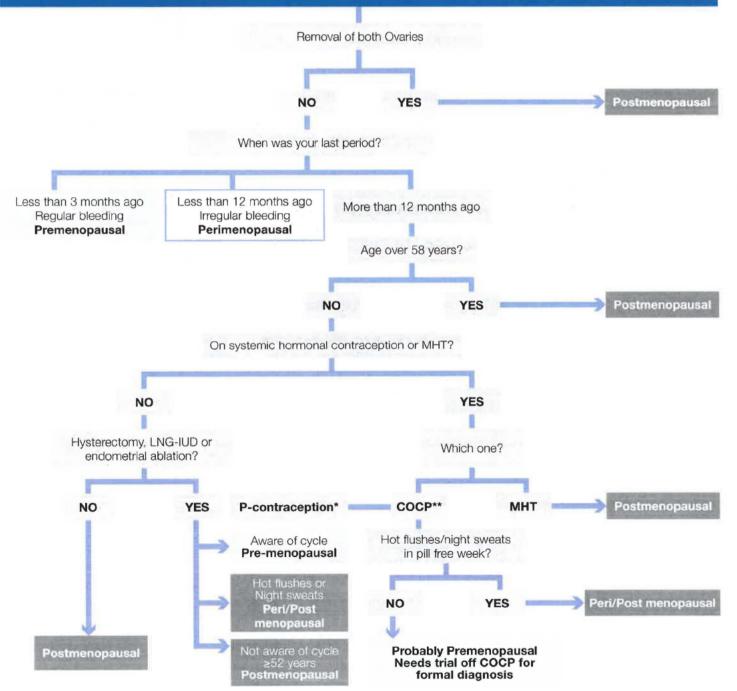


### **About Professor Davis AO**

Professor Susan Davis AO is a leading endocrinologist-researcher, who heads the Women's Health Research Program within the School of Public Health and Preventive Medicine at Monash University, Australia. She has specific expertise in the role of sex hormones in women across the lifespan. She is a Fellow of the Australian Academy of Health and Medical Sciences, a co-founder of Jean Hailes for Women, a past President of the Australasian Menopause Society and of the International Menopause Society.

#### A Woman\* (40 years+) presents with: **Symptoms** Concerns Irregular bleeding Cognitive concerns Osteoporosis Vasomotor Urogenital symptoms Cardiovascular risk - Hot flushes - Vaginal dryness/soreness Dementia - Night sweats - Bladder/urinary Sx Diabetes Poor sleep AND/OR Lost interest in sex Obesity Joint pain Central weight gain

# Is this Patient Pre/Peri/Postmenopausal?



# assigned female at birth; "diagnosis of menopausal status requires detailed reproductive history; \*\* In some women an option is to cease the COCP and then review

Anxiety/low mood

# What do you need to know?

### Full assessment recommended for midlife women

### **Medical History**

### Relevant gynae facts:

- · Bleeding pattern or LMP
- · Past surgery eg hysterectomy/oophorectomy
- · Current use of any exogenous hormones
- · +/- contraceptive needs

### Major medical illnesses - ask about:

- DVT/PE
- · Breast cancer/endometrial cancer
- Thyroid disease
- Cardio/cerebrovascular disease including HT
- Osteoporosis
- Diabetes
- Depression/anxiety/postnatal depression
- · Recurrent UTI's
- Liver disease

### Family History:

- Cardio/cerebro vascular disease
- Osteoporosis/fractures
- Dementia
- Cancer

### Smoking/alcohol use

Current medication including non prescription medications

Social history

Sexual wellbeing

### **Examination**

- · Height and weight
- Blood pressure
- Breast exam (not required if recent breast imaging/ breast checks)

# Investigations for menopause diagnosis

### ≥ 45 years old

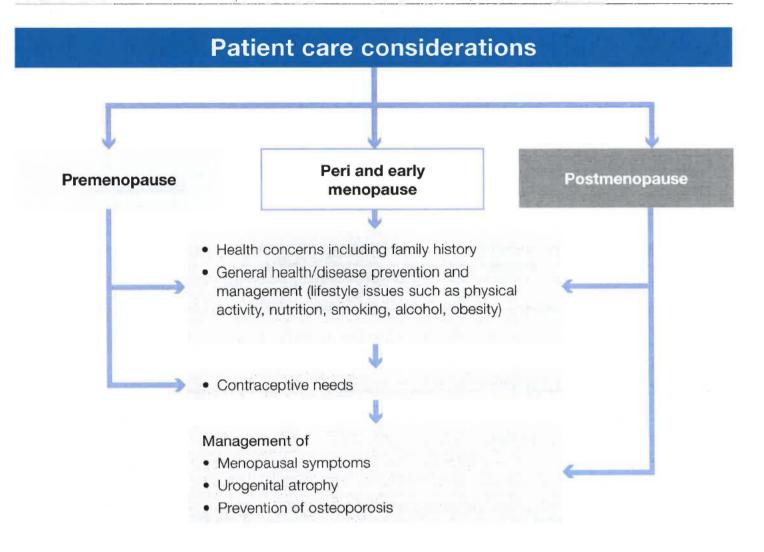
- Diagnosis symptom based; measure FSH and E only if atypical presentation
- < 45 years old
- Measure FSH and E

   Of no value in women
   on COCP
- Prog/LH/AMH levels of no diagnostic value

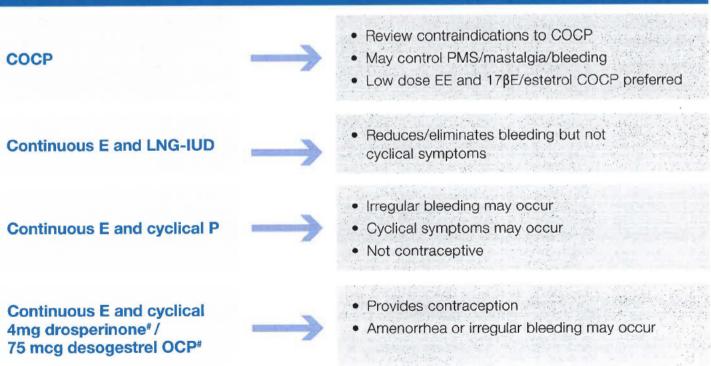


### Midlife women general health assessment:

- Cervical screen test
- · Mammogram (if available)
- Lipid profile
- FBG
- TSH
- · Renal and liver function
- FBE/ferritin
- FOBT
- Vit D in at risk women

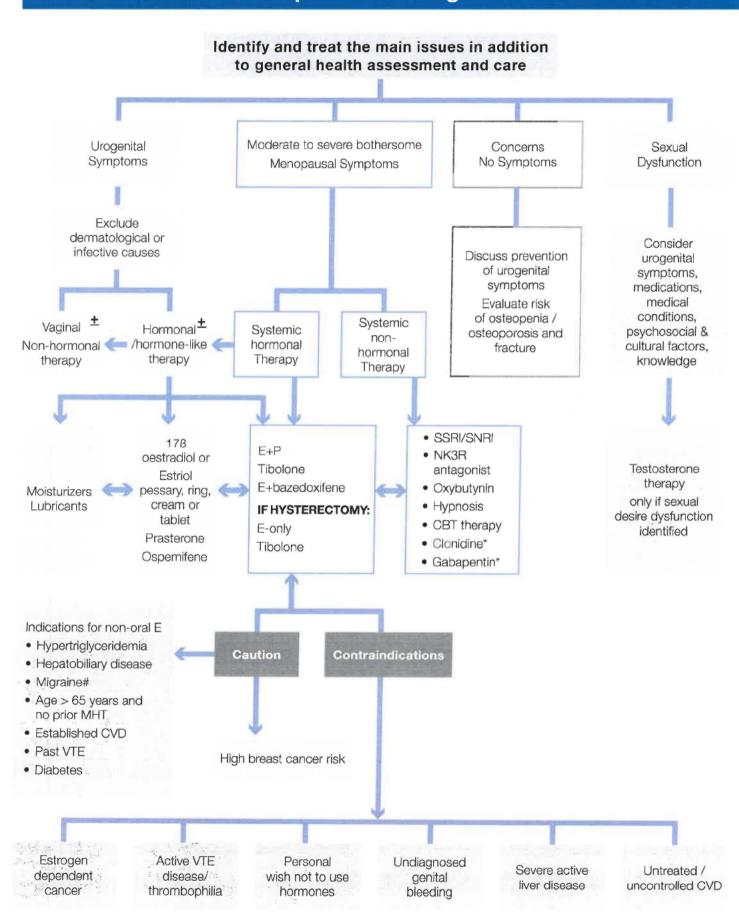


# **Management of Perimenopause**



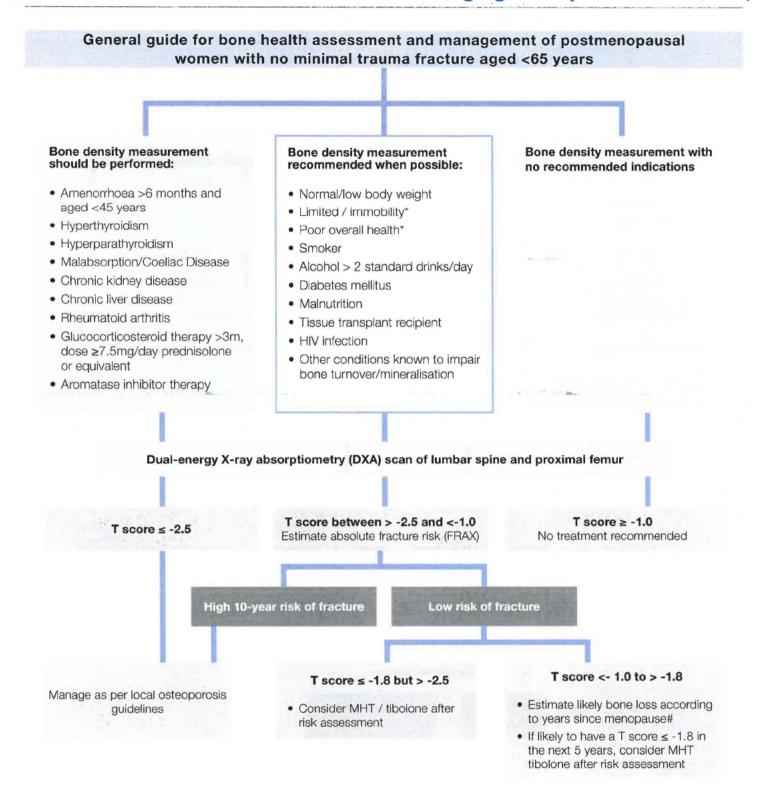
#off-label use, # desogestrel may not give adequate endometrial protection.

### Menopausal management



<sup>\*</sup>Caution due to side effects at therapeutic doses

<sup>#</sup> Migraine with aura requires early review to ensure no increase in migraine symptoms



For all women: Review adequate vitamin D, calcium, magnesium and protein intake; vegans at risk of zinc deficiency. Encourage physical activity, minimising alcohol, and smoking cessation.

# In women with BMI 27 kg/m2 (loss greater with lower BMI and less with higher BMI)

Lumbar spine loss ~2.5%/year for first 2 years post final menstrual period/estimated menopause, ~1%/years 2 to 5 years postmenopause, then ~0.7%/year with age.

Femoral neck loss ~1.8 %/year for first 2 years post final menstrual period/estimated menopause, ~1%/years 2-5 years post menopause, then ~0.5%/year with age.

(Greendale G et al JCEM 2012; Writing Group for PEPI Trial JAMA 1996).

<sup>\*</sup> Strong independent risk predictors and encompass other risk factors in the list (Miller et al Arch Intern Med. 2004)

# **MHT Dosing\***

	Low dose	Mid-range dose	Highest dose#
CEE	0.3-0.45 mg	0.625 mg	1.25 mg
17β estradiol	0.5 mg	1.0 mg	1.5-2.0 mg
Estradiol valerate	0.5 mg	1.0 mg	2.0 mg
Estriol	1.0-2.0mg		
Transdermal estradiol patch	25-37.5 mcg	50 mcg	75 -100 mcg
Estradiol gel	0.5 mg	1.0 mg	1.5 mg
Estradiol hemihydrate gel	0.75 mg (1 pump)	1.5 mg (2 pumps)	2.25 - 3.0 mg (3-4 pumps)
Estradiol hemihydrate skin spray	1.53 mg (1 spray)	3.06mg (2 sprays)	4.50 mg (3 sprays)

### Sequential P – daily dose for 12-14 days per month for endometrial protection:

	With Low dose E	With mid to highest dose E
Dydrogesterone (oral)	5 mg	10 mg
Micronized progesterone (oral)	200 mg (efficacy of lower dose not established)	200 mg
Medroxyprogesterone acetate (oral)	5 mg	5-10 mg
Norethisterone acetate (oral)	1.25 mg-2.5mg	2.5-5mg
Transdermal norethisterone acetate (with estradiol) patch		releases 0.140 - 0.250mg / day

### Continuous P - daily dose for endometrial protection:

	Low dose E	With mid to highest dose E
Dydrogesterone (oral)	2.5-5mg	5-10mg
Drospirenone (oral)	2.0 mg	
Micronized progesterone (oral)^	100 mg	100 mg for mid dose E; (however, this dose may not always provide sufficient endometrial protection with highest dose E)
Medroxyprogesterone acetate (oral)	2.5 mg	2.5 - 5 mg
Norethisterone acetate (oral)	0.1mg with 0.5mg estradiol 0.5mg with 1.0mg estradiol	1.0 mg - 2.5 mg
Transdermal norethisterone acetate (with estradiol) patch		releases 0.140-0.250mg/day
Levonorgestrel (with estradiol) patch		releases 0.015mg/day
LNG-IUD	Device initially releasing 20 mcg/	day

### Other options:

Tibolone	1.25 - 2.5 mg/day
CEE + bazedoxifene	0.45 + 20 mg/day

<sup>\*</sup> Availability of hormonal/non hormonal treatment and indications for use from regulatory bodies vary between countries; #"highest dose" refers to the highest approved prescription doses; ^ is occasionally prescribed to be use vaginally off-label.

# MHT Dosing for vaginal symptoms

Inserts	Estradiol vaginal tablet	0.01 mg	Nightly for 2 weeks then 2-3 x/week
	Estriol	0.5 mg	Nightly for 3 weeks then 2 x/week
	Prasterone (DHEA)	6.5 mg	Nightly
Creams	Estradiol 0.01% cream	0.1 mg estradiol/g	2- 4 g daily for 1-2 weeks, then 1 g, 1-2 x/week
The County of New York and Associated States of States o	Estriol	0.5 mg	Nightly for 3 weeks, then 2 x/week
	CEE 0.625mg/g	0.625 mg/g	Cyclic use of 0.5 - 2 g intravaginally daily for 21 days then off for 7 days
Gel	Estriol	0.050/g	Nightly for 3 weeks then 2 x/week
Vaginal Ring	Estradiol 2 mg	.0075 mg/day	3 monthly
to the same produce of the	Estradiol acetate 12.5 mg, 24.8 mg	0.05, 0.1 mg/day	3 monthly
Oral	Ospemifene tab	60 mg daily	daily

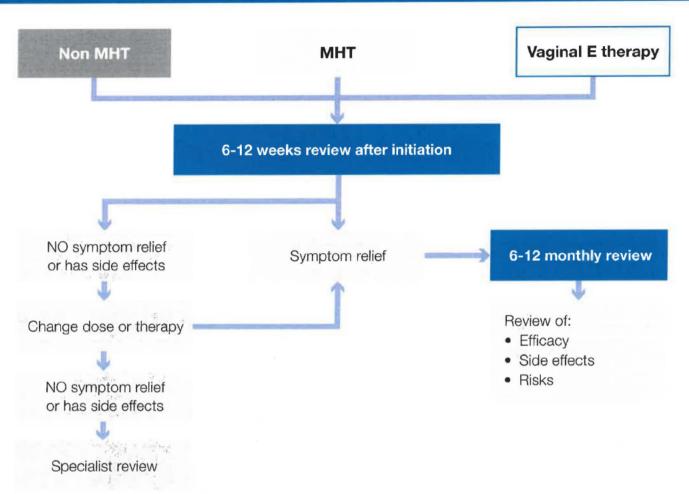
# **Evidence-based Non-Hormonal Treatments** for vasomotor symptoms

SSRI or SSRI/SNRI-low dose	Generally effective daily doses: venlafaxine 75mg, desvenlafaxine 100mg, citalopram 20mg, paroxetine 7.5*-20mg, escitalopram 10-20mg/day
Fezolinetant*	45 mg daily
Clonidine*	25 to 100 mcg daily
Oxybutynin	2.5mg-5mg bd (oral); the dose of transdermal patch for VMS not established
Gabapentin	Start 100mg nocte up to 900mg/day#
Hypnosis	
Cognitive behaviour therapy	
Weight loss for women with obes	sity
Stellate ganglion blockade - for t	treatment resistant VMS; requires expertise

<sup>\*</sup> has regulatory approval for VMS in some countries # higher doses can be used but side effects more likely

Availability of hormonal/non hormonal treatment and indications for use from regulatory bodies vary between countries

# **Review of Treatment**



# **Abbreviations**

AMH	Anti-mullerian hormone
β	Beta
вмі	Body mass index
CBT	Cognitive behaviour therapy
CEE	Conjugated equine estrogen
COCP	Combined oral contraceptive pill
CVD	Cardiovascular disease
DHEA	Dehydroepiandrosterone
DVT	Deep vein thrombosis
E	Estrogen
EE	Ethinylestradiol
FBE	Full blood examination
FBG	Fasting blood glucose
FOBT	Faecal occult blood test
FRAX	Fracture risk assesment tool
FSH	Follicle stimulating hormone
g	Gram
HIV	Human immunodeficiency virus
HT	Hypertension
inc	including

IUD	Intrauterine device		
LH	Luteinizing hormone		
LMP	Last menstrual period		
LNG-IUD	Levonorgestrel IUD		
mcg	microgram		
mg	milligram		
мнт	Menopausal Hormone Therapy		
NK3R	Neurokinin 3 receptor		
OCP	Oral contraceptive pill		
Р	Progestogen		
PE	Pulmonary embolism		
PMS	Premenstrual syndrome		
Prog	Progesterone		
SNRI	Selective noradrenaline reuptake inhibitor		
SSRI	Selective serotonin reuptake inhibitor		
Sx	Symptoms		
TSH	Thyroid stimulating hormone		
ITU	Urinary tract infection		
/MS	Vasomotor symptoms		
/TE	Venous thromboembolism		



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