

Menopause Priority Setting Partnership

PROTOCOL Version [1.1]

Purpose of the PSP and background

The purpose of this protocol is to clearly set out the aims, objectives and commitments of the Menopause Priority Setting Partnership (PSP) in line with James Lind Alliance (JLA) principles. The Protocol is a JLA requirement and will be published on the PSP's page of the JLA website. The Steering Group will review the Protocol as needed and any updated version will be sent to the JLA.

The JLA is a non-profit making initiative, established in 2004. It brings patients, carers and clinicians together in PSPs. These PSPs identify and prioritise the evidence uncertainties, or 'unanswered questions', that they agree are the most important for research in their topic area. Traditionally PSPs have focused on uncertainties about the effects of treatments, but some PSPs have chosen to broaden their scope beyond that. The aim of a PSP is to help ensure that those who fund health research are aware of what really matters to patients, carers and clinicians. The National Institute for Health and Care Research (NIHR – www.nihr.ac.uk) coordinates the infrastructure of the JLA to oversee the processes for PSPs, based at the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), University of Southampton.

The Menopause Priority Setting Partnership (MAPS) group is a clinician researcher led project to establish a Priority Setting Partnerships (PSPs) in menopause. This will bring together clinicians and those with lived experience on an equal footing to identify evidence gaps that are important to both groups. By identifying evidence gaps, MAPS will improve clinical practice and outcomes for women experiencing menopause.

The Problem

Menopause is a condition that arises due to ageing and a health priority area identified through our clinical practice and those with lived experience. Although menopause eventually affects all women it is an under-researched area. Basic understanding of why menopause occurs and why experiences differ so much between women is lacking. There is a lack of consensus about what symptoms menopause causes and this is problematic for patients and clinicians (1). Not surprisingly, many women report feeling unprepared for menopause and dissatisfied with information and education available (1). There are racial/ethnic variations in menopause timing and symptoms which are poorly understood (2). This uncertainty and substantial variation between the quality of care provided to women experiencing menopause limits the provision of evidence-based care by their healthcare providers.

Gaps in the evidence

Although >70% of women report menopausal symptoms, there remains significant evidence gaps, as symptom severity and duration cannot be reliably predicted (1). Marginalised populations, such as transgender individuals, face elevated risks due to stigma, limited access to treatment, and financial insecurity (2). Premature or early menopause affect around 10% of women (3), and more information is needed about causes, symptom differences and the optimum dose and duration of menopausal hormone therapy (MHT) in younger women (4). Little is known about the impact of menopause in the LGBTQTI+ population. Clinical research has primarily focused on medical therapies for vasomotor symptoms (hot flushes/night sweats), overlooking other priority symptoms for patients such as sleep difficulties, fatigue, and joint pains (5). MHT is effective for vasomotor symptoms but carries health risk and non-pharmaceutical or “natural” approaches are usually preferred for mild symptoms (6). The relative efficacy, risks, and benefits of emerging non-hormonal treatments remain poorly defined. Menopausal symptoms often start in the perimenopause, but the relative safety and efficacy of treatments at this stage uncertain. Similarly, it is uncertain whether MHT has a role for preventing diseases such as CVD or dementia (7). Menopause is largely managed in primary care, but the optimal model of care is unknown. In developed countries, women are nearly half the paid workforce >70% of the unpaid/voluntary sector and often work over the menopause transition. Menopause may impact on work participation and performance, disproportionately affecting female-dominated sectors such as health and education.

A better understanding of women's menopausal health and preferences, along with healthcare providers' perspectives, would inform research and improve care for this growing population.

This PSP came about through collaborations between clinicians and researchers working in the field of menopause who identified a gap in the evidence around priorities for research for both clinicians and those with lived experience of menopause.

Aims, objectives and scope of the PSP

Aim:

We want to understand the questions that people with lived experience and health care professionals have about menopause. This includes women and people assigned female at birth who are perimenopausal or menopausal and health care professionals who care for menopausal patients.

Objectives of the PSP are to:

- Work with those with lived experience and clinicians to identify uncertainties about menopause and perimenopausal
- To include as wide as possible range of voices, including LGBTQTI+ (particularly Trans) communities, those with premature ovarian insufficiency, Ethnic minority and culturally and linguistically diverse groups, and those with menopause because of medical treatment
- To agree by consensus a prioritised list of those uncertainties, for future research
- To publicise the PSP process and results
- To take the PSP results to research commissioning bodies to be considered for future funding

In scope for the PSP are the following:

1. Those with lived experience: Women who have experienced menopause, are peri- or post-menopausal. This also includes those with
 - a. Premature ovarian insufficiency

- b. Menopause because of medical treatment
2. Marginalised groups including LGBTQTI+ (and particularly transgender community) individuals, ethnic minority, culturally and linguistically diverse groups, premature/early menopause, menopause after cancer, and those with low literacy.
3. Healthcare providers who provide primary, secondary and tertiary menopause care, pharmacists and psychologists.

The scope is international, primarily Australia, USA and UK, but all international contributions will be accepted if in English.

The PSP will exclude from its scope questions not asked in English, personal clinical questions, and questions about access to services in specific geographical locations which are not generalisable.

The Steering Group is responsible for discussing what implications the scope of the PSP will have for the evidence-checking stage of the process. Resources and expertise will be put in place to do this evidence checking.

The Steering Group

The Steering Group (SG) includes lived experience representatives and healthcare professionals (¹), as individuals or representatives from a relevant group. The SG is a working group, contributing to the running of the PSP, ensuring timely delivery and adherence to the JLA principals of transparency, inclusion, equality and use of existing evidence. The SG ensures that the process is documented, open and transparent and adheres to the survey responses and evidence review.

The JLA Adviser supports and guides the PSP, ensuring fair and transparent processes with equal input from all groups. The Adviser provides advice and materials for use of the JLA methodology, survey design, documentation, tools, data management, and communications and chairs the SG meetings.

Engagement of those with lived experience is fundamental to the process of PSP and lived experience members will be actively engaged at all stages. Our global SG of approximately 20 people includes ≥ one quarter lived experience members. The SG also includes healthcare professionals across relevant disciplines (gynaecology, endocrinology, specialist nurses, GP, psychiatry) and cultural contexts.

Martha Hickey leads the SG She recently led the first Core Outcome Set in menopause across 26 countries, and we will draw on these networks for MAPS (^{14,15}). The SG will complete the JLA interests and privacy declarations.

An experienced JLA advisor (Toto Gronlund) and information specialist (Kristine Stanley) is part of the SG. The SG will meet every 1-3 months, depending on the stage and needs of the PSP.

The Menopause PSP will be led and managed by a Steering Group including the following:

¹ In some cases, it has been suggested that researchers are represented on the Steering Group, to advise on the shaping of research questions. However, researchers cannot participate in the prioritisation exercise. This is to ensure that the final prioritised research questions are those agreed by patients, carers and clinicians only, in line with the JLA's mission.

Lived experience representatives:

- Karen Giblin, President & CEO/Founder Red Hot Mamas, USA
- Deborah Garlick, Henpicked, UK
- Karen Nakawala Chilowa, Teal sisters project in Zambia - gynae cancer, Tanzania
- Viktoria Rother, Women's mental health lived experience advocate, Australia
- Nina Kuypers, Black Women in Menopause, UK

Clinical representatives:

- Martha Hickey, Professor of Obstetrics and Gynaecology, Clinical Lead, Gynaecology Research Centre. University of Melbourne Department of Obstetrics & Gynaecology (Royal Women's Hospital), Victoria, Australia (Chair) (PSP leader)
- Zachary Nash, Clinical Research Fellow Gynaecology, University College London Hospital and University College London (PSP co-ordinator)
- Monica Christmas, Gynaecologist, University of Chicago, USA
- Jenifer Sassarini, Consultant Gynaecologist and Obstetrician, Glasgow Royal Infirmary and Honorary Clinical Senior Lecturer, Glasgow University, UK
- Sarah Hillman, Senior Lecturer in General practice, University of Warwick, UK
- Andrew Fisher, Gynaecologist, University of Chicago, USA
- Jo Burgin, Academic Primary Care Trainee, University of Bristol, UK
- Shibani Nicum, Oncologist, University College London Hospitals, UK
- Janet Carpenter, Distinguished Professor and associate dean for research at the Indiana University School of Nursing, USA
- Sheryl Kingsberg, OB/GYN Behavioral Medicine - Sex Medicine, USA
- Hadine Joffe, Psychiatrist, Harvard University, USA
- Susan Davis, Professor of Endocrinology, Australia
- Jane Daniels, Professor of Clinical Trials, Nottingham Clinical Trials Unit, UK
- Sharon Dixon, NIHR Doctoral Research Fellow and General Practitioner, University of Oxford UK
- Samar Elkhoudary, Professor, Epidemiology, University of Pittsburgh
- Claire Hardy, Senior Lecturer in Organisational Health and Well Being, Lancaster University
- Gita Mishra, Professor of Epidemiology, The University of Queensland, Australia.
- Michelle Peate, Principal Research Fellow, Obstetrics and Gynaecology, University of Melbourne, USA

The Partnership and the priority setting process will be supported and guided by:
The James Lind Alliance (JLA) advisor: Toto Anne Gronlund

Information Specialist: Kristina Staley, TwoCan Associates

The Steering Group will agree the resources, including time and expertise that they will be able to contribute to each stage of the process, with input and advice from the JLA advisor.

Partners

Relevant organisations and groups will be invited to be involved with the PSP as partners. Partners will commit to supporting the PSP, promoting the process, and encouraging their represented groups or members to participate. Partners represent the following groups:

- People who have lived experienced of Menopause

- Health and social care professionals with experience of caring for those experiencing Menopause

Confirmed Partner Organisations:

Royal College of Obstetricians and Gynaecologists, UK
 Royal Australian and New Zealand College of Obstetricians and Gynaecologists
 Primary Care Women's Health Forum, UK
 Australasian Menopause Society, Australia
 Wellbeing of Women, UK
 Jean Hailes, USA
 Black Women in Menopause, UK
 Callen-Lorde Community Health Center, USA
 Red Hot Mamas, USA
 Henpicked, UK
 British Menopause Society, UK
 The Menopause Society, USA
 Royal Australian College of General Practitioners
 Menopause Friendly Australia
 Menopause Foundation of Canada

Exclusion criteria

Some organisations may be judged by the Steering Group to have conflicts of interest. These may be perceived to potentially cause unacceptable bias. As this is likely to affect the ultimate validity of the findings of the PSP, those organisations will not be invited to participate. It is possible, however, that interested parties may participate in a purely observational capacity when the Steering Group considers it may be helpful.

The methods the PSP will use

This section describes a schedule of proposed steps through which the PSP aims to meet its objectives. The process is iterative and dependent on the active participation and contribution of different groups. The methods used in any step will be agreed through consultation between the SG members, guided by the PSP's aims and objectives. More details of the method are in the guidebook section of the JLA website at www.jla.nihr.ac.uk.

A period of 18 months will be given to complete this exercise (which may be revised by the Steering Group if required).

Awareness raising

The PSP will raise awareness of the project among lived experience and clinician communities, to secure support and participation.

Awareness raising has several key objectives:

- to present the proposed plan for the Menopause PSP
- to generate support for the process
- to encourage participation in the process
- to initiate discussion, answer questions and address concerns.

The SG and partners will raise awareness of the PSP amongst communities, through the media and via the MAPS website in order to secure support and participation. The SG will create a short video targeting potential participants to explain the PSP purpose and process, an approach effectively used by other PSPs ⁽¹⁶⁾. The survey will be launched through social and mainstream media, using our partner organisations and SG networks to disseminate the survey. The headline message will be:

“Do you want to shape the future of menopause research?”

Identifying evidence uncertainties (unanswered questions)

The Menopause PSP will gather uncertainties (unanswered questions) from patients, carers, and clinicians.

The SG will design the survey with guidance from the JLA, JLA advisor, information specialist and previous successful PSPs. Live experience members will be engaged at all stages. Steering group members will contribute to the survey design and development.

The survey will target:

1. Those with lived experience: Women who have experienced menopause. These will be targeted through our extensive SG and partner networks and through social media groups.
2. The Menopause PSP recognises that the following groups may require additional consideration:
 - a. Premature ovarian insufficiency
 - b. LGBTQI+ (and particularly trans) individuals
 - c. Ethnic minority and culturally and linguistically diverse groups
 - d. Menopause because of medical treatment

We will target marginalised groups using our strong established SG networks including cancer patients, Black and Hispanic women, the transgender community, premature/early menopause, menopause after cancer, culturally and linguistically diverse groups, and those with low literacy.

3. Healthcare providers who provide primary, secondary and tertiary menopause care, pharmacists and psychologists.

The survey will cover three areas:

1. Demographic information including age, ethnicity, language spoken at home, SES, geographical location (rural/metro), sexual orientation and gender, age at menopause, cause of menopause (eg surgical, chemoradiation, natural) and use of treatments for menopausal symptoms including MHT.
2. Respondent group (lived experience, HCP, researcher), recognising that respondents may identify in more than one group (e.g. HCP and postmenopausal).
3. The key unanswered questions for menopause research by asking:

“Please list up to 3 questions about menopause that you would like to see answered by research.”

Participants can provide up to 3 responses. We will specify that personal questions about menopause care cannot be answered. Participants can choose to provide their contact details to receive information or be involved in future stages of the PSP. This helps with disseminating and

targeting recruitment to the final consensus workshop. Participant names and contact details will not be linked to their survey responses.

We will widely disseminate the survey using contacts from our SG, partners, social media, consumer groups, targeted communication, and advocacy groups. Our partners are well placed to promote and disseminate the survey. For example, The Australian Menopause and Perimenopause Support group has 26,000 members, Red Hot Mamas has 25,000 members and Henpicked works with over 300 workplaces to become “menopause friendly”. Based on similar PSPs (eg contraception), our global team and our focus (menopause), we anticipate up to 3000 responses. Survey respondents are often educated white people. Quality of responses is a priority for MAPS. The survey will be available in online and paper versions.

The survey will be live for 4 weeks. We will check for saturation after 4 weeks and monitor responses for any new questions/topics. At saturation or after 3000 responses the survey will close. Otherwise, it will remain open for 4 more weeks with additional promotion through our partners and social media, or targeted promotion.

Existing sources of evidence uncertainties may also be searched.

Organising and summarising the responses

We anticipate responses to be a mix of specific questions, personal stories and themes or issues. Survey responses are rarely formed as research questions but will contain a question or issue that is important to the respondent.

The review methodology is a qualitative, interpretative, and iterative exercise conducted by an independent JLA information specialist, Kristina Staley (KS). The responses will be read, categorised and summarised by KS, with the support of the SG. Similar or duplicate responses will be combined where appropriate into summary questions. Out-of-scope and ‘answered’ responses will be compiled separately. The aim is to develop a manageable number of summary questions for the first stage of prioritisation, aiming for 50-60 questions.

The SG provide governance, ensuring that the original responses are interpreted fairly, checking those identified as out-of-scope, and checking singleton questions to determine if they stand alone or should be merged with another question. The summary questions should include a balance of responses from diverse groups. The SG will also ensure that the summary questions are clear, accessible and unambiguous. A focus group may be formed and consulted to support this review of responses. The JLA Adviser will observe to ensure accountability and transparency.

The analysis will result in a list of in-scope summary questions. These are not framed as research questions, as this may make them too technical for a non-research audience. They are framed as researchable questions that capture the themes and topics that people have suggested in their responses.

These summary questions will be checked against the evidence to determine whether they have already been adequately answered in published research. We will search PubMed for RCT, systematic reviews and clinical guidelines to establish whether high-quality evidence already exists to answer the questions identified in the survey. The search will be extensive and include websites of national organisations, professional societies, and guidelines databases. Clinical trials.gov will be searched for relevant trials in progress. The Cochrane Library and PROSPERO database will be searched for completed or in progress systematic reviews. The Turning Research Into Practice (TRIP) and PubMed databases will be searched for evidence-based guidelines and systematic reviews. When the evidence is uncertain (“borderline questions”) will be discussed amongst the Steering Group and Focus Groups to determine whether these questions are already ‘answered’

or 'unanswered'. Level of evidence will be graded using the updated Grading of Recommendations, assessment, development and evaluations (GRADE) approach ⁽¹⁷⁾.

The summary questions that are verified as being unanswered form the long-list for the first stage of prioritisation.

The SG will consider how to deal with the responses that have already been answered and those considered out of scope. This may include sign-posting to available sources of information or support.

Both the original survey responses and summary questions will be published on the JLA website at the end of the PSP. An audit trail is maintained for transparency showing how the summary questions have been developed, including the original responses, the respondent group, and other demographics. The responses should be anonymous, but are checked for any inadvertent personal information. Full anonymity will be maintained throughout.

The PSP will complete the JLA Question Verification Form, to document the process used to verify the uncertainty of the questions, before starting prioritisation. This will be published on the JLA website, to enable researchers and other stakeholders to understand how the PSP has decided that its questions are unanswered, and any limitations of this.

Prioritisation – initial and final stages

There are usually two stages of prioritisation.

Initial prioritisation by individuals

Initial prioritisation is the stage where the long-list of questions is reduced to a shorter list that can be taken to the final priority setting workshop.

Based on similar PSP (Contraception <https://www.jla.nihr.ac.uk/priority-setting-partnerships/contraception/downloads/Contraception-PSP-final-report.pdf>) we anticipate that the long list will contain around 50-60 unanswered summary questions.

We will target the same stakeholder groups as the first survey. We aim to involve as many people as possible, including those who did not contribute to the first consultation. Participants will be asked to select the top 10 questions that are most important to them. The results will be analysed and balanced by group, to avoid skewing the results if there are unequal numbers of participants in each stakeholder group. Where the interim prioritisation does not produce a clear cut off point, the SG may decide which marginal questions should be taken forward, also considering the balance of themes/topics. The interim prioritisation allows the long list of 50+ summary questions to be reduced to a short list of up to 20. These will be reviewed by the steering group and taken to the final priority setting consensus workshop.

Consensus workshop

The aim of the final stage of the PSP is to prioritise through consensus the identified unanswered questions about menopause. This will involve input from the priority population and HCPs.

The final priority setting process will be a full day workshop facilitated by the JLA and held in Melbourne in October 2024. The senior JLA Advisor (Toto Gronlund) will attend in person and chair the workshop. With guidance from the JLA and input from the Steering Group, up to 30 people with lived experience and HCPs will be recruited to participate in a day of discussion and ranking, to determine the top 10 questions for research.

The meeting will be a hybrid (including online participants) to facilitate participation by consumers and others who are unable to attend in person, this hybrid model has worked well for other PSP⁽¹⁸⁾. Participants will equally represent each stakeholder group and include diverse experiences. All participants will declare their interests. The SG will advise on any adaptations to ensure the process is inclusive and accessible. The workshop will follow the standard JLA priority setting approach, drawing on Nominal Group Technique. This involves participants being provided with the shortlist of questions, which they review and rank for themselves in advance of the workshop. Through a series of small and large group sessions at the workshop, the questions will then be ranked by consensus discussion, facilitated by JLA Advisers.

Dissemination of results

The Steering Group will identify audiences with which it wants to engage when disseminating the results of the priority setting process, such as researchers, funders, and lived experience communities. They will need to determine how best to communicate the results to these groups. Previous PSPs' outputs have included academic papers, lay reports, infographics, conference presentations and videos for social media.

It should be noted that the priorities will all be published and made available for research. Those that did not make the top 10 will not be abandoned. The priorities are not worded as research questions. The Steering Group should discuss how they will work with researchers and funders to establish how to address the priorities and to work out what the research questions are that will address the issues that people have prioritised. The dissemination of the results of the PSP will be led by Zachary Nash and Martha Hickey.

The JLA encourages PSPs to report back about any activities that have come about because of the PSP, including funded research and the JLA will be kept updated.

The top 10 will be launched at the International Menopause Society Conference in October 2024 where healthcare professionals discuss the most recent scientific and research developments in the field.

The SG will identify the key audiences who should be aware of the Top 10 including researchers, funders, patient and advocacy groups, conference presentations, social media. Steering group and partners will disseminate amongst networks (#menopausetop10). We anticipate that our findings will be published in high-impact journals.

We will work with global funding bodies and advocacy groups to promote the value of supporting research questions prioritised.

Agreement of the Steering Group

The Menopause PSP Steering Group agreed the content and direction of this Protocol on 11 October 2023.

References

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