Bridging the innovation gap in personalised menopause healthcare through technology

Student: Maria Inês da Cruz Branco

Program: Executive Master's in Marketing & Strategy

Advisor: Eduardo Redondo

Accredited by: AACSB ACCREDITED, EQUIS ACCREDITED, ASSOCIATION AMBA ACCREDITED

Ranked by: eduniversal, FT FINANCIAL TIMES

NOVA Executive Education
NOVA SCHOOL OF BUSINESS & ECONOMICS

Abstract

Menopause is a condition that affects all women, with substantial physical and psychological impacts. Despite the sizable population affected over time, the research-based knowledge and education of women, healthcare professionals, and society still needs improvement. Innovation for healthcare has historically prioritised curative measures over preventative ones. However, in perimenopause, where reducing post-menopause disease risk is a crucial outcome, the industry needs to change its approach. Therefore, closing the innovation gap between the standard of care and a personalised approach holds substantial economic and preventative potential. Furthermore, addressing menopause is essential to improving women's health and well-being.

Keywords:

Innovation; Personalisation; Menopause; Technology

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Introduction

The challenges in women's health are a broad topic that has often been restricted to sex-specific problems (National Institutes of Health 2023). Women can spend up to 25% of their lives in a worsened health condition than men (World Economic Forum 2014). For instance, Westergaard et al. (2019) identified 770 diseases where women were diagnosed later than men. In societies where gender equality is expected in professional and personal settings, healthcare is expected to catch up (Westergaard, Moseley, et al. 2019).

Managing women's healthcare throughout their lives can have a significant economic impact. The World Economic Forum reports that closing the healthcare gap between men and women can contribute 1 trillion dollars to the global economy by 2040 (World Economic Forum 2014). The World Health Organization defines menopause as a point in women's life stages that marks the end of their reproductive years. As a naturally occurring condition, it's divided into three stages: perimenopause, menopause, and post-menopause. Despite being associated with several possibly debilitating symptoms, none of the menopause stages fall into the disease category (World Health Organization 2024). The stigma that still exists around menopause makes it potentially one of the most ignored conditions in modern-day healthcare (Barber e Charles 2023).

In caring for women, the healthcare sector has often focused on curing as a primary outcome. However, a more valuable indicator in perimenopause is the reduction of disease risk post-menopause (Kaminska, et al. 2023, Faubion, et al. 2015).

Menopause, in all its stages, is a personal journey that affects women differently through physical and psychological symptoms and sociological responses. Similarly, women also respond very differently to the current standard of care that targets the management of symptoms (Barber e Charles 2023).

Hormonal replacement treatment (HRT) is the most common medical solution for managing symptoms during perimenopause (Trémollieresa, et al. 2022). However, non-hormonal drugs and complementary and alternative medicine (CAM), mainly in the form of dietary supplements, have been rising in popularity (Davis, et al. 2023, Cardini, et al. 2010), leading stakeholders to question the best choice for each woman and how it will evolve.

Despite the existence of different approaches, women still feel unsupported in the journey of menopause (Barber e Charles 2023), and more needs to be done to address their unmet needs and support their patient's journey.

Technology development has profoundly changed healthcare, from diagnosis to therapies, self-tracking, etc. In the current environment of tech development, it is crucial that institutions in the healthcare sector – healthcare providers, payers, pharma and biotech, consulting, medical devices, health tech, etc. – work together to achieve a patient-centric healthcare sector that addresses the exact needs of individuals. This transition characterises the foundation of future innovation in the healthcare industry – pharma, biotech, medical nutrition, and devices (Thimbleby 2023).

Data is the key to a healthcare sector that can connect its players and deliver a fully patient-centric approach to prevention, treatment, and prognosis (NTTDATA s.d.). There is a growing expectation of a personalised customer experience throughout the service journey (Lindecrantz, Gi e Zerbi 2020). Healthcare, particularly for women undergoing perimenopause, is no different, making personalisation the new frontier for innovation.

Innovation is crucial to the industry's growth. This growth in the pharmaceutical industry mostly comes from new product development, which can cost billions. Successful innovations are deemed critical to the healthcare industry's competitiveness. Nevertheless, in a survey for PWC, pharmaceutical executives say that new product launches account for less than 14% of revenue (PWC 2023).

The laborious path to innovation has traditionally led companies to partner with suppliers, academics, or competitors in the same segment. However, the role of data, digitalisation and analysis is no longer a dream. Companies like Alphabet Inc. have acquired startups in the drug discovery space. DeepMind has developed an AI that can predict 3D protein structures based on their amino acid sequence and be utilised in drug discovery (DeepMind 2014).

Other examples of tech-driven patient-centric approaches are the applications for drug dosage management, overall health management or self-diagnosis. The Japanese Cabinet Office uses “society 5.0”, "a human-centred society in which economic development and the resolution of social issues are compatible with each other through a highly integrated system of cyberspace and physical space" (Japan Cabine Office 2015). This Japanese vision uses AI to analyse physiological data, medical information, healthcare, infections, and the environment in real-time. It can deliver early disease detection and treatment optimisation and reduce the burden on healthcare and elderly care.

Despite significant technological advancements, a gap exists in finding solutions for women experiencing the stages of menopause, particularly in personalised healthcare. This work project investigates emerging technologies and how these can be leveraged to bridge this gap between the current standard of care and personalised innovations. The healthcare industry can tailor innovation strategies by employing emerging technology to deliver a unique menopausal experience. The cornerstone of collaborative innovation is the design of information feedback that provides personalised information to patients and collects relevant data for product development. As such, the industry can maximise the data to transform the user experience with new products, new delivery methods, and timings and support a larger cross-section of patients with preventative approaches. Healthcare leaders are crucial in bringing data to concept and, ultimately, to a product, ensuring practical and meaningful outcomes.

In today´s context, the role of each participant in the innovation paradigm of personalising final products is still unclear. Thus, this work project aims to explore the crucial role of technology in collaborative innovation for perimenopausal women. To conduct this research, specific objectives have been established: Identify the current limitations and gaps in the standard healthcare approach towards a personalised precision approach; understand the role of emerging technologies in personalise menopausal healthcare; identify the potential changes in the healthcare industry in a technology-led innovation process for personalised care of menopause.

Key Research Questions:

1. What are the current limitations and gaps in the standard healthcare approach towards a personalised precision approach?
2. How can emerging technologies like AI, wearable sensors, and big data analysis be utilised to personalise menopausal healthcare?
3. How can healthcare providers and technology developers collaborate to create user-centred and accessible personalised solutions for women experiencing menopause? (partnering with tech?)

Literature Review

Menopause:

Menopause is a natural physiological event determined by the cessation of ovarian function and the absence of menstruation (Davis, et al. 2023). The nomenclature associated with this condition varies in the literature (Ambikairajah, Walsh e Cherbuin 2022), so this work project will divide it into 3 stages: perimenopause, menopause, and post-menopause.

Perimenopause is the transitional period leading up to menopause. It typically starts when a woman is in her 40s and can last from 8 to 10 years before menopause. During perimenopause,

the ovaries gradually stop relacing oocytes, and reproductive hormones (estrogen and progesterone) can fluctuate, resulting in over 30 physical and psychological symptoms with various levels of severity between individuals (Dorr 2022).

Perimenopause commonly presents with vasomotor symptoms, such as hot flashes and night sweats, vaginal dryness, decreased libido etc. Other symptoms, like depressive symptoms and cognitive difficulties, have a more tenuous connection to the reproductive hormonal changes, and their association with perimenopause can be easily dismissed (Santoro, Epperson e Mathews 2015). In addition, 42% of women reported that symptoms were worse than anticipated, and 41% reported feeling isolated with not enough support. This makes perimenopause a challenging condition to manage. Women, families, and HCPs often feel unsure of how best to navigate this difficult time (Currie e Moger 2020).

Menopause is the period of 12 months without menstruation that is not caused by any other apparent physiological or pathological reason or clinical intervention (World Health Organization 2024).

Post-menopause begins at the end of the menopause period. Many symptoms will subside at this stage, and estrogen levels will remain stable and low clinically (Cleveland Clinic 2021). In post-menopause, women suffer from the long-term adverse effects of estrogen absence. They are at an additional risk of cardiovascular disease, osteoporosis, and type 2 diabetes, which, in turn, is a risk factor for dementia and Alzheimer's (Santoro, Epperson e Mathews 2015, Kim e Brinton 2020).

Many individual factors, such as age, diet, genetics, etc., can significantly affect the severity of perimenopausal symptoms. Understanding individuality is essential to adequately address the unique health needs of women during this period. Proper management is pivotal in decreasing the risk of disease in postmenopause (Prior, et al. 2023), reducing the burden on society and healthcare systems.

Demographics & economics:

There has been a significant demographic shift in the population. With the increase of life expectancy, women will spend about 40% of their life in post-menopause (Takahashi e Johnson 2015). This has important implications for women's disease risk in post-menopause (Prior, et al. 2023) from healthcare to social and economic standpoints.

Women going through any stage of menopause comprise 55% of the workforce in Europe and are one of the fastest-growing demographic groups in companies today. Therefore, a significant impact of menopausal symptoms on work productivity can be expected (O'Neill, Jones e Reid 2020).

Perimenopausal symptoms significantly affect quality of life (QoF), which leads to increased use of healthcare resources and higher associated costs, paired with loss of work productivity (Dibonaventura, et al. 2012, O'Neill, Jones e Reid 2020). Further evidence indicates perimenopause is linked to women's premature departure from the workforce, with 10% of women leaving their jobs in the UK due to debilitating symptoms (Barber e Charles 2023).

A 2024 report from the World Economic Forum estimates that addressing the currently unmet need in this domain has a market potential of $120–$230 billion globally for medication alone. However, the true value of the menopausal business might be even more significant, with 1 billion women worldwide expected to be in menopause by 2025, potentially unlocking a market worth up to $600 billion (World Economic Forum 2014, Bloomberg 2021).

It is reasonable to infer that there are as many menopausal experiences as there are women and as many forms of managing the menopause journey. Inevitably, the question remains of how the healthcare industry can realise this market potential and the role of innovation.

The direct costs of care for perimenopausal symptoms can be substantial. These costs are often comparable to or even exceed the direct healthcare expenses associated with several medical conditions that frequently necessitate medical attention among menopausal women, such as

osteoporosis, diabetes or anxiety (Assaf, et al. 2017) This financial strain not only affects individual budgets but also places an additional load on healthcare systems that are already stretched thin.

Understanding these costs is crucial for both policymakers and individuals alike. Only by recognising the economic impact of menopause-related care can society advocate for better support systems and resources tailored specifically to women's health needs during this transitional period.

Standard of Care:

Since it was first introduced in the 1960s, HRT has been used as the standard treatment for managing perimenopausal symptoms. It is acknowledged as the most effective therapy for mitigating the symptoms (Trémollieresa, et al. 2022). However, in 2002, the Women's Health Initiative (WHI) study found that HRT increased the risk of heart disease, stroke, and breast cancer in postmenopausal women, which led to a decline in the use of HRT.

There are about 39 HRT products approved by the major regulatory body worldwide. 13 are estrogen and/or progestogen combinations, with 12 different dosage forms and four different routes of administration (Kim e Brinton 2020). (Appendix I)

A woman's clinical and biological characteristics impact individual responses to HRT. Understanding these parameters may allow for tailoring formulations, dosages, and delivery routes and predicting risks and outcomes (Manson 2023).

There are also non-hormonal pharmaceutical options to manage menopausal symptoms, commonly used when HRT is not an option. Selective serotonin reuptake inhibitors (SSRIs), Gabapentin and Pregabalin, are prescribed to manage menopausal symptoms, including vasomotor symptoms. In the UK, only Clonidine is licenced to manage vasomotor symptoms (Wattar 2024). However, these medications are generally indicated for other conditions, such as depression, epilepsy, neuropathic pain and hypertension (Edinoff, et al. 2012, Landmark, et

al. 2015, Gourlay, Stead e Benowitz 2004). However, the pharmacokinetics of these drugs have not been extensively tested on menopausal women (Sramek, Murphy e Cutler 2011, Laufer, et al. 1982).

Historically, women have been subject to significantly less clinical research than men. The researcher would be concerned that hormonal cycles reduce the homogeneity of the population and affect the results. Thus, women can represent as much as 24 % of the sample in drug trials (Geller, Adams e Carnes 2007). However, clinical studies in women have often generated results that differ from those in men (Beery e Zucker 2011). Furthermore, women can have up to twice as many adverse drug reactions as men. 50% of the studies still don't analyse the results by sex, if women were included at all (Zucker e Prendergast 2020). This indicates a low level of knowledge and diminished data specific for each stage of menopause.

Women will search for alternative options to manage their symptoms. Up to 70% of women will use CAM, mostly in the form of dietary supplements, outside the medical council (Geller e Studee 2005) as they perceive these products as safe. However, some of these options have not been subjected to rigorous research. Some of the most used products, such as isoflavones, Red Clover and Black Cohosh, are ill-advised in women with a history of breast cancer (British Menopause Society 2024).

Interventions in the management of perimenopause must be carefully selected as individual characteristics can greatly impact long-term health outcomes. Managing perimenopause is challenging and requires a holistic patient-centric approach that considers individual characteristics, (Kim e Brinton 2020, Genazzani e Divakar 2024) for instance:

- Genetics can determine an individual's response to HRT, increasing the risk of venous thromboembolism (VTE) and breast and ovarian cancer (Kim e Brinton 2020).
- Physiological health, with the reduction of estrogen in circulation affects body composition. Fat mass deposits move from the gluteofemoral area to the abdominal

area, and there is a decrease in energy expenditure and fat oxidation (Frank, et al. 2019). Alterations in body fat mass can signal conditions associated with heart disease, hypertension, type 2 diabetes, etc. (Jull, et al. 2014).

- Lifestyle, literature review by Capel-Alcatraz et al. (2023) has found that different strength exercises can significantly improve women's QoF during the menopausal journey. Improving physical health through exercise directly impacts bone density, cardiovascular disease, and hormonal and metabolic levels (Capel-Alcaraz, et al. 2023, Won-Mok Son 2021). Berin et al. (2019) showed that strength exercises increase skeletal muscle and decrease heart rate and hot flashes (Berin, et al. 2019).
- Age, the prevalence of symptoms was significantly more prominent in the 50-54 age group and the 55-59 age group than in the 60-64 age group (Trémollieresa, et al. 2022).

Personalisation of Care:

Personalised care is almost the opposite of standard care. It focuses on caring for the individual first instead of the condition (Coulter e Oldham 2016). According to The European Commission, it uses individuals' characteristics like phenotypes and genotypes (e.g., molecular profiling, medical imaging, lifestyle data) to determine the predisposition to disease and tailor the therapeutic strategy for the right person at the right time to deliver timely and targeted prevention/ treatment (European Commission s.d.). In perimenopausal, this means understanding women experience varying levels of reproductive hormones (Meyers, Fehring e Schneider 2023) that trigger different mechanisms of action and symptoms (Whitcomb 2019, Kaminska, et al. 2023). Therefore, personalised care can be a compelling hypothesis for delivering precise and timely care, supporting an earlier intervention and reducing later disease. This approach to perimenopause can support a better QoL for women and reduce the burden on families, businesses and society (Currie e Moger 2020).

Collaborative Innovation for Perimenopause:

In a highly competitive industry where innovation is a crucial growth driver (PWC 2023), personalisation represents an opportunity to create value for patients and the industry. With improved patient outcomes, there is an expectation of reduced risk of adverse reactions, resulting in fewer wasteful and ineffective treatments (Merger 2023).

In a collaborative innovation, end users cannot articulate their exact needs, as women cannot indicate specific drugs, doses, and routes of delivery that best match their biological profile (genetics, age, etc.). Thus, to fulfil the exact needs of women, both known and unknown to them, the healthcare industry must identify and access precise information (Gilmore e Pine 1997). So, to create value through innovation, patients and their data must be at the core of the process (Zillner, et al. 2016).

The wide range of information needed to personalise the menopause experience implies a data infrastructure with four steps: pre-data generation, data generation, data aggregation, and data analysis (McKinsey 2023).

Innovation Through Technology:

In an increasingly digitalised world, healthcare generates 2.3 zettabytes of data, but only 3% is used. The quantity and variety of data produced by hospitals, institutions, devices, etc, present an opportunity for all the healthcare industry to do much more and better with the existing data. It also presents a challenge to create an innovation network that can aggregate, harmonise, and analyse this data to transform it into insights (McKinsey 2020, World Economic Forum 2014). Innovation is a data-driven iterative process that aims to create new products, processes, knowledge, or services using new or existing knowledge (Kusiak 2009). These are heavily human-dependent. However, to personalise an approach to menopause care, innovation must be collaborative and integrate the personal needs of menopausal women. This approach deepens the relationship between industry and customer (patient) (Gallaud 2013).

Women are already adopting technology in the form of mobile apps that focus on common symptoms and wearables, and they are also a resort for online education. Research done with women going through menopause has indicated that they know that the tech solutions can collect data (passively and actively) to track and monitor the experience, understand symptoms, and support clinical data (Backonja, et al. 2012).

With the constraints placed on women's access to care and the severity with which menopause can affect longevity, QoL, employment and the economic impact it can have. This work project has the objective of understanding the status of healthcare for women in menopause. It proposes the following question: Can the healthcare industry capitalise on significant data generation to better inform and deliver on innovations women in perimenopause need? Given the tech already being used in healthcare, can wearables, AI, nanotechnology, 3D printing, etc., be used to personalise innovation for menopausal women?

Methodology

The question posed in this work project concerns exploring the future, how the personalisation of care will affect product innovation pipelines, and what role technology plays.

The future is an uncharacterised phenomenon; therefore, understanding it involves exploring present variables and speculating about potential emerging dynamics. To look to the future through the lens of personalisation, innovation, technology, menopause, and their interaction, one must be receptive to undocumented perspectives acquired through experience subjective to the environment (Patton 2002).

This work project bases its discovery methods on qualitative methods, including semi-structured expert interviews, to provide valuable insights beyond surface-level data. This approach can achieve a deeper and more nuanced understanding. Contextual information can

then be analysed to identify patterns, themes and unique insights that can inform decision-making and drive meaningful change.

This chapter delves into the methodology underpinning the data collection process. The basis for these interviews was a rigorous assessment of relevant experts in the subject matter, ensuring their credentials and experience were ideally suited to inform the research.

Questionnaire structure:

The interview script was divided into four parts. It started with a personal introduction and general framing questions to ease the process, followed by open questions that required the interviewee to consider the answer and provide a more extensive and information-rich answer (Gill, et al. 2008, Saunders, Lewis e Thornhill 2015).

Expert Interviews:

Seven semi-structured interviews were conducted to identify the gaps in a collaborative innovation process dedicated to menopause management.

The interviews were conducted online in a semi-constructed framework, using consistent themes as open questions guided by the literature review while allowing the interviewees to explore the theme and formulate their statements. The flexibility inherent to the semi-structured interview will enable interviewees to express their knowledge and insight freely. It gives the interviewer the flexibility to adapt the conversation to the shared data and, as such, formulate a better understanding of the nuances. Given the complexity and speculatory nature of the topic, the semi-structured interview offers credible and reliable data (Patton 2002, Saunders, Lewis e Thornhill 2015).

The interviews were set for one hour, and all participants received an information sheet introducing the topics and detailing the objectives of the work project. The pre-interview communication was intended to inform the interviewee of the details of the study and ethical

principles and convey the study objective. The information provided before the interview was designed to make them comfortable and create an honest environment.

Interviewee Selection:

The experts were selected by purposeful sampling. The subject matter is subjective, and the sample must be experienced and informed about the different aspects of innovation, technology, and menopause and how these subjects interact. The selected experts were not expected to represent a target population statistically (Table 1). However, they were chosen due to their practice in different geographies and experience across various product development, healthcare industries, and menopausal support. This selection aims to maximise and validate the knowledge collected (Patton 2002, Palinkas, et al. 2015).

These interviews were selected through personal contacts and personal references in post-interview support. The findings of the interviews were anonymised and categorised to protect the interviewees and maintain the integrity of the data.

Target Population Sample

Interview code	Function	Healthcare Experience	Innovation Experience	Technology Experience	Menopause-care Experience
E047	Director	Y	Y	Y	Y
E167	CIO	Y	Y	Y	N
E307	CEO	Y	Y	Y	N
E018	Senior Manager	Y	Y	N	Y
E138	CPO	Y	Y	Y	N
E298	CEO	Y	Y	Y	Y

Table 1 (Y-yes; N-no)

Qualitative Data Analysis and Data Evaluation:

The chosen method was a qualitative content analysis, intending to interpret the data within its context and identify its underlying meaning using interpretative analysis.

The interview process collected a tremendous amount of data. The open nature of the interviews required that each answer be interpreted within the context of the person's profile and considered in the analysis (Saunders, Lewis e Thornhill 2015). To identify and extract the information contained within the transcripts, the data was worked through four steps: 1st decontextualisation, 2nd recontextualisation, 3rd categorisation, and 4th compilation.

In the decontextualisation stage, the transcripts were individually broken into the major themes in the interview. This process generates a broader insight and defines relevant industries and chronology in which this insight would fit from now to the future of personalised healthcare. Followed by the recontextualisation stage. After determining the major themes, there is a need to re-read the transcripts with a critical mindset and define what is unimportant and what is an inflexion point previously overlooked. In the categorisation stage, the information needs to be condensed into categories to generate significant results that can translate and summarise all the data collected. In the final stage, the categories and themes are organised into a table displaying the different perspectives, identified gaps, relevant technologies, and relevant players (Bengtsson 2016).

Results & Discussion

The future of healthcare is increasingly personalised. In fact, experts point out that personalisation is "*...probably the biggest trend... it's more preventative medicalisation as opposed to the cure after the fact*" (E307). This requires further understanding of individual needs and how to obtain the best out of one's constantly changing body because *what is personalised today is great. Still, tomorrow may be completely different* (E167). This is

especially key for women, as *the whole healthcare system has been designed for men. Women have very different needs. They are kind of cyclical across the lifespan. But that's never been taken into account, and it still isn't. It will change, but it's going to take a long time. So that whole thing of having clear clinical measures, because women are so individual when it comes to their cycle. And when it comes to perimenopause and menopause, there's no cycle, and women are all very different. It needs to be approached differently*. Therefore, the *whole healthcare system, or the whole way we look at women overall, needs to be very different, and it needs to be personalised. The reason is that there is no clear definition of what it will look like in me versus you or some other woman* (E298).

The market will transform the care for the menopausal journey from personalisation to longevity & prevention. As experts confirm, *the future is much more going to be about longevity than curing since women will spend more time in menopause than not* (E047).

Personalising perimenopausal care empowers women to take control of their health and understand their bodies. This can only be done through technology, supporting women in self-discovery. The first symptoms might be disguised, "*Losing muscle, you don't feel it, increased blood sugar, you don't feel it until it's too late*" (E047) or inconsistent "…*you might be going through perimenopause and have night sweats and anxiety. I might be going through perimenopause and only have vaginal dryness and not notice some of the other symptoms*" (E298).

Data, wearables, AI, and other tech solutions will enable real-time monitoring and allow adjustments, ensuring optimal self-care and potential manufacturing. *The person's reaction to the drug and supplement can be continuously monitored and adjusted* (E167). Real-world applications already exist for glucose monitoring and delivery (e.g., Medtronic—MiniMed™ 780G system), dose prediction, molecule design treatment (e.g., Exscientia), and precise drug pairing.

Other industries are now taking advantage of this space, with the *wellness and beauty industries breaking the taboo of menopause. The first industry to break the taboo was real cosmetics…, which translated the notion of ageing into a problem. The first level was calling it anti-ageing and then translating the ageing problem into symptoms, such as wrinkles* (E047).

Education:

Menopausal women/ Consumers

The current need for body literacy among women hinders their ability to recognise and understand their symptoms of perimenopause. *Women don't often know they are beginning perimenopause. They have symptoms and are frustrated with their lack of understanding of their bodies* (E047).

Given the number of options positioned for perimenopause, like HRT, drugs and dietary supplements paired with lifestyle choices, diet changes, and other environmental factors, there are too many factors at play. Yet, if women don't understand what makes a difference, they can overmedicate or even counteract what works: "…*One of them might be working, and then they're terrified of getting off any of them*" (E298). So, at first, *technology and data will make symptoms that are sometimes denied by the medical and pharmaceutical and ignored by females real* (E047).

Personalisation is empowerment (E307). Personalising women's health during perimenopause *empowers individuals to make informed decisions about their health* (E307). That requires a comprehensive approach beyond hormone monitoring. *It doesn't mean much to a woman that her estrogen levels are going up or down. She needs to understand what that means and what the effect is on her symptoms* (E298). This can be achieved, but *technology is fundamental to personalisation* (E307). In the market, wearables can play an essential role: "…*wearables will help women track their symptoms and measure the type of symptoms they're having. So I'm a huge believer that the wearables play a big role in women identifying their symptoms, but also*

for women to understand what's happening to their bodies… if she had a bad night of sleep and can relate it to something she ate" (E298). The interpretation function needs to be powered by AI, and *a woman is her own cluster. And the point, the actions or the recommendations are going to be personalised* (E047).

Healthcare Professionals (HCPs)

The education gap goes beyond consumers and can also be identified in the medical field, with little education in the non-menopause specialities.

While other conditions have clear diagnostic parameters, *doctors don't have any clear diagnostic tests for perimenopause. They rely on point-in-time blood testing, which is not helpful for perimenopause because of the fluctuations and is not in the guidelines* (E298).

Combined with an absence of targeted training, HCPs have few options, further widening the unmet needs of this population. Without an HCP's understanding of the missing information, there is no demand for solutions and little incentive to invest in research.

Social

The low levels of social education on the topic of menopause bring a level of shame that inhibits women from discussing symptoms, leading them to feel unheard, underserved and increasingly isolated. This is also visible in research, "…*a lot of research shows that there's a lot of shame around menopause. Women are ashamed to say it, even to their doctors. So, if they're afraid of communicating because they're so driven by shame, how are they? How's the data coming out?*" (E047) Uninformed consumers limit the market demand for perimenopausal-associated solutions, which diminishes the industry's ability to understand women's unmet needs: *It starts with understanding the consumer needs and designing products that fit the need* (E018). Even though business tends to dictate the investment in an innovation project, it is noteworthy that the male interviewees pointed out that the hierarchies are still male-dominated and that it *has*

an impact because the scientific community has a lot of men (E307). Also*, traditionally, women's healthcare was presided over by men to a large degree. It probably still is* (E138).

Data collection:

The basis of any innovation is data, and currently, *data sets have been collected on men and women but not collected with women's biology in mind* (E298), particularly those experiencing perimenopause, menopause and post-menopause *data sets don't exist whatsoever, and that's data on women going through perimenopause and menopause* (E298).

No data means "…*many women look for non-medical solutions. And there's very, very limited out there, very much in the subspace of vitamins, but none of them are proven, so they're very much underserved*" (E018), which present a clear opportunity to address this population, "…*And it's a shame because it's, it's an audience that's willing to spend. And if they're, if you capture them and women find the solutions, that solution that's effective for them, they tend to stick for it for a few years*" (E018).

To advance women's health, it is imperative to collect a comprehensive and personalised data set of women of *different ethnicities with different symptom profiles regarding different treatments, lifestyles, and medications* (E298).

This data will allow a suitable AI to answer "…*with time, to say, okay, here's your solution. It tracks you, and then it will say 80% of women of your profile, your ethnicity, your BMI, this is what works*". Using technology to gather and interpret symptom data might be the first answer to this complex problem, "…*we can't understand disease risk because the symptoms themselves are individual factors of disease risk factors, and nobody's collected that. How can we collect that data?* (E298) Wearables can be used *to measure and track the effectiveness better. So, moving from more clinical evidence to real-world evidence where you can measure the impact of a product based on wearable technologies* (E018). This technology can create a real-time information loop that feeds the innovation pipeline aimed at symptom reduction.

Innovation Production:

Awareness is the first layer. Now, this first layer is superpowered by all the wearables in the world… the second thing is, at the same time, can medical and pharmaceutical companies react? (E047)

The human factor is an enormous part of the entire process, and in a personalised approach, this represents a significant limitation. "*We would have to eliminate the human factor. Without a doubt, it would have to be a fully automated process*" (E167) and "*…in terms of technologies, I don't yet see technologies that could do this in the short term. I think that, eventually, something could be done, but not from A to Z*" (E167) therefor, technologies, such as 3D printing, nanotechnology, and others need to evolve further in this context to be a part of a fully automated process.

However, with the correct data set, technology to participate in ideation, and *AI learning to understand the needs early* in development and testing *regarding effectiveness… wearables can be an easy way to measure the effect* (E018).

Safety and effectiveness testing for the target is required before authority approval and market launch. However, *in terms of policymaking, there is an old-school thinking. And it takes a long time to change that*. (E307)

With these insights, wearable technology can collect data to feed an AI feedback loop, which in turn feeds insights into the next round of products. Other technologies, such as 3D printing, will need to evolve further in this context to become part of a fully automated process.

Conclusion

There is no question that healthcare and technology go hand in hand, and one cannot evolve without the other. Therefore, the road for the healthcare industry to use patient data and personalised care is divided into what can be done today and what steps need to be taken to

ensure the future of personalised innovation for women in every stage of menopause. Current diagnosis, prescription, and treatment innovation development depends on technology-powered human knowledge.

Key Answers:

- What are the current limitations and gaps in the standard healthcare approach towards a personalised precision approach?

The gaps in menopause care start with primary stakeholder education. However, there is also a significant limitation regarding the amount of research and understanding of women's biology, which is more pronounced during perimenopause, as the severity and long-term impact of symptoms is more relevant. Therefore, as reflected in the results chapter, the first challenge of the innovation strategy is the need for reliable data in all stages. Furthermore, social education is vital in reducing shame and encouraging more women to demand better support and understanding.

- How can emerging technologies like AI, wearable sensors, and big data analysis be utilised to personalise menopausal healthcare?

Technology is an unescapable partner in the personalisation of menopausal care. Starting with data capture, as data sets are needed to generate actionable insights. For this, wearables are beginning to support the identification and tracking of symptoms evolution, paired with general data such as heart rate, exercise effort, etc. Data intelligence, powered by AI, is the next step that connects women in the different stages of menopause with their genomic, clinical, imagery, lab, environmental, and socially determined data and provides insights. However, this is a long-term endeavour (World Economic Forum 2014), as technology for each step is not yet available. Nevertheless, the experts believe that all emerging technologies discussed (wearables, AI, 3D printing, nanotechnology, etc.) will have a role to play.

There is a complex relationship between technology and purpose. When evaluating the relevance of collecting a type of data, accuracy and efficiency need to be considered, as there is a risk of introducing data bias into the sets, which in turn affects the AI interpretation.

- How can healthcare providers and technology developers collaborate to create user-centred and accessible personalised solutions for women experiencing menopause?

With the growth of tech development, a new set of players has entered the healthcare space, which will continue to impact the industry's behaviour. Several tech companies are already operating in molecule discovery and developing language processing modules. Experts agree that further partnerships between health and tech are unavoidable. However, it needs to be made clear what role both industries will play (purchaser vs. acquired).

Understanding the timing and speed of implementing strategies and tech adoption is essential to advance personalised innovation for menopausal women. Therefore, the healthcare industry must act to prepare for the medium and long term and support today's care. This goes beyond tech adoption to motivating policymakers, payers and other stakeholders that have a role in the personalisation of innovation for menopausal women.

In the vision for a setting where personalised care is an integral part of women’s menopause journey, the innovation pipeline must exist in an automated loop from data collection, assessment, and production, with AI-powered decision-making technology as an integral part of the process. Although technology’s capabilities are ever-evolving, they can’t be said to exist in the personalised tech scope.

In the medium term, personalised technology needs to evolve to provide personalised recommendations. It is believed that this will be the way of wearables powered by AI.

Before integrating personalised tech in healthcare systems, research must be conducted to better understand the journey of menopause, validate the tech capabilities, identify new markers, and

contribute to the overall development of personalisation. The adoption of AI technologies has limitations. As databases are assembled, the data must be monitored for bias and lack of interpretability (Vora 2023).

For immediate action, it is critical to educate women and HCPs, allowing them access to credible information. This can, in turn, support the de-stigmatisation of peri- and menopause.

Given the data gap, the priority must be symptom understanding and reduction to support today's peri- and menopausal women directly. Symptom measurement and self-assessment technology, such as wearables and apps, can serve two purposes: helping women know what works for them individually and building their own data set.

Limitations:

Several limitations have been identified in this WP. The expert sample selected is small and broad in expertise, limiting the specificity of the results. Furthermore, only stakeholders involved in innovation on the industry side were engaged. Therefore, women, HCPs, and policymakers' openness to a personalised approach were not addressed.

Dealing with personal data is subject to dedicated legislation not discussed in this WP.

Moreover, this WP's investigation did not include regulations concerning commercialising personalised innovations or ethical considerations.

The cost of integrating a personalised approach to menopause when technology is available would be substantial and represent a significant limitation that can affect payers and budget holders. In addition, manufacturing, supply chain management, resource prioritisation, and personalisation of ingredients also present barriers not discussed in this document.

Further investigation:

To further the topic of personalised innovation for menopausal women, each stakeholder (women, HCP, tech developers, researchers, etc.) needs to be addressed individually regarding tech adoption and data collection.

From an industry standpoint, it would be relevant to investigate the impact of gender in leadership roles and the investment in menopause dedicated to research and innovation.

Policymakers and regulatory bodies are essential to any product's innovation process and rote-to-market. Therefore, registering and bringing to market personalised products needs further discussion from a legislative and regulatory point of view.

Technology is a critical player. Therefore, essential steps to evolving fem tech in the right way, assuring the safety and efficacy of the technologies discussed, should be further investigated.

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