



SHPA response to Inquiry into the issues related to menopause and perimenopause, February 2024

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional organisation for the 6,100+ Hospital Pharmacists, and their Hospital Pharmacist Intern and Hospital Pharmacy Technician colleagues working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. Embedded in multidisciplinary medical teams and equipped with exceptional medicines management expertise, SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care.

Women make over half (51%) of the country's population in Australia, implying more than half of Australians may at some point experience the debilitating symptoms of menopause and perimenopause. For a condition that affects such a large population cohort, its management is poorly understood by both women and healthcare practitioners. Furthermore, despite readily available, safe hormonal and non-hormonal therapies, over 85% of women with bothersome symptoms are not receiving evidenced-based care.¹ This highlights the multitude of barriers that currently exist for women accessing care in managing their menopause and perimenopause in Australia.

SHPA convenes a Women's and Newborn Health Specialty Practice Group, who include a network of SHPA members promoting the health and wellbeing of women by improving medication management across all aspects of women's health, including menopause and perimenopause. As the medicine experts, pharmacists are ideally placed in community and acute care settings to provide education and reassurance to women seeking help on managing their menopause, and work in collaborative care teams to provide advanced care and optimise treatment options related to menopause for individual women.

With consideration of the priorities of the *National Women's Health Strategy 2020-2030*², SHPA welcomes the opportunity to respond to the Inquiry into the issues related to menopause and perimenopause and provides the following recommendations in addressing the terms of reference (f): "The level of awareness amongst medical professionals and patients of the symptoms of menopause and perimenopause and the treatments, including the affordability and availability of treatments"

Recommendations

Recommendation 1: Ensure comprehensive training on menopause and perimenopause is included in all undergraduate medical, nursing, pharmacy, and allied health degrees to support healthcare professionals to provide holistic care to women at all stages of life

Recommendation 2: Support pharmacists to undertake Registrar Training Programs in Women's Health to produce a highly skilled pharmacy workforce competent in the management of menopause and perimenopause

Recommendation 3: Include menopause and perimenopause as core curriculum of graduate training for general practitioners

Recommendation 4: Support ongoing research into the management and impact of menopause in Australia



Recommendation 5: The Pharmaceutical Benefits Advisory Committee (PBAC) should consider further PBS coverage for menopausal hormone therapies to facilitate choice and reflect current clinical guidance

Recommendation 6: The value of therapies for menopause and perimenopause should be holistically assessed to fully realise its impact on health outcomes

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on .



Introduction

Menopause or perimenopause is a natural physiological aging process affecting all women between the ages of 40 to 59 years, translating to 3.28 million women in Australia alone.¹ Irrespective of the common vasomotor symptoms such as hot flushes and night sweats, menopause causes silent biological changes that may increase women's risks of cardiovascular disease, diabetes, osteoporosis, and some cancers.¹ As such it should be expected that all health professionals should be adequately equipped to provide best evidence-based practice and menopause advice to all women. Unfortunately, this is not the case in Australia.

The release of the *Women's Health Initiative (WHI)* study in 2002 on the use of hormone replacement therapy (HRT) in menopause became a catalyst for huge change in HRT use across the globe.³ The initial results and the proceeding media reports of increased risk of breast cancer from HRT use led to the sudden cessation of HRT in thousands of women. Since then, reanalysis of the data from WHI, particularly to stratify results by age and years since menopause showed that HRT was found to have beneficial effects on cardiovascular health if commenced in women aged 50-59 years or within a decade of post-menopause.^{3,4}

Despite the publication of reanalysis data from the WHI study, the following decades of conflicting information and debate on the risks versus benefits of menopausal hormone therapies (MHTs) have negatively affected women's beliefs, prescriber attitudes, and prescribing practices, ultimately leading to the underuse of these treatments even when considered appropriate or beneficial. Although over 50% of post-menopausal women have vulvovaginal atrophy symptoms, fewer than 7% are prescribed effective, safe vaginal oestrogen therapy.¹ First line management of menopause and perimenopause associated issues should be addressed in primary care, yet menopause is not among the top 15 conditions most frequently managed by general practitioners (GPs).¹

Several barriers exist both for healthcare practitioners and patients in providing and accessing treatments for menopause and perimenopausal symptoms. Addressing these barriers should be highlighted as a national priority, in line with the *National Women's Health Strategy 2020-2030* to improve the health and wellbeing of women in Australia.

Issue 1: Lack of awareness of the symptoms of menopause and perimenopause and the treatments amongst healthcare professionals

While it appears that Australian healthcare practitioners have generally good understanding of menopause and its consequences, they are often uncertain about its management, including the prescribing of MHTs.⁵ Currently the Therapeutic Goods Administration (TGA) lists approved estrogen therapies 'for the prevention of postmenopausal bone mineral density loss', amongst other indications. Despite this, Australian GPs and gynaecologists continue to reserve prescribing MHTs for severe symptoms with associated impaired quality of life. This highlights existing knowledge gaps in the management of menopause by healthcare practitioners and their lack of confidence in prescribing MHT where appropriate. The upskilling of healthcare practitioners providing care for women at midlife, especially with respect to the indications for and prescribing of MHT needs to be addressed.

Recommendation 1: Ensure comprehensive training on menopause and perimenopause is included in all undergraduate medical, nursing, pharmacy, and allied health degrees to support healthcare professionals to provide holistic care to women at all stages of life



University health undergraduate degrees should aim to produce graduates who are competent in managing the symptoms of menopause and its associated health conditions upon entering the workforce. The topic of menopause and consideration of its impact on women's health is omitted or inadequately addressed in most undergraduate and post-graduate medical and allied health training, subsequently underpreparing our future health practitioners in providing quality care for women in Australia.

The lack of educational training on menopause and perimenopause from undergraduate studies translates into lack of proactiveness and even avoidance of these topics with women in clinical practice, further perpetuating the associated stigma and embarrassment.⁶ We must empower undergraduate students to positively engage patients on these topics so that once qualified they can provide reassurance and guidance to women in their midlife seeking safe and effective care.

Pharmacists equipped with knowledge from undergraduate studies are valuable assets in community and hospital care settings, as they are optimally placed to provide lifestyle education and disseminate research-guided clinical evidence and information to women experiencing menopause and perimenopause.

Recommendation 2: Support pharmacists to undertake Registrar Training Programs in Women's Health to produce a highly skilled pharmacy workforce competent in the management of menopause and perimenopause

It is important to ensure that postgraduate studies, including accredited training in menopause is made available for health practitioners to continue upskilling in the management of menopause and perimenopause with emerging evidence, and enable practitioners to confidently assess, diagnose, and treat complex cases, including early menopause and menopause following breast cancer.

SHPA recently launched The Australia and New Zealand College of Advanced Pharmacy (ANZCAP) in October 2023, a landmark recognition programme for pharmacists and pharmacy technicians working across Australia and New Zealand, providing a platform for practitioners to track and manage their careers towards three progressive levels of specialisation: Resident, Registrar, and Consultant (Fellow). As part of the ANZCAP recognition pathway, SHPA provides Resident Training Programs for pharmacists wishing to advance their practice into specialist areas, including one which is currently in development for the Women's and Newborn Practice Area Pathway.

Specialisation training programs such as SHPA's Registrar Training Programs can help address knowledge gaps for pharmacists in the management of menopause and perimenopause, who are optimally placed both in community including general practices and in acute care settings to educate, support, and assist in the management of menopausal symptoms. Pharmacists who graduate from Resident Training Programs can also work in collaborative care teams across all health care settings, including in menopause clinics, to provide expert pharmaceutical knowledge on therapies to manage menopause, promoting quality care for women, including those with complex and advanced care needs.

Recommendation 3: Include menopause and perimenopause as core curriculum of graduate training for general practitioners

First line management of menopause and perimenopause associated issues should be addressed in primary care, yet menopause is not among the top 15 conditions most frequently managed by GPs. Widespread misinformation on the safety and efficacy of MHTs, lack of awareness and confidence in prescribing pharmacological treatments for menopausal symptom management, and low availability of approved



treatments of Australia present as challenges for GPs in providing quality care. Additionally, short consultation times during GP visits also present as a barrier for GPs to conduct in-depth consultation with women where a significant amount of time may be required for comprehensive assessment.

A cross sectional analysis from the Registrar Clinical Encounters in Training cohort study⁷ showed GP trainees in Australia seek more assistance and further knowledge about menopause compared with other conditions. They especially find the area challenging and could benefit from further education regarding managing menopause.

Upskilling of GPs with contemporary knowledge and skills will enable them to have positive conversations with women on menopause and perimenopause without embarrassment, empowering women to make informed choices about their menopause and individual circumstances.

Recommendation 4: Support ongoing research into the management and impact of menopause in Australia

In line with the priorities of the *National Women's Health Strategy 2020-2030*, further research into the impact of menopause should be supported to inform best-practice clinical guidance, thereby addressing key stakeholder uncertainty in treating women with menopause.

The 2023 Practitioner's Toolkit for Managing Menopause⁸ is an example of research informed development of a clinical decision tool, guiding healthcare practitioners to support women in the treatment of menopause based on robust up-to-date clinical evidence. The ongoing research and subsequent development of clinical tools and guidelines such as this will also support increased medicines availability in Australia.

Furthermore, measuring and reporting on the economic and societal impact of menopausal symptoms is particularly important to ascertain the cost-effectiveness of menopause and perimenopause. It is estimated that menopause is currently costing Australian women a collective loss of \$15.2 billion in foregone income and super for every year of early retirement.⁹ Continued understanding of how menopause and perimenopause impacts quality of life and associated health costs through research is imperative to supporting the expansion of quality care and availability of pharmacological treatment in Australia.

Issue 2: Lack of awareness of the symptoms of menopause and perimenopause and the treatments amongst patients

Women are taking an increasingly greater role in decisions about managing symptoms of menopause and perimenopause, with the consumer's choice dominating the clinician's decision when deciding on preferred treatment.⁴ However, professional guidance is still critical to ensuring patients are appropriately informed of the efficacy and safety of the variety of treatment options available, particularly as the legacy of the WHI studies persists in many women who continue to express concerns on the safety of MHTs.

In Australia, women are more likely to use complementary or alternative medicines (CAMs) to manage vasomotor symptoms than MHTs, with less than 5% of women using topical vaginal estrogen.⁵ Despite limited evidence of CAMs, most health practitioners in Australia supports women trialling CAMs for their menopausal symptoms, further reinforcing women's negative attitudes to MHT. Consequently a significant proportion of highly symptomatic women, and women at high risk of postmenopausal bone loss, continue to be provided with substandard care. As such, patient education is key to improving the lives of women at menopause and beyond.



SHPA members report that other clinical areas are deemed to be of higher clinical risk and priority than reproductive services in acute care settings. Compounded by Australia-wide pharmacist workforce shortages, as demonstrated in the National Skills Commission's Skills Priority List 2023, the provision of clinical pharmacy services to this cohort of patients is often deprioritised, with clinical pharmacists assigned to 'higher risk' patient cohorts and wards. This leads to lost opportunities for qualified pharmacists to engage women in conversations about their reproductive health and provide services related to the correct prescribing, procurement, and supply of menopausal treatment.

Pharmacist presence across all healthcare settings can help to facilitate the correct utilisation of clinical evidence and dissemination of appropriate education and knowledge in the management of menopause and perimenopause for women in Australia. In the context of hospital-based care, this can be achieved through the adoption of SHPA's pharmacist-to-bed ratios as outlined in the *SHPA Standards of Practice for Clinical Pharmacy Services*¹⁰, which recommends one clinical hospital pharmacist to every 30 patients (1:30) to ensure safe high-quality medicines management. This includes providing inpatient pharmacy services such as:

- taking a medication history and ensuring medications are charted correctly and available at admission to be administered in a timely manner
- regular review of the safety, quality, storage and supply of medications during hospital stay
- review of discharge prescriptions, dispensing a sufficient supply of medications to take home
- counselling patients on their medications and communicating changes to primary healthcare providers
- ensuring appropriate follow-up and monitoring of medications post-discharge including in specialised clinics and outpatient services and checking for adverse reactions to medications

Additionally, pharmacists can promote safe use of medicines in menopausal women who require special consideration, such as those with existing comorbidities, raise awareness of appropriate treatment options, and assist in the development and implementation of gynaecological guidelines including treatment menopause and perimenopause.

Issue 3: Reduced affordability and availability of treatments for symptoms of menopause and perimenopause in Australia

The impact of WHI 2002 was generalised to most MHT products on the market, irrespective of class, strength, and route, leading to mass cessation of hormonal therapy in menopausal women in Australia.³ The sustained low use of MHT thereafter led to product discontinuation over time. Most oral MHT was not subsidised by the Australian government after 2009, with most treatments now only accessed through private prescription and full payment, creating further inequities in medicines access especially for women who are already disadvantaged.

The discontinuation and removal of MHT products from the pharmaceutical benefit schedule (PBS) also restricts available treatment options for healthcare practitioners, reinforcing the downward utilisation trend of MHT use in Australia. Of note, the discontinuation and short supply of oestradiol containing transdermal patches containing in 2021 left many women distressed as the limited number of products available created access issues. This highlights the growing importance of continuing availability of a range of treatment options to accommodate individual circumstances of the patient experiencing menopause or perimenopause.



The current low number of subsidised treatments under PBS also forces clinicians to rely on off-label prescribing of hormonal and non-hormonal treatments, on which there are limited guidance available in Australia. The lack of regulatory approval for these treatments in the first instance impacts on clinician confidence and ability to safely prescribe off-label medicines, with varying care amongst different GPs further creating inequitable access to quality care.

The heavy reliance on off-label medicines also implies menopausal treatments have higher out-of-pocket costs compared to treatments for other common conditions, creating inequities and further disadvantaging women in managing symptoms. We should be supporting women to access quality care for treating menopause which is unavoidable for all women going through this natural aging process.

Recommendation 5: The Pharmaceutical Benefits Advisory Committee (PBAC) should consider further PBS coverage for menopausal hormone therapies to facilitate choice and reflect current

The lack of PBS funded menopause therapies not only discourages the safe utilisation of these treatments in Australia, but also disincentivises pharmacies to carry stock of MHTs, creating barriers to timely access of these therapies. In the context of women admitted to hospital, hospital dispensaries carrying minimal range of supply of products to treat menopause and perimenopause are often unable to provide supply of MHTs as women in community frequently access off-label and/or privately funded treatments. This results in temporary cessation of menopausal treatment, or forces women to continue supplying their own treatment out-of-pocket during inpatient stay, leading to suboptimal care.

In line with priority area 1 of the *National Women's Health Strategy 2020-2030*, SHPA recommends that the PBAC considers further PBS coverage for MHTs to facilitate increased medicine availability in both community and hospital care settings that reflects current guidance. This includes consideration of treatment options as per the clinical guidance published by key stakeholders such as the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and the Australian Menopause Society.

Recommendation 6: The value of therapies for menopause and perimenopause should be holistically assessed to fully realise its impact on health outcomes

The need for a robust evidence base is essential when assessing the quality and safety of a medicines. However, it can at times prove to be a barrier to timely access of therapies especially when challenges exist in collating sufficient data. In the case of menopause and perimenopause, the preceding decades of misinformation, the low utilisation of therapies for menopause, and dwindling research into this area has prohibited pharmaceutical companies from applying to register products in Australia. This is compounded by the lack of impact assessment that looks beyond conventional health outcomes. Menopause affects not only clinical outcomes, but potentially affects employment, work performance and retention, all of which are important considerations in assessing its impact on quality of life.

In SHPA's submission to the *Health Technology Assessment (HTA) Policy and Methods Review*¹¹, SHPA made several recommendations to address the current barriers to accessing novel therapies in Australia, which can be applied in the context of assessing the access to menopausal therapies:

- Establishing a nationally coordinated and systematic process of identifying and monitoring emerging technologies that have the potential to significantly impact the health care sector,



- Collecting data on the use of non-PBS medicines across all care settings, including the use of unregistered medicines and off-label medicines, to inform future funding decisions, policies, regulations and clinical guidelines preventing future medicine-related hospital admissions,
- Developing a repository of non-PBS, off-label and Special Access Scheme (SAS) medicines data gathered from all hospitals across Australia to facilitate more timely decision making and provide Australians with early access to medicines.





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