

Female health and wellness: from niche to the next big thing

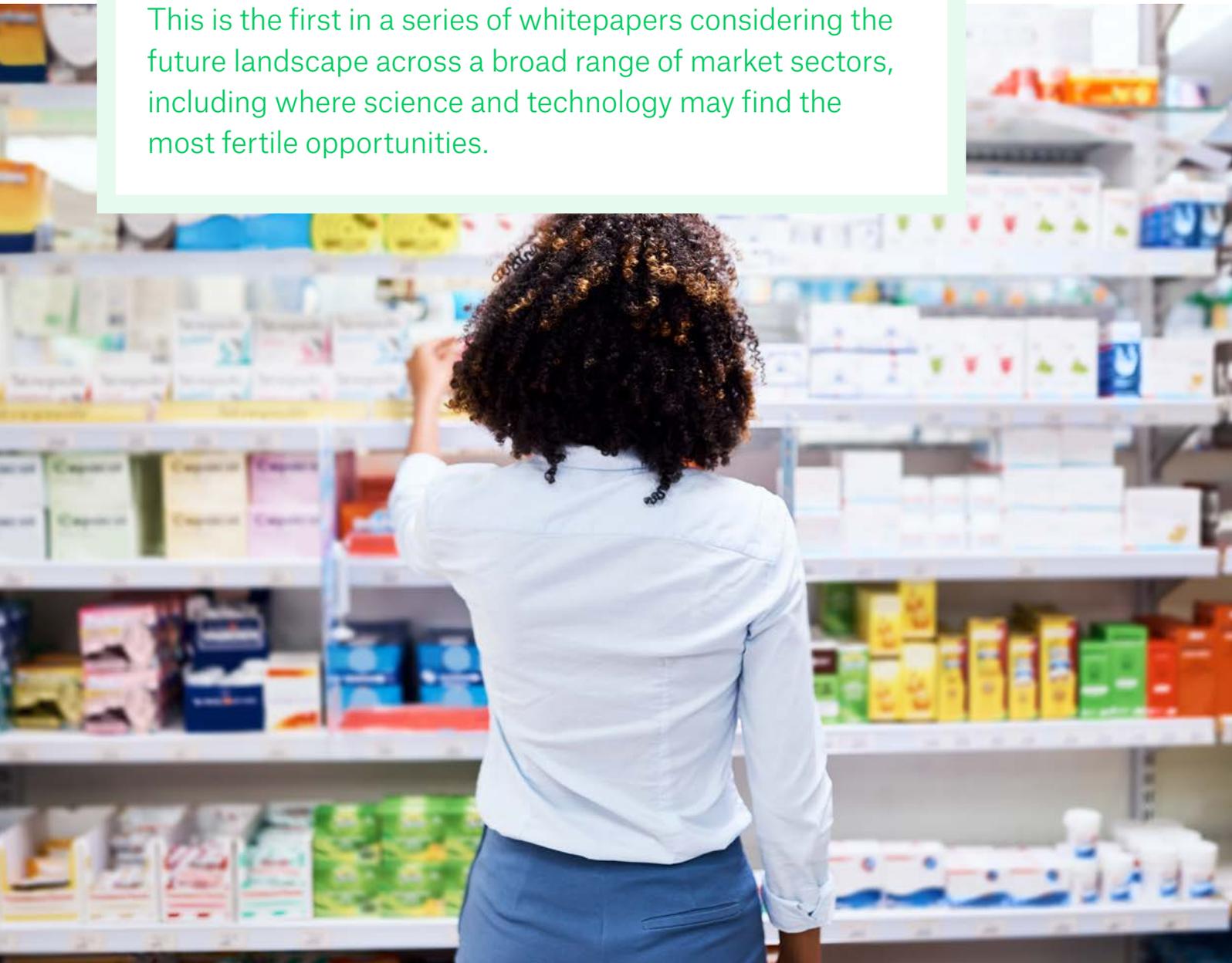
Enabling women around the world to achieve a more complete state of wellbeing requires targeted innovation, and the time to act is now.



The historic lack of funding and research in female health and wellness has led to a corresponding gap in data. We believe that addressing this data gap will result in a more complete understanding of female health, ensuring innovation is grounded in science. The tide is already turning, marked by favourable investment, technology advancements and ambitious femtech start-ups.

Oakland Innovation and Sagentia are at the forefront of new thinking in the female health and wellness space.

This is the first in a series of whitepapers considering the future landscape across a broad range of market sectors, including where science and technology may find the most fertile opportunities.



The science of female health and wellness

What do we mean when we talk about female health and wellness? In the broadest sense, we're referring to the preservation of wellness and prevention of illness in the female population, focusing on conditions that are unique to females, more common in females, or biologically different in females.

Figure 1 shows some examples of specific female health conditions, illustrating the magnitude of this space.

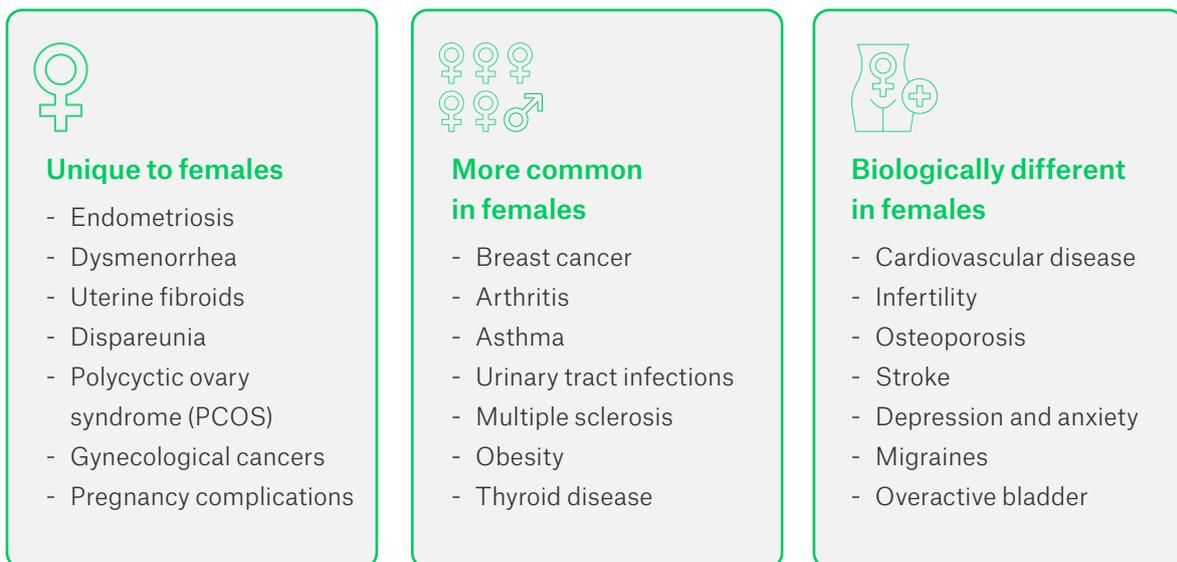


Figure 1 - Examples of specific female health conditions

For the purposes of this paper, we focus on female health, using the binary terms 'man' and 'woman' interchangeably with 'male' and 'female'. However, it is certainly worth noting that the distinctions between sex and gender play an important role in healthcare, as do other demographic variables

such as age, race, ethnicity, culture, sexual orientation, religion, and socioeconomic status. The diversity in our global population must be reflected in the design of new solutions to ensure safe, effective and personalised care for each individual.

Sex-specific (biological) factors include genes and chromosomes, hormones, reproductive anatomy and metabolism. Each of these parameters can have a critical impact on how conditions are diagnosed, treated, and managed. For example, a recent article in Medical News Today¹ highlighted the importance of sex differences in COVID-19. Initial analyses indicate that men are more than twice as likely to die from the virus – and women’s innate immune response could be a factor. The article did note, however, that there isn’t yet enough data to draw scientific conclusions, especially since many countries haven’t published sex-disaggregated data.

Gender (defined by behaviour, society, culture and identity) can also have a significant influence on clinical outcomes. In the case of COVID-19, “the fact that societies have traditionally placed women in the role of caregivers...and the fact that the vast majority of healthcare workers are women could place them at a higher risk of contracting the virus.”¹ Researching the differences in how men and women contract and

respond to disease is fundamental to creating effective strategies and interventions. For example, if we could understand what makes women more resilient to COVID-19, perhaps we could design new drugs that more effectively bolster men’s immune response.

Female health is a complex and multifaceted issue, spanning the entire care continuum, and influencing the wellbeing of society as a whole.

In this paper, we consider the repercussions of the historic female health gap, exciting opportunities for science and technology innovation, and emerging challenges faced by the female health and wellness market.



The historic health gap

Despite scientific understanding of the biological differences between the sexes, there has been an historic lack of female representation in research and clinical trials². This extends even to pre-clinical animal studies, where the vast majority of animal models used are male. This bias isn't malicious – typically, it stems from convenience, cost concerns, experimental simplicity, or indeed government guidelines. In 1977, FDA Guidance 'General Considerations for the Clinical Evaluation of Drugs' effectively banned women of childbearing potential from participation in early phase clinical trials. This wasn't reversed until 1993³.

There has been overrepresentation of men in clinical trials, a lack of gender-specific medical guidelines, and a dearth of innovation in healthcare technologies specifically geared toward women.

HitLab⁴

Inclusion of women in research is not enough however. Results gathered during trials must also be disaggregated by sex to analyse differences in disease risk, symptoms, diagnostic sensitivity and response to therapy. In 1994, the FDA established the Office of Women's Health (OWH), whose mission was founded on the principle that "Sex as a Biological Variable (SABV) should be factored into research design, analysis, reporting and education"⁵. Despite this effort, of ten prescription drugs withdrawn from the US market between 1997 and 2001, eight posed greater health risks to women than to men.⁶

Interestingly, the gender data gap extends beyond the healthcare sector. A 2019 study on vehicle safety from the University of Virginia found that the odds of being injured in a frontal car crash were 73% greater for a female occupant than for a male occupant. This was largely due to the fact that the majority of crash test dummies were based on the 50th percentile male. "An average adult female crash test dummy simply did not exist"⁷.

While the gender data gap spans industries and has historic roots, it is not an historic problem. Nor is it unique to either developed or developing nations. Progress is underway, but targeted action is required to ensure a more data-driven, nuanced and holistic approach to female health.



The technology enabling a revolution

Current technologies and trends – including at-home diagnostics, wearables, artificial intelligence (AI), precision medicine and telehealth – are enabling new opportunities to address the gaps in female health and wellness. Importantly, many emerging technologies also offer ways to support women in remote or low-income areas with reliable information and services, helping to democratise female healthcare.

As Figure 2 shows, the challenges and conditions faced by women evolve through life. Analysing and understanding female health at every life stage can reveal previously unmet needs and exciting whitespace opportunities for new products and services.

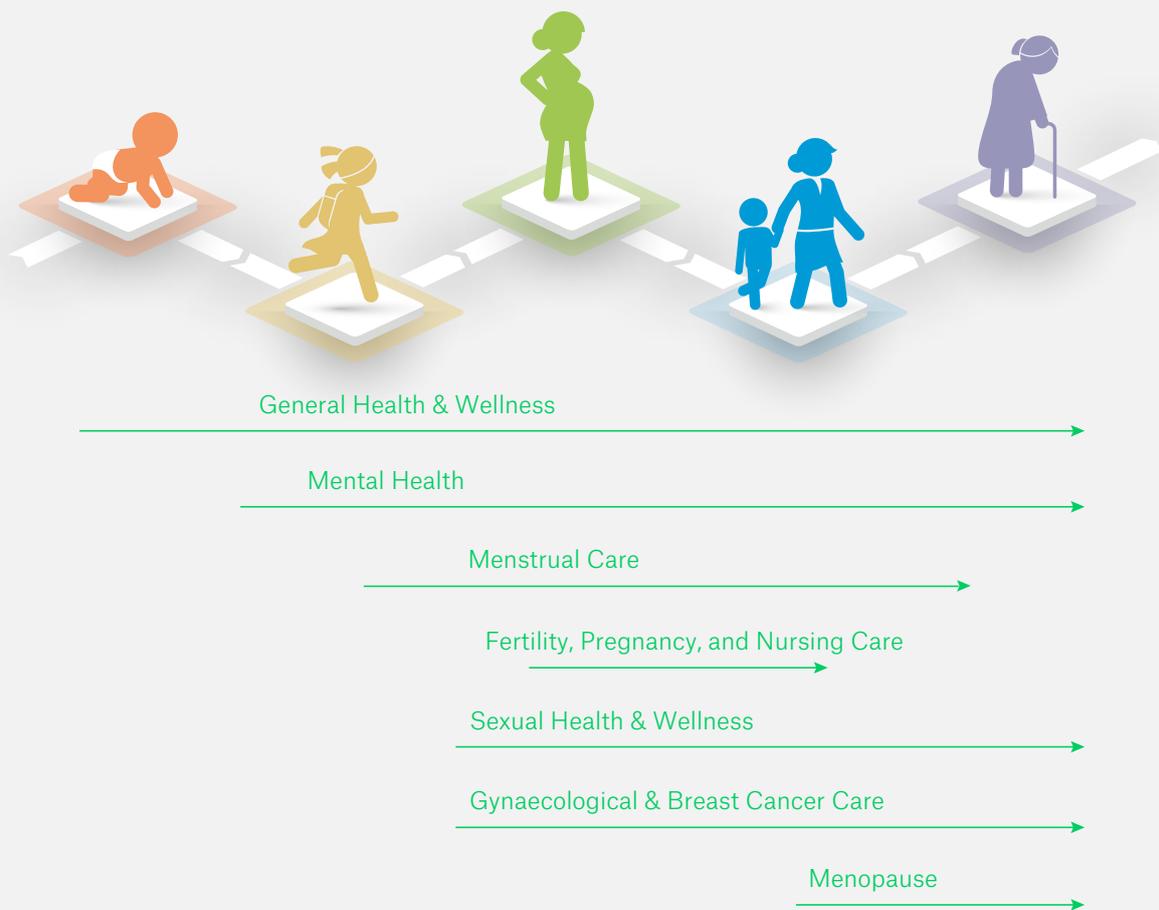


Figure 2 - Female health & wellness timeline



For example, what if AI could get you pregnant? Artificial intelligence is being deployed in a myriad of ways to address infertility, from predicting ovulation, to sperm cell classification and embryo selection during in vitro fertilisation (IVF). 1 in 8 couples struggle with infertility⁸, and irregular or abnormal ovulation accounts for 25% of female infertility issues⁹. Treatment can include medication or invasive surgery – but if you could use AI to accurately pinpoint ovulation, could you increase your chances of natural conception? One company looking to empower women with this type of data is Mira. Mira’s FDA registered at-home urine test measures Luteinizing Hormone (LH) level, the most accurate indicator of ovulation, and provides women with AI-powered personalised fertility insights.

Other thought-provoking possibilities include: using liquid biopsy in breast cancer care to monitor treatment response and predict disease progression; offering menopause diagnosis and treatment via telehealth platforms to address the lack of access and support; and diagnosing conditions such as endometriosis and cancer using smart tampons.

The technology is ready,
the market is primed, the
research is catching up,
and the possibilities are
boundless.



Femtech: an embryonic market

One of the newest markets fuelling growth and innovation in female health is femtech. Femtech (short for female technology) encompasses software, diagnostics, products and services that use technology to improve women's health. Mainly consisting of start-ups, this once niche market is now a burgeoning industry.

Femtech leverages the increasingly influential role that women are playing across the care continuum, as consumers, decision makers and healthcare professionals. Femtech start-ups, many of which are led by female founders, have secured well over \$1bn in funding since 2014. According to Frost & Sullivan, the market is set to be worth \$50bn by 2025. One great example is Elvie, a British start-up recognised for its smart pelvic-floor trainer and wearable breast pump. Elvie raised \$42m in 2019 in one of the biggest femtech funding rounds yet. Also in 2019, a start-up called Progyny became the first fertility benefits company to go public, raising \$130 million at the offering price.

To date, the most successful femtech start-ups have related to reproductive health. The commercial opportunity in fertility, for instance, is easy for venture capitalists to understand (especially since 88% of venture capital decision makers in the US are men¹⁰). However, female health involves so much more than women's childbearing potential. As femtech has gained traction, the next wave of inclusive technology companies have risen to the fore. These include start-ups tackling traditionally taboo subjects such as menstruation, menopause, miscarriage and sexual wellness.

...investors, scientists and thought leaders are increasingly emphasising the need to evolve the original concept of femtech beyond reproductive health and what concerns the female reproductive organs, to that of a lens through which we look into health issues that impact us differently, especially those that disproportionately affect women.¹¹

Forbes

The femtech movement

The role of femtech is not to reinforce the niche position that historically hindered female health and wellness. It's to inclusively address the diverse needs of women through innovation and personalised care, unlocking new approaches and refocusing on previously underrepresented sectors. There is much potential for breakthrough products and services here, and not just for start-ups. Larger players in the consumer and medical markets will be quick to turn their attention, and budget, to the female health and wellness category.

For example, P&G acquired This is L. last year, a femtech start-up developing organic period care products. Johnson & Johnson has been co-sponsoring women's health innovation summits, and pharma companies are starting to pay attention to direct-to-consumer contraception start-ups like Nurx. Finally, even Apple is getting involved. Late in 2019, The National Institute of Health (NIH), Apple and Harvard University announced their partnership for a major long-term study of women's health. Their research will focus on conditions such as polycystic ovary syndrome (PCOS), menopause, infertility and osteoporosis.

With increased research and investment, awareness is growing of the commercial opportunity in female health and wellness. There is a strong push from patients, consumers, clinicians, payers and service providers for comprehensive, value-based care for women globally.

The challenge for many new entrants has been understanding the user needs and technology landscape, and identifying the evolving whitespace opportunities.



The emerging challenges

Technology advancements and the rise of femtech have evolved the female health and wellness space. However, new challenges are emerging.

1. Lack of clinical evidence

According to digital health analyst Research2Guidance¹², there are currently more than 3,000 app-based women's health products on the market, with the majority of products focused on fertility and pregnancy. Ralf Jahns, managing director of Research2Guidance, has said that work still needs to be done to validate these technologies and make them payer ready as:

“only a minority of them have been able to put together some kind of evidence that their solution does provide some benefits for the patient or for the payer organisation.”

Evidence, especially clinical evidence in the case of medical devices, is key to ensuring accurate, actionable insights are delivered to all stakeholders. For example, a recent Australian study of the most downloaded fertility apps found that more than half could not accurately predict ovulation, with less than 10% providing references for claims¹³. Whether you're trying to get pregnant or avoid pregnancy, the consequences of this inaccuracy could be devastating.

2. Navigating the regulatory pathway

Understanding the differences between consumer and healthcare products, and the implications for regulatory compliance, is critical. At what point does your period tracking app constitute a medical device? And how is the user data being collected, stored, and analysed? What about data privacy and security? Knowing how your product relates to current regulations and best practice guidance is vital at every stage in development.

3. Ensuring diversity by design

User-centric design is essential to ensuring advancements that can benefit the entire female population. This starts with understanding how women of diverse ages, races, cultures, etc., engage with new solutions. For medical products, this understanding is even more critical, and inclusive clinical trials will be required to verify safety and efficacy for all patient groups. Gathering and incorporating this diversity data will allow us to provide women with truly personalised products, grounded in science.

The holistic future of female health and wellness

Addressing the gaps in female health and wellness requires targeted innovation right across the care continuum, for the full spectrum of the female population.

As markets shift towards value-based care models, disruptive solutions will aim to bridge the intersection of care, in order to provide holistic and continuous support. As shown in Figure 3, each stage in the journey, from wellness to diagnosis to treatment to monitoring, has scope for technical innovation. User experience and patient outcomes will both be key measures of success.



Figure 3 - Female health & wellness care continuum

At Oakland Innovation and Sagentia, we specialise in focused innovation strategy and insight-led design and development. Our multidisciplinary teams include scientists, engineers, designers, software specialists, business strategists and regulatory advisors. We deliver technology and market insights, striving for balance between technical feasibility, commercial viability and user experience to deliver meaningful differentiation in a constantly changing world.

We believe female health is set to become a significant movement driving more holistic, end-to-end solutions. This presents opportunities across the consumer and medical markets. In the coming months, we will be publishing a series of whitepapers exploring how to break new ground with revolutionary approaches to female health and wellness.

To receive the next papers in our female health & wellness series, get in touch by emailing info@oaklandinnovation.com



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- ¹<https://www.medicalnewstoday.com/articles/mnt-134418>
- ²<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4800017/>
- ³<https://www.fda.gov/science-research/womens-health-research/regulations-guidance-and-reports-related-womens-health>
- ⁴<https://www.hitlab.org/blog/femtech-by-the-numbers>
- ⁵<https://www.fda.gov/about-fda/office-commissioner/office-womens-health>
- ⁶<https://www.gao.gov/new.items/d01286r.pdf>
- ⁷<https://www.consumerreports.org/car-safety/crash-test-bias-how-male-focused-testing-puts-female-drivers-at-risk/>
- ⁸<https://resolve.org/infertility-101/what-is-infertility/fast-facts/>
- ⁹<https://www.reproductivefacts.org/faqs/quick-facts-about-infertility/>
- ¹⁰<https://www.forbes.com/sites/geristengel/2020/01/01/the-next-decade-will-bring-more-venture-capital-to-female-founders/#1a94c7616b0f>
- ¹¹<https://www.forbes.com/sites/estrellajaramillo/2020/01/08/femtech-2020-investors-trends-and-opportunities-in-womens-health-technology/#2f205a97d542>
- ¹²<https://www.mobihealthnews.com/news/femtech-rise-new-companies-have-homework-theyre-ready-payers>
- ¹³<https://www.abc.net.au/news/health/2019-09-17/fertility-ovulation-apps-half-ineffective-study-finds/11520074>

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