The Future of FemTech

INNOVATIONS IN HEALTH TECHNOLOGY & WOMEN'S WELLNESS

PFG medcomm

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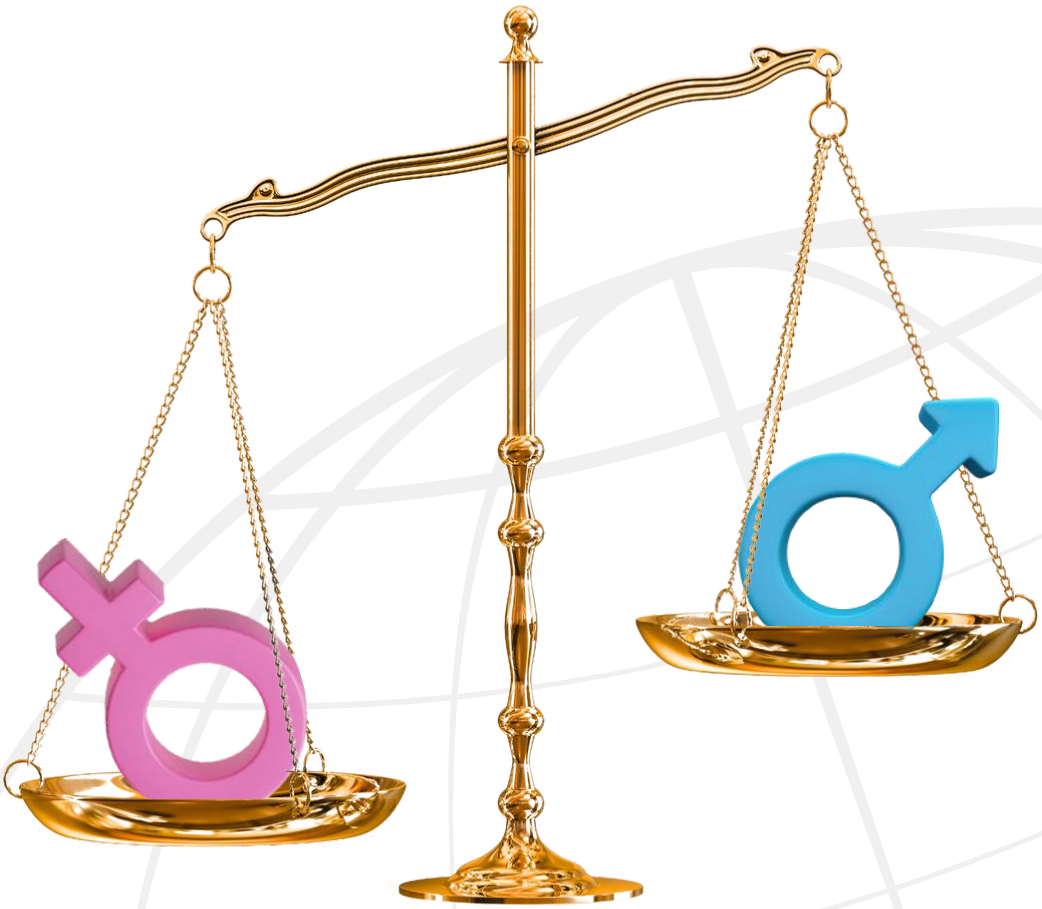
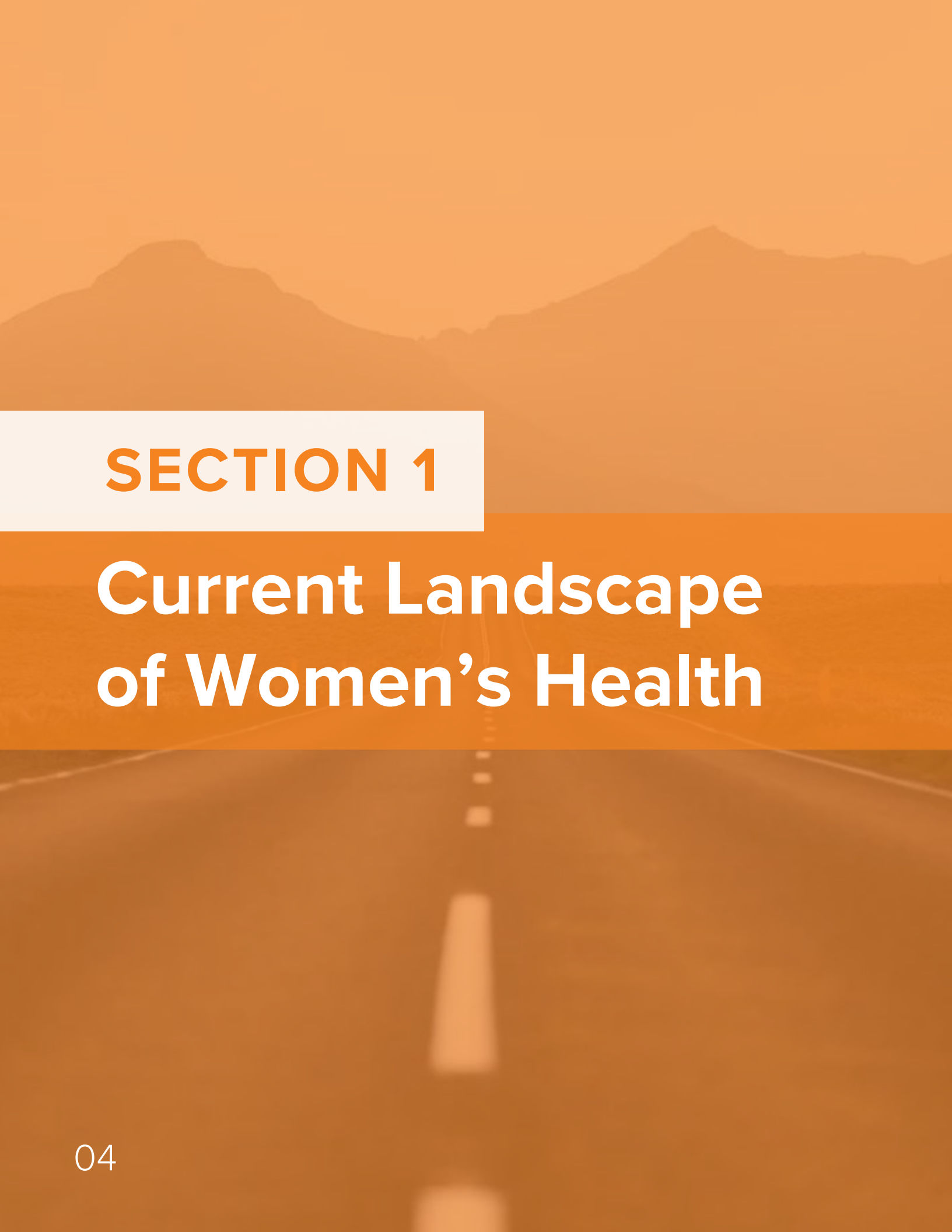
OVERVIEW

Gender has proven to be an influential social determinant of health impacting the quality of life of women globally.[1] A lack of bodily autonomy, unequal pay, and the burden of gender roles continue to plague women's health outcomes. Mental health, cardiac, and oncological conditions have disproportionate impacts on women.[2-4] Additionally, treatments for these conditions are often geared toward men, reducing the efficacy of interventions when used for women.[5] To understand the current state of women's health, it is vital to understand the history of social norms, healthcare, and policy.





SECTION 1

Current Landscape of Women's Health

WOMEN'S HEALTHCARE & RESEARCH HISTORY

Resources for women's health were scarcely available prior to the 1900s. Women with physical symptoms were often disregarded as hysterical and prescribed bed rest.[6] Pregnancy and childbirth were often dangerous conditions, and mortality from sepsis and abortion was frequent.[7] The average woman would birth as many as 8 children, typically at home, as hospital births were extremely uncommon.[7] Many women began implementing family planning methods, such as the rhythm method or withdrawal, during the 1800s.[8] Despite abortion and contraception becoming illegal by 1840, birth rates decreased as women became aware of potential methods for avoiding pregnancy.[8] In the early 1900s, women's fight for access to birth control gained traction. Obstetric nurse Margaret Sanger studied birth control methods and published works to inform women about how to prevent pregnancy.[9] Despite multiple arrests for her illegal publications, Sanger ultimately opened Planned Parenthood, an organization known for providing low-cost gynecological and family planning services.[9]

During this time, the lack of research dedicated to women's health became an important component of the women's rights movement, as well.[10] In 1986, the National Institute of Health (NIH) created the first official policy meant to address inequities in women's health research, the Inclusion of Women and Minorities in Clinical Research policy.[10] Four years later, the Office of Research on Women's Health was created as the first public health office dedicated to specifically promoting women's health research in the NIH scientific community.[10] Despite these efforts, equity in women's health and minority research remains stagnant, and this is reflected in the poor health outcomes of women.

SOCIOECONOMIC & CULTURAL FACTORS

The disparity in health outcomes between men and women stems not only from a lack of dedicated scientific research, but also educational, socioeconomic and cultural foundations. Globally, only 49% of countries have achieved gender parity in primary education.[11] In the US, the law guaranteeing women the right to education without sex discrimination was only enacted in 1972.[12] A lack of access to education has a direct link to health outcomes for women and girls, as individuals with less education are more likely to experience obesity, substance use, and injury.[13]

In addition to education, income plays a significant role in individual and community access to healthcare. In 2022, women were paid about 18 cents less for every dollar made by a man.[14] Women experience higher rates of poverty in the US, which is a known risk factor for chronic disease, mental illness, and lower life expectancy.[15,16] A low socioeconomic status (SES) can contribute to increased stress, especially during pregnancy.[17] Additionally, women in poverty are at higher risk for cancer death due to a lack of screening, prevention, and treatment.[15]

Racism has a significant impact on the physical and mental health of communities and individuals, as well. People of color are at an increased risk for certain chronic conditions compared to White individuals.

This includes a higher risk for conditions such as diabetes, hypertension, asthma, and heart disease.[18] Healthcare may also be more difficult for minority communities to access, as non-elderly American Indian/Alaskan Native, Hispanic, Native Hawaiian and other Pacific Islander (NHOPI), and Black people are more likely to be uninsured in the US than White people.[19] Racism, both interpersonal and systemic, also impacts health outcomes of pregnant women and their infants. For pregnant Black women, the risk of death during childbirth is two to three times higher than White women.[20] Implicit medical bias can also lead to worse health outcomes, as medical professionals may be unaware of their bias and how it negatively impacts patient care.[21] The risk of experiencing serious health conditions during pregnancy is also significantly increased for pregnant Black women, even after adjusting for income level.[22]

For pregnant Black women, the risk of death during childbirth is

2x-3x

than White women.[20]

An individual's sexual orientation can also place them at higher risk for poor health outcomes. Cervical cancer screening rates are lower for members of the LGBTQ+ community than non-LGBTQ+ individuals.[23] Additionally, individuals in the LGBTQ+ community have a high prevalence of sexually transmitted infections (STI), including HPV, further emphasizing the importance of screening and early treatment.[24]

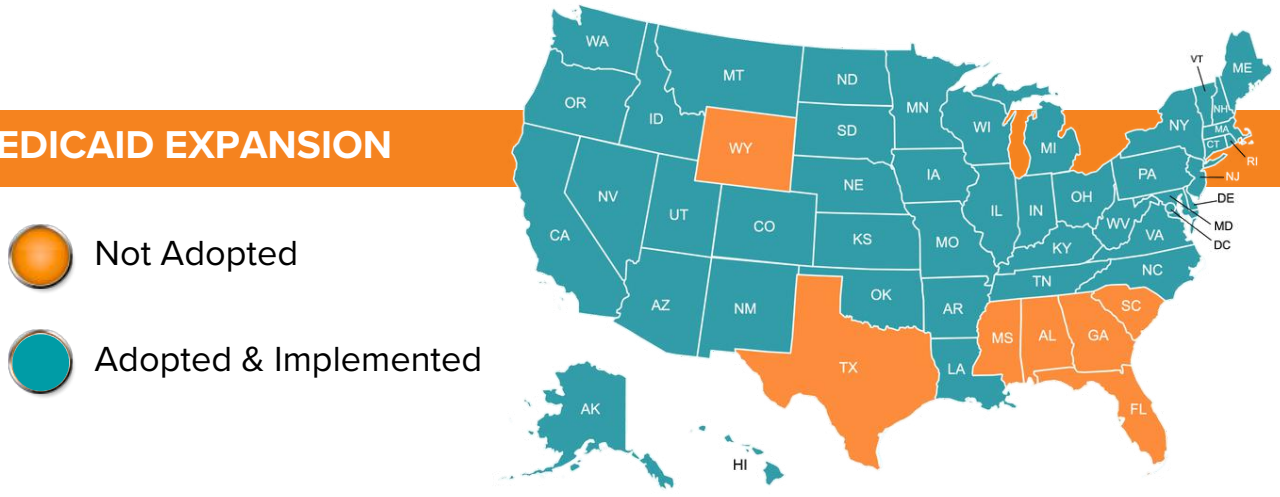
GAPS IN ACCESS TO CARE

In the US, 9.5 million women are uninsured, with rates being highest in states without Medicaid expansion and low-income communities.[25] Women face significant barriers to reproductive care, such as access to childcare, transportation, geographical location, and cost.[26] The Centers for Medicare and Medicaid Services (CMS) manages and executes the US healthcare marketplace, Children's Health Insurance Program (CHIP), Medicare, and Medicaid.[27] Medicaid is an important aspect of women's health, as it provides millions of women with healthcare coverage.[28] Medicaid generally covers low-income, non-elderly individuals and pregnant women, though specific income guidelines differ by state. Currently, 41 states have expanded Medicaid to include non-elderly adults up to 138% of the Federal Poverty Level (FPL).[29] However, for those in non-expansion states, 2.2 million people fall into a gap of coverage because their income is too low to qualify for subsidies in the US healthcare marketplace and too high to qualify for Medicaid. This gap in coverage impacts approximately 800,000 women of reproductive age, two-thirds of which are women of color.[30]

Medicaid financially supports 40% of births in the US and is required to provide 60 days of postpartum care. After this period, many women lose coverage, particularly in non-expansion states. Healthcare coverage is vital during pregnancy and postpartum period, and limited coverage during this time can be detrimental to health outcomes. Currently, 46 states have extended Medicaid to cover postpartum women for 12 months with the goal of improving maternal health and coverage stability.[31]

Geographically, patient care deserts are continuing to reduce access to care, especially for pregnant women.[32] In the Midwest and Southern US, pregnant women have limited options for locations to give birth or receive maternity care.[32] These care deserts are directly linked to poor health outcomes for women and infants, exacerbating the maternal mortality crisis in the US.[32]

MEDICAID EXPANSION



RECENT TRENDS IN WOMEN'S HEALTH

Heart Health

Heart disease is the leading cause of death among women in the US accounting for 1 in 5 female deaths.[33] Heart health is an important aspect of women's health, especially for pregnant women. Women without previous heart health issues may be more susceptible to heart disease after experiencing postpartum depression or high blood pressure during pregnancy.[33-35] Other aspects of a woman's reproductive system, such as menstruation, can impact future risk for cardiovascular disease. Irregular menstrual cycles are significantly associated with an increased risk for the development of cardiovascular disease.[36] While heart disease is the leading cause of death for women in the US, there are still inequities in the clinical research and treatment landscape due to severe underrepresentation in clinical trials and cohort studies researching the efficacy of cardiac medical devices.[37]

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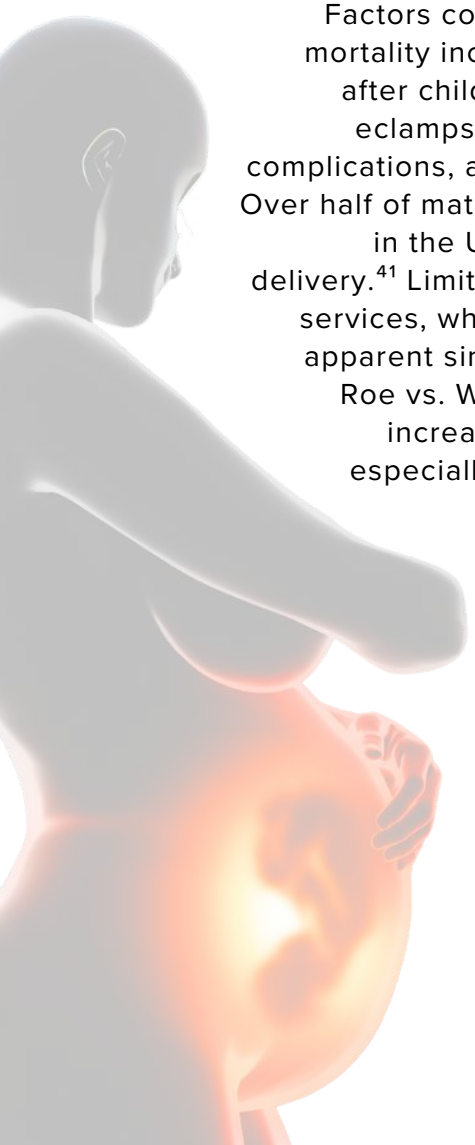
RECENT TRENDS IN WOMEN'S HEALTH

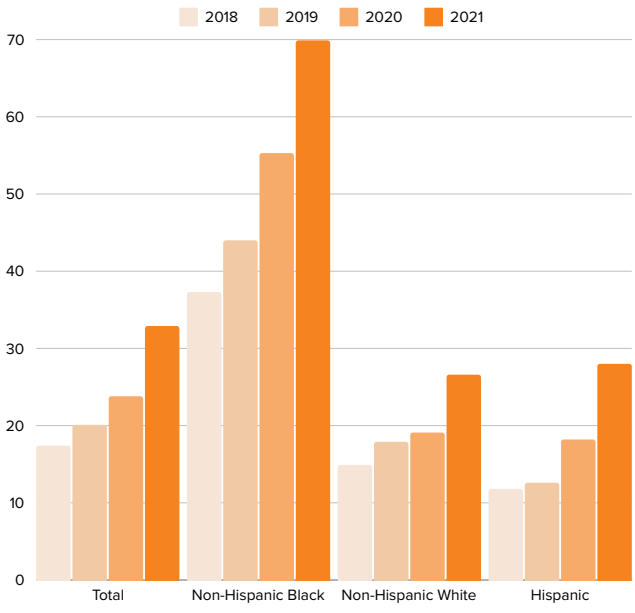
Maternal Mortality

Maternal mortality is formally defined as "the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes."[38] The maternal mortality rate (MMR) in the US is alarmingly high, with a rate 10 times higher than any other developed country.[39] The MMR is continuing to rise in the US, with an increase of 23.8 to 32.9 deaths per 100,000 live births between 2019 and 2021.[20] Disparities in maternal mortality between races is similarly alarming, as the MMR for non-Hispanic Black women is 69.9 deaths per 100,000 live births.[20]



Factors contributing to maternal mortality include severe bleeding after childbirth, infections, pre-eclampsia/eclampsia, delivery complications, and unsafe abortion.[40] Over half of maternal mortality deaths in the US occur the day after delivery.[41] Limited access to abortion services, which has become more apparent since the overturning of Roe vs. Wade in 2021, can also increase maternal mortality, especially for Black women.[42]

MATERNAL MORTALITY RATES
BY RACE & HISPANIC ORIGIN
IN THE USA 2018-2021[20]



RECENT TRENDS IN WOMEN'S HEALTH

Oncology

In addition to underrepresentation in cardiac clinical trials, women face limited representation in oncologic clinical trials. Despite cancer being the second leading cause of death for women in the US, oncologic clinical trials were only comprised of 42.9% women.[3] Breast cancer is the most common cancer in women and lung cancer is the leading cause of cancer death.[43] Racial disparities are apparent in the oncologic space, as Black women are more likely to die from breast cancer than White women, even though disease incidence is similar. Similarly, the mortality rate of ovarian cancer for Black and Asian women is 1.3 times higher than for White women, despite disease incidence being highest among White women.[44]

Metabolic Health

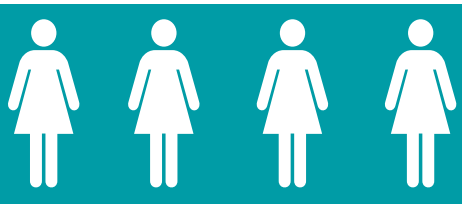
Rates of stress are generally higher among women than men, likely due to societal and biological factors.[45] Stress responses differ between men and women based on variations of hormones and psychological conditions. Chronic stress in women can lead to high cortisol levels, which often impacts metabolic processes, inflammation, blood sugar and blood pressure.[45,46]

Metabolic syndrome is a condition associated with an increased risk for developing heart disease, stroke, and type 2 diabetes.[47] The risk of developing metabolic syndrome increases with age and hispanic women have the highest incidence of this condition.[47] Metabolic syndrome also impacts 33% of women with Polycystic Ovary Syndrome (PCOS), though it is not a well-researched aspect of PCOS.[48] Women who work or have low household incomes are also at a higher risk for developing metabolic syndrome, further emphasizing the relationship between stress, cortisol, and metabolic dysfunction.[49]

RECENT TRENDS IN WOMEN'S HEALTH

Mental Health

One in 5 women in the US suffers from a mental health condition, and depression is the most common mental illness impacting women.[2] Twice as many women experience depression, post-traumatic stress disorder (PTSD), or panic disorder compared to men.[2] Women face risk factors for mental illness such as earning less than men and often carrying the role of primary caregiver for families.[2] Over half of caregivers are women, and female caregivers provide up to 50% more time providing caregiving service than male caregivers.[2] These high-stress situations can place women at risk for developing conditions such as depression or anxiety.[2] Postpartum depression is another mental health condition that can impact women's quality of life after pregnancy.[50] As many as 1 in 5 new mothers have postpartum depression, and if left untreated, it can be life threatening.[50]



1 in 5 women in the US suffer from a mental health condition & as many as 1 in 5 new mothers have postpartum depression .[2]

Menopause

While menopause is a normal aspect of the female reproductive system, the stigma surrounding it has a significant impact on how it is discussed and managed. Hormone changes with menopause can leave women susceptible to adverse health outcomes.[51] Menopause is associated with physical symptoms such as hot flashes, mood changes, night sweats, and sleep issues.[52] Additionally, psychological symptoms such as brain fog, memory problems, anxiety, and depression are common.[51] Unfortunately, the timeline and symptoms of menopause are not widely discussed, and women may be unaware of the signs of menopause.[51] Many women do not report symptoms of menopause to their doctor and 73% do not receive any treatment.[53] Even medical residents have very limited training and knowledge surrounding the menopause treatment landscape.[53]

73% of women do **NOT** receive treatment for menopause symptoms.[53]

RECENT TRENDS IN WOMEN'S HEALTH

Menstruation

Like menopause, menstruation faces stigma and negative attitudes from society and media. In a national survey conducted by Thinx period underwear, over 42% of women stated they had experienced period shame in the past.[54] Menstruation has been continuously considered a taboo topic and is often surrounded by negative communication among both men and women. Along with physical and psychological symptoms that often affect women and girls during menstruation, there is an added burden of low access and high costs of hygiene products.[52] In 21 US states, there are additional taxes on essential hygiene products necessary for menstruation.[54-55] In developing countries, "period poverty" remains a pervasive issue further stigmatizing menstruation.[55] When young girls do not have access to menstrual hygiene products, they are more likely to miss school.[55] This can negatively impact young girls' education which is associated with child marriages, early pregnancy, and domestic violence.[55]

Sexual Health

Sexual health can significantly impact the mental health of individuals and is an important aspect of overall well-being. Ethnic and racial minorities experience higher rates of sexually transmitted infections (STIs) than White individuals.[56] Additionally, socioeconomic status and cultural factors can influence sexual health outcomes.[56] In comparison to men, women typically present with less STI symptoms, which can lead to delayed diagnosis and other reproductive issues.[57] Additionally, discussions of sexual health are considered taboo in many cultures which can lead to negative health outcomes.[58] Cultural competence must be utilized when physicians discuss sexual health with patients to ensure patient acceptance and adherence of safe-sex practices.[56]

Addressing women's health disparities is a fundamental aspect of improving gender equity and improving health outcomes. The transitional periods throughout women's lifespans can place them at risk for health conditions and decreased quality of life. The gaps in medical coverage that exist in the healthcare landscape exacerbate the disparities women face. The history of discrimination, socioeconomic factors, and cultural norms continue to impact health outcomes and innovation in women's health.

SECTION 2

Innovations in Women's Health

WHY IS IT HARD TO INNOVATE IN WOMEN'S HEALTH?

Women's health conditions have been stigmatized for centuries. Women's physical ailments were frequently misdiagnosed as "hysteria," a diagnosis that plagued women for 4,000 years.[59] "Hysterical neurosis" remained in the Diagnostic and Statistical Manual of Mental Disorders until the 1980s.[59] While there have been significant strides in accurately diagnosing and treating women, gender bias still impacts women seeking medical care. The women's health landscape is relatively new and is still considered a niche field.

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The biological changes throughout a woman's life span create a unique opportunity for interventions targeting specific periods of time. Childhood, adolescence, adulthood, pregnancy, postpartum, and menopause are specific transition periods with significant impacts on women's physical and mental health.[60] Additionally, acknowledging sex differences such as hormones, anatomy, inflammatory response, physical function, and body size is an important component to effectively developing medical devices or medications appropriate for women.[61] Despite the complex aspects of women's health and the need for innovation, research, funding and media coverage remain limited.

RESEARCH LIMITATIONS

Conditions specific to women are continuously underfunded and understudied. For example, Alzheimer's disease, rheumatoid arthritis, and depression have a higher burden of disease in women yet have significant gaps in research.[60] Clinical trials continue to exclude women or underrepresent the true female population.[62] Clinical trials for conditions that primarily impact women do not include a proportionally appropriate number of women.[63] The same trend occurs in studies utilizing cells or animals.[64] While Alzheimer's disease primarily affects women, animal studies of the condition often focus on male subjects.[64] The pervasive history of discrimination in women's health can lead to medical hesitancy for women, especially during experimental trials.[65] This further emphasizes the importance of inclusive and unbiased care.

The inequitable gender distribution also exists for researchers. Only one-third of NIH research grantees are women.[52] The proportion of principal investigators receiving 3 or more NIH research grants increased threefold from 1991 to 2020 from 3.7% to 11.3%, respectively.[66] Despite the increase in these principal investigators, women were 34% less likely to be included in this group.[66]

FUNDING LIMITATIONS

In 2020, the biopharmaceutical sector contributed approximately $198 billion toward medical research, yet only 1% of this funding was spent on female-specific health conditions.[60] Additionally, only 3% of digital health funding is allocated to FemTech companies.[67] This lack of funding is surprising considering the market for female-specific medical devices, such as gynecological devices, have been valued at approximately $9.5 billion.[68] This is in stark contrast to the value of gender nonspecific markets—for example, the orthopedic medical device market has been valued at only $36.3 billion.[69]

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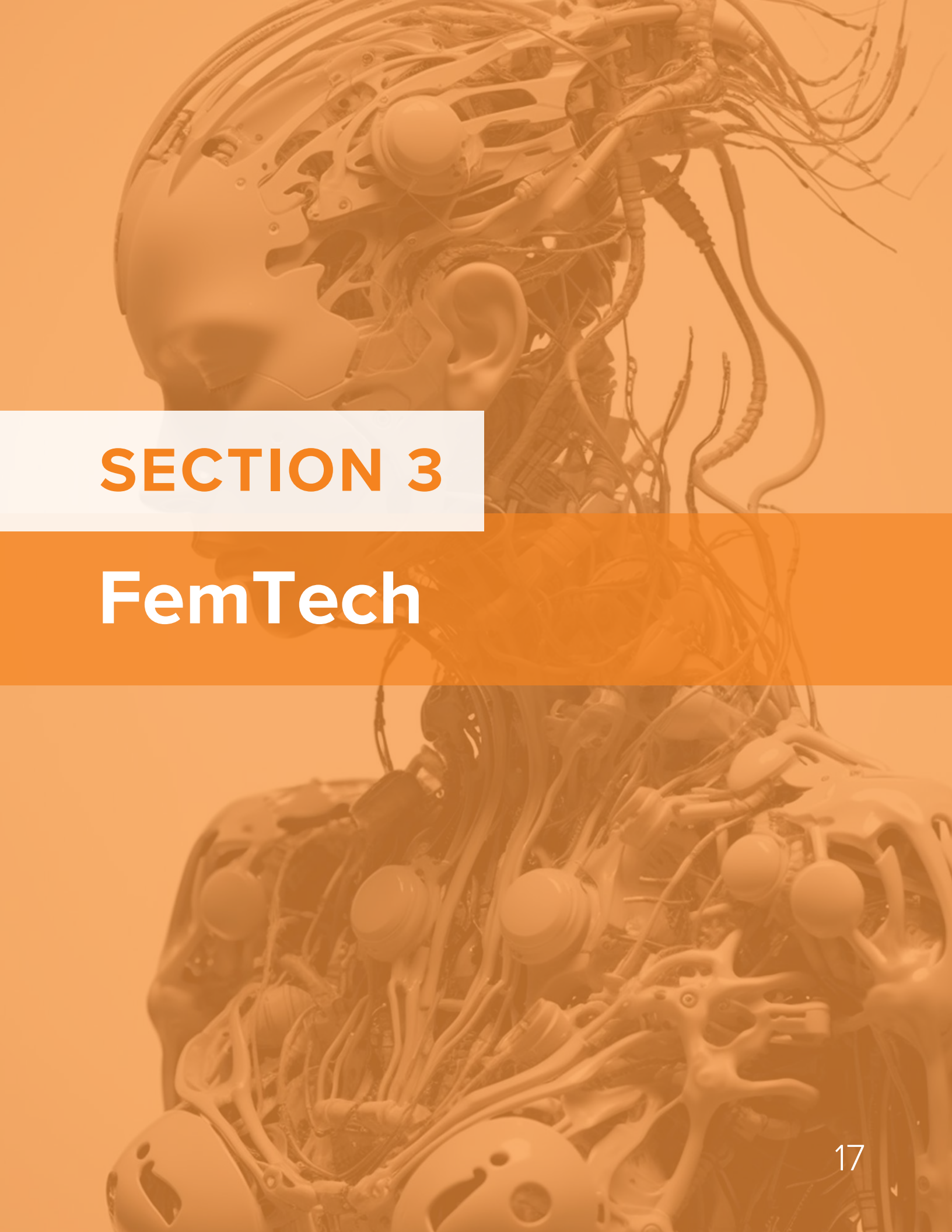
Funding is a vital component of improving the representation of women in clinical trials which can vastly improve women's health outcomes. A study evaluating the National Cancer Institute's funding of 18 different types of cancer found that funding for gynecologic conditions was not proportional to the years of life lost.[59,70] Overall, funding tends to be higher for conditions that impact men, like prostate cancer.[59]

The NIH is the nation's leader in medical research with the goal of addressing urgent health needs and disparities.[71] Despite millions of dollars spent by the NIH on health issues, only 10.8% of the NIH budget in 2020 was spent on women's health research.[72] Conditions specific to women are understudied and the funding allocated to researching these ailments is not consistent with their burden on women.[72] The NIH applies a disproportionate share of its resources towards conditions that mainly affect men.[59] In 75% of cases where a condition primarily impacts one gender, NIH funding favors the male-dominated condition.[59] Specific institutes within the NIH also underfund women-specific conditions—the National Cancer Institute only allocated 1.4% of their budget to cervical cancer. This lack of funding self-perpetuates, as the lack of female-specific data available makes it difficult for researchers to receive funding when applying for NIH grants.[73,74] In 2023, the White House launched an initiative that aims to address the gaps in women's health research and identify opportunities for funding.[75]



SECTION 3

FemTech

THE RISE & FUTURE OF FEMTECH

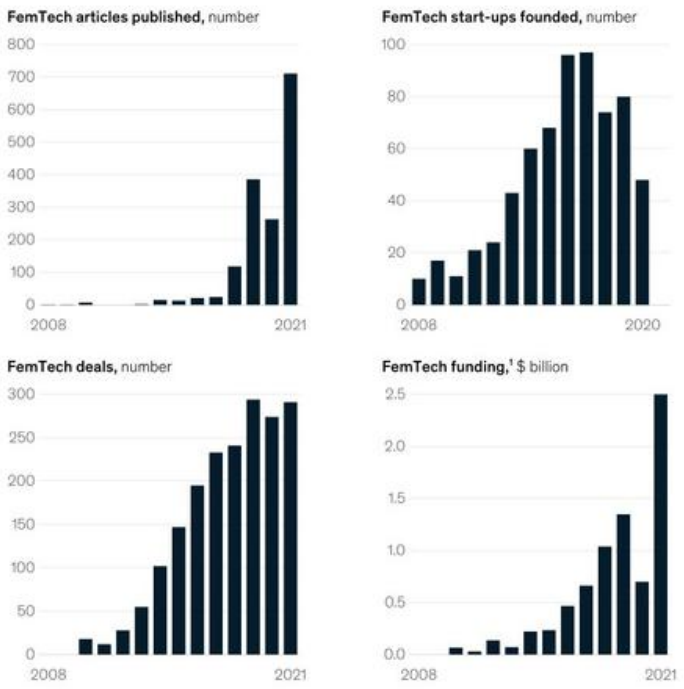
History

In 2016, entrepreneur Ida Tin, the founder of the Clue period and fertility tracking mobile app, introduced the term “FemTech”.[76] The term refers to technological solutions for female-specific conditions.[67] Identifying a gender gap in investment opportunities, especially for products tailored to women, Ida was determined to build a more inclusive startup environment. This initiative was prompted by the prevalent trend that most investors with the financial capacity to support startups were men.[77] FemTech is a blend of female-centric technology, encompassing a diverse array of solutions dedicated to enhancing healthcare for women. FemTech represents a comprehensive initiative aimed at revolutionizing and prioritizing women's well-being as the cornerstone of technology and healthcare innovation.[67]

Current Landscape

The current FemTech market is in its early stages of development, poised for significant growth. With the ongoing rise of digital convergence, the intersection of women's and digital health is rapidly expanding. It is essential for companies to identify and address unmet needs within the industry to capitalize on this strategic opportunity.[78] While the current FemTech market primarily focuses on maternal health, consumer menstrual products, gynecological devices, and fertility solutions, there are still unaddressed needs within the female health sector related to gynecological infection, contraception, and oncology.[67] Additionally, the health and well-being of the growing aging female population represents an over-looked sector. While aging women are more prone to chronic and terminal health conditions such as breast cancer, osteoporosis, diabetes, arthritis, heart disease, dementia, and depression than men, they also have longer lifespans.[79] This reflects booming opportunities for investors and entrepreneurs to develop products and services that address the rising unmet needs within the FemTech sector.

FemTech Research & Startup Landscape[67]



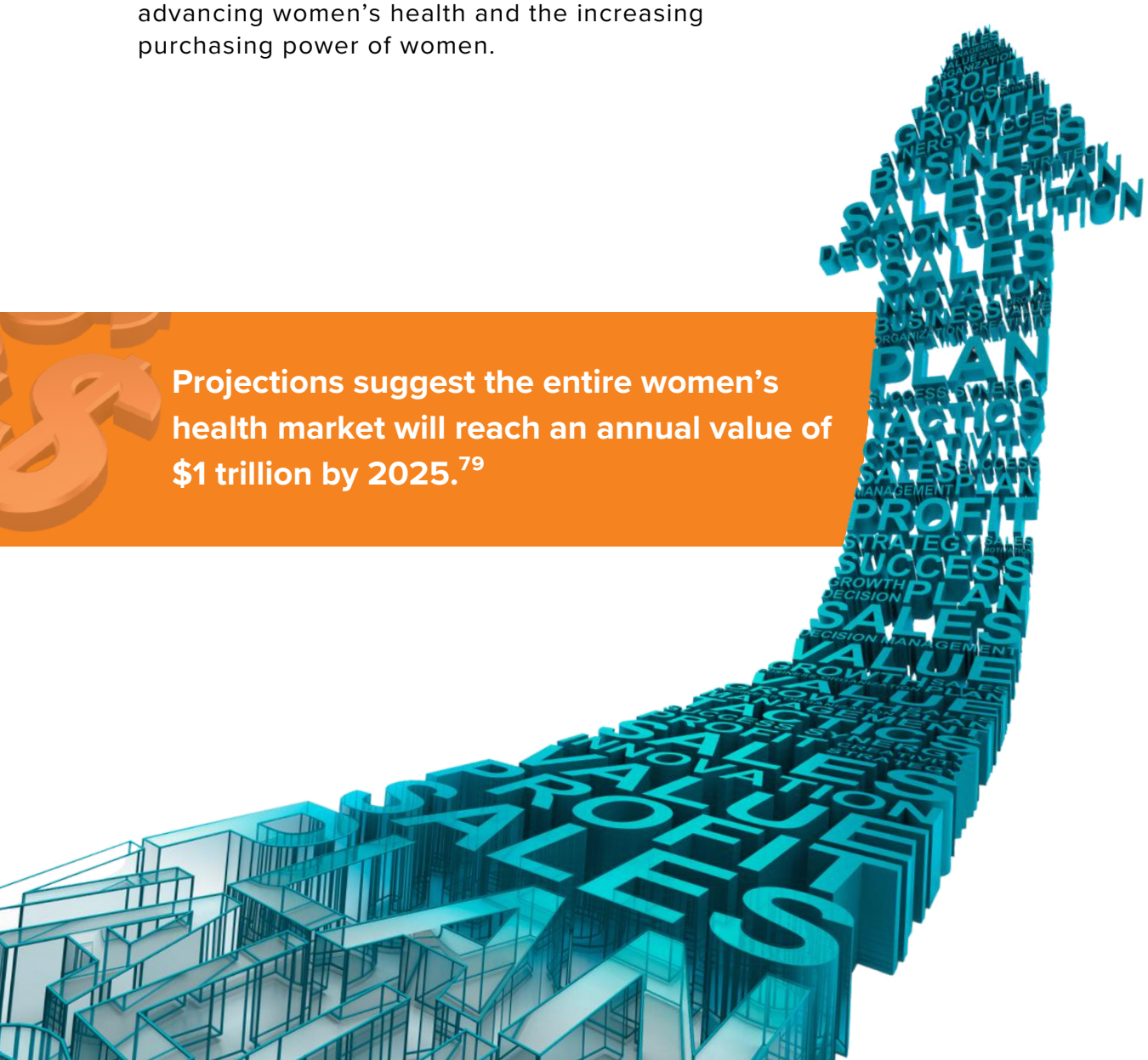
[1]Includes all forms of capital raising, including venture capital, private equity, debt, and IPO. Funding for 2021 reflects data through December 9, 2021.
Source: Factiva, accessed 2021; PitchBook; press search

THE RISE & FUTURE OF FEMTECH

The Future of FemTech

FemTech's current market size is estimated between $500 million and $1 billion, with promising forecasts predicting double-digit revenue growth.[67] Moreover, reports reveal that women expended an estimated $500 billion on medical expenses in 2020, and projections suggest the entire women's health market will reach an annual value of $1 trillion by 2025.[79] More broadly, as women take on active roles in caretaking and healthcare decision making, it is estimated that they influence 80% of healthcare decisions, solidifying their key, indispensable role in shaping the healthcare landscape.[79] With the market continuing to expand, FemTech holds significant potential, driven by its vital contribution to advancing women's health and the increasing purchasing power of women.

Projections suggest the entire women's health market will reach an annual value of $1 trillion by 2025.[79]



SECTION 4

Strategic Product Development

TARGETING UNMET NEEDS & CHALLENGES

Solving for an Unmet Need

Every innovation should have an unmet need it is solving for, therefore identifying specific disease states and current treatments is an essential aspect of healthcare product development. From reproductive health to addressing conditions such as endometriosis or cervical cancer, strategic product development aims to bridge gaps in medical care.

DotLab is an example of an innovative solution targeting an unmet market need by revolutionizing endometriosis diagnosis with its non-invasive blood test, presenting a more accessible, efficient, and streamlined approach for early detection.[80] Endometriosis leads to inflammation, heightened menstrual pain, and potential organ damage and fertility issues. Pelvic pain, the primary symptom, often results in misdiagnosis due to its association with various diseases. The diagnostic process is a significant unmet need in this disease state, taking up to 10 years and requiring invasive procedures.[81] If left untreated, the condition can lead to irreversible effects, emphasizing the importance of early detection and intervention in women's health.[81] DotLab's innovative diagnostic method mitigates the risk of untreated disease progression, highlighting a transformative approach. It emphasizes addressing unmet market needs and driving innovations to enhance diagnostic accessibility. The innovation shows potential to identify endometriosis in 25-50% of patients with unexplained infertility.[80]

Another example of targeting unmet need is Curvia's cutting-edge medical device, the diaPatch. This innovation is specifically designed for the early detection of cervical cancer. Utilizing digitized microneedles, this innovative tool can identify novel targets during clinical visits. Unlike traditional invasive methods like Pap smears and colonoscopies, the diaPatch offers a faster, more accurate, and non-invasive diagnosis.[82] Cervical cancer, which develops in the cervix, often remains asymptomatic during its early stages. However, if symptoms do manifest, the most common one is unusual vaginal bleeding, which may occur after sex, between menstrual cycles, or after menopause.[83] Given the discreet nature of cervical cancer's signs and symptoms, routine screening is essential. The earlier cervical cancer is detected, the more promising the prognosis is for patients. For instance, those diagnosed with stage 1 cervical cancer have an 80-99% chance of living at least five years after diagnosis and intervention. In contrast, patients detected at stage 4 face only a 20% chance.[84] Both healthcare professionals and patients benefit significantly from the diaPatch. It enhances guideline management, improves patient compliance, and ultimately leads to better outcomes. The diaPatch's capability to provide same-day results with approximately 43% more sensitivity and 3.7% more specificity than Pap smears ensures more accurate test results.[82]

TARGETING UNMET NEEDS & CHALLENGES

Challenges & Considerations in Assessing FemTech Product Efficacy & Quality

While conceptualizing a solution for an unmet need is foundational; ensuring efficacy, safety, and non-inferiority are central to developing a reliable and valuable product for users. Clinical evidence describing the efficacy of various FemTech products is difficult to find and understand. This is influenced by several factors such as limited research, privacy concerns, a wide range of products, rapid technological advancements, reliance on user generated data, and regulatory complexity.[85] For instance, FemTech applications primarily focus on reproductive health, encompassing period and pregnancy symptom tracking, and aim to serve as tools for general patient education, personal health tracking, decision-making, or accessing common reference information. Such software for general health education, tracking, or reference is not subject to FDA regulation.[86] Consequently, many FemTech products lack FDA oversight, leading to potential discrepancies in safety, efficacy, or accuracy standards, ultimately resulting in unverified claims or ineffective outcomes. A recent study revealed that more than 85% of FemTech applications fell short of a 65% quality threshold, assessed on criteria such as user experience, data security, and clinical assurance, indicating areas requiring enhancement in these FemTech products.[86,87]

Examples of High Scoring Reproductive FemTech Applications

ORCHA, a digital health assessment technology, has reviewed hundreds of FemTech applications based on criteria including data security, clinical assurance, and user experience.[87] The following are among the highest scoring FemTech reproductive health applications:[88]

- Natural Cycles tracks fertility and serves as birth control in the USA and Europe. Using a smart algorithm analyzing basal body temperature, it identifies ovulation. Backed by research, it's the first digital birth control in both regions, with an 84% ORCHA Score on iOS and Android, making it the top-rated pregnancy app on ORCHA's App Library.
- Mush connects moms, fostering local friendships, advice sharing, and support. Mush facilitates socialization, filling gaps between healthcare appointments, and supports those lacking nearby family networks. It scored 83% in their ORCHA Review on iOS and Android.
- Mum & Baby, developed with NHS trusts in London, supports pregnancy to early parenthood. It helps navigate maternity care options and plan personalized care. ORCHA scored the application 82% on Android and 81% on iOS.

TARGETING UNMET NEEDS & CHALLENGES

Economic Impact

Financial burden and existing treatment options must be considered to comprehensively assess the holistic impact of the disease. Understanding the cost implications associated with the disease and current treatment regimens provides a foundation for evaluating the potential economic advantages of introducing a new product. By projecting the cost savings achievable through the implementation of an innovative solution, one can elucidate the economic benefits it may offer. Integrating QOL (Quality of Life) results into studies may offer a nuanced understanding of the product's efficacy. In instances where direct QOL data may be challenging to obtain, projecting the anticipated positive impact on patients' quality of life using the new product can serve to reinforce its significance and potential contribution to overall well-being.

MobileODT's FDA-approved colposcope is an example of a device with beneficial economic impacts. The advanced visual assessment solution leverages smart devices for high-quality, medical-grade image and video capture, revolutionizing cervical cancer screening in low-resource areas. This innovative approach reduces the economic burden of cervical cancer, bringing precision and accessibility to underserved communities. MobileODT's commitment to bridging healthcare gaps is evident in this streamlined solution that combines regulatory approval with mobile convenience for impactful, cost-effective cervical cancer screening.[88] This new method reduces the economic burden of cervical cancer screening by providing precision and accessibility to underserved communities. This showcases the ability to bridge healthcare gaps with a streamlined, cost-effective solution.

TARGETING UNMET NEEDS & CHALLENGES

Why Products Should Consider How They Can Reduce Risk and Decrease Liability

Prioritizing risk reduction and mitigating liability is essential when developing products. In reproductive health, privacy and cybersecurity issues surrounding data are particularly pertinent. Reproductive-based mobile apps must carefully review their data collection practices, ensuring that only essential data is collected for the app's functionality.[90] Considering evolving abortion laws in the United States, consumers may express concerns about period-tracking or fertility apps storing information that could reveal sensitive details about abortion or contraceptive care.[90,91] Moreover, FemTech health data misuse in the workplace poses a threat to women's equity, with potential discrimination based on pregnancy or infertility affecting salary and promotion opportunities.[91] Health insurance companies, utilizing FemTech data for algorithm training, may inadvertently contribute to harmful predictions such as increased insurance costs tied to perceived infertility.[91] As such, product developers need to navigate these intricacies carefully, implementing safeguards to protect user data and privacy across various domains.

Business Case

To enhance revenue streams for women's health or FemTech products, implementing strategic initiatives such as referral programs can prove instrumental. Referral programs increase revenue for healthcare organizations and enhance accessibility to essential services.[92] For instance, developing a targeted referral program for specialized technologies or centers, like mammography, can amplify impact by directing attention to critical areas of women's health.[92] Companies seeking to establish the value of their products to Value Assessment Committees (VAC) or Formulary committees should employ proven market access data strategies. By substantiating the value proposition through data-driven approaches, companies can demonstrate the efficacy and relevance of their women's health or FemTech products, thereby facilitating market acceptance and potentially broadening revenue streams.

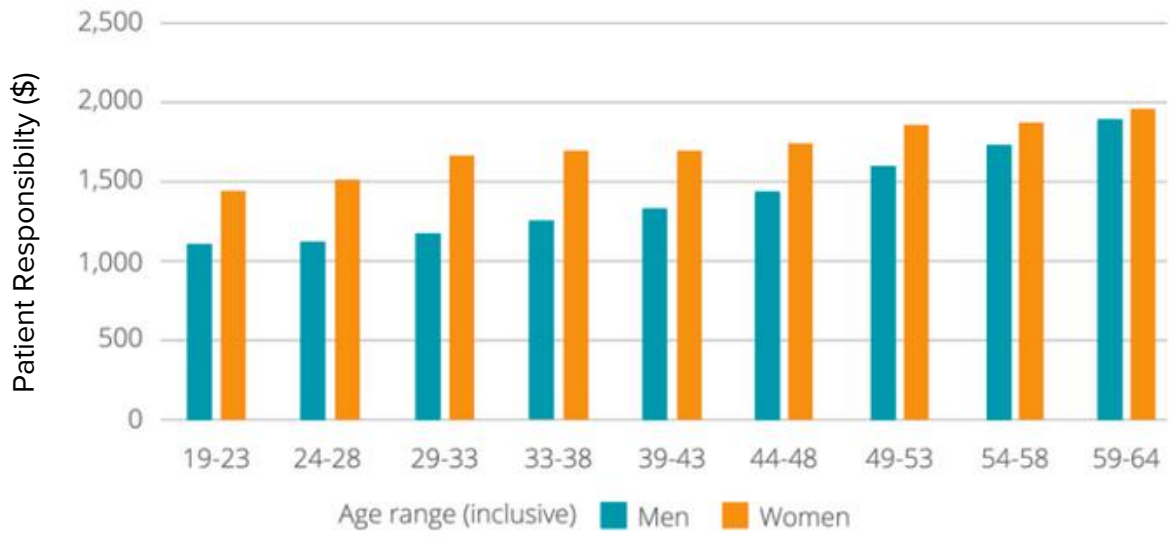
SECTION 5

Payor Perspectives

BRIDGING GAPS IN COVERAGE, INNOVATIONS, & CARE

Women in the US spend more on health insurance coverage than men, yet they receive fewer tangible benefits from their coverage.[93] Screenings and preventive treatment for women-centered conditions, including breast cancer and cervical cancer, are recommended at earlier ages than male conditions.[93] Additionally, women are more likely to seek out healthcare services and spend more on out-of-pocket services.[94]

Average out-of-pocket medical spend by age and gender [94]



BRIDGING GAPS IN COVERAGE, INNOVATIONS, & CARE

Member health outcomes

Payors have an increased interest in customer-centered services and investors are interested in companies that can utilize technology to track member health data from payors and create interventions.[95]

From a women's health perspective, the growing interest of payors in customer-centered services and investors' focus on technology-driven health data tracking present a unique opportunity to enhance and personalize healthcare experiences for women. This shift towards a more patient-centric approach, driven by advancements in technology, has the potential to address specific challenges and improve overall well-being for women across different life stages.

Personalized Women's Health Interventions:
With an increased focus on technology-enabled health data tracking, payors and investors can support initiatives that specifically cater to women's health needs. Tailored interventions, based on real-time data, can be designed to address issues such as reproductive health, maternal care, menopause management, and chronic conditions that disproportionately affect women.

Reproductive Health and Family Planning:
Technology can play a crucial role in providing women with access to accurate information about reproductive health and family planning. Apps and wearable devices can track menstrual cycles, ovulation, and fertility windows, empowering women to make informed decisions about family planning and reproductive choices.

Maternal and Postpartum Care:
Investing in technology for tracking maternal health during pregnancy and postpartum can lead to improved outcomes for both mothers and infants. Remote monitoring, telehealth services, and data-driven interventions can ensure timely and personalized care, reducing the risk of complications and enhancing the overall maternity experience.

Chronic Disease Management:
Many chronic conditions, such as autoimmune disorders and osteoporosis, are more prevalent in women. By utilizing technology to track health data, payers and investors can support the development of innovative solutions for managing these conditions. This might include personalized treatment plans, remote monitoring, and digital support networks.

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Mental Health and Well-being:
Women often face unique mental health challenges, including postpartum depression, hormonal fluctuations, and societal pressures. Technology-driven interventions, such as mental health apps and virtual support communities, can provide accessible and personalized mental health resources to women, promoting overall well-being.

Preventive Care and Screenings:
Technology can facilitate proactive health management for women by encouraging regular check-ups, screenings, and preventive care. Wearables and health monitoring devices can track vital signs, ensuring that potential health issues are detected early, leading to more effective and less invasive treatments.

Data Security and Privacy Concerns:
As health data becomes more central to personalized care, it is crucial to address concerns regarding data security and privacy, especially when dealing with sensitive women's health information. Payors and investors should prioritize robust security measures and transparent policies to build trust among users.

The intersection of payors' interest in customer-centered services and investors' focus on technology-driven health data tracking presents an exciting opportunity to revolutionize women's healthcare. By leveraging these advancements, we can create a more inclusive, personalized, and effective healthcare ecosystem that caters specifically to the diverse and unique needs of women across their lifespan.

CONCLUSION

The complexity of transitional periods throughout women's lifespans poses unique challenges and health risks. These transitions are often accompanied by hormonal fluctuations, physiological changes, and psychosocial adjustments. The complexity of these periods can be further compounded by gaps in medical coverage, funding, and research, leaving women vulnerable to adverse health outcomes and decreased quality of life.

Despite significant investments by research organizations on certain health problems, women's health conditions are often deprioritized or excluded. Similarly, clinical trials lack female representation and further exacerbate healthcare and research gaps. This gender bias in research worsens existing healthcare disparities and impedes the development of effective and tailored interventions for women. The promising field of FemTech aims to address these gaps in innovation and prioritize women's quality of life and overall wellness. Addressing unmet needs is a vital component of strategic product development, and ensuring efficacy, safety, and non-inferiority are central to developing a reliable and valuable product for users.

FemTech, a novel field focused on developing technology-driven solutions for women's health, holds promise in addressing these gaps in innovation. By leveraging digital health tools, wearables, and telemedicine platforms, FemTech aims to empower women to take control of their health and well-being. These technologies have the potential to provide personalized care, improve access to healthcare services, and bridge the gap between patients and providers.

In strategic product development within the FemTech industry, it is crucial to prioritize addressing unmet needs among women. This involves conducting thorough needs assessments, engaging with diverse communities of women, and ensuring that products are designed with their specific concerns and preferences in mind. Moreover, prioritizing efficacy, safety, and non-inferiority in product development processes is essential for building trust and confidence among users.

Ultimately, by recognizing and addressing the multifaceted challenges facing women's health, stakeholders in the healthcare industry can work towards closing the existing gaps in research, access, and quality of care. Through collaborative efforts between policy-makers, healthcare providers, researchers, and technology innovators, we can strive to achieve better health outcomes and improved quality of life for women across their lifespans.

About PFG MedComm

A Strategic Market Access Agency

PFG MedComm is an award winning woman and minority owned strategic communications agency - we specialize in achieving health access goals through medical and value communications strategy. Having transformed the traditional agency model, our approach takes a holistic 360° view that considers the research and clinical development continuum.

We are experts in developing end-to-end communication strategies and tactics for all healthcare stakeholders, from clinical to the general public. We are specialists in the areas of clinical and medical information, population health, health economics, patient outcomes, social determinants of health, racial and other health disparities, and more.

As a **full-service** strategic market access **agency**, we focus on leveraging **value communication** to **achieve market access priorities.**

60+ BRANDS

33+ US & GLOBAL LAUNCHES

50+ INDICATIONS

20+ THERAPEUTIC CATEGORIES

10+ YEARS IN BUSINESS

Certifications

Women Owned — Certified by Women's Business Enterprise National Council

NMSDC — National Minority Supplier Development Council

Asian Indian Chamber of Commerce

SBA WOSB — Woman Owned Small Business

Professional Organizations

WIB — Women In Bio — Promoting Diversity and Inclusion for All Women in the Life Sciences

American Medical Writers Association — The Resource for Medical Communicators

USWE

HBA — Healthcare Businesswomen's Association

Awards

MM M 40 Under 40 — 2024 Honoree

Platinum Winner

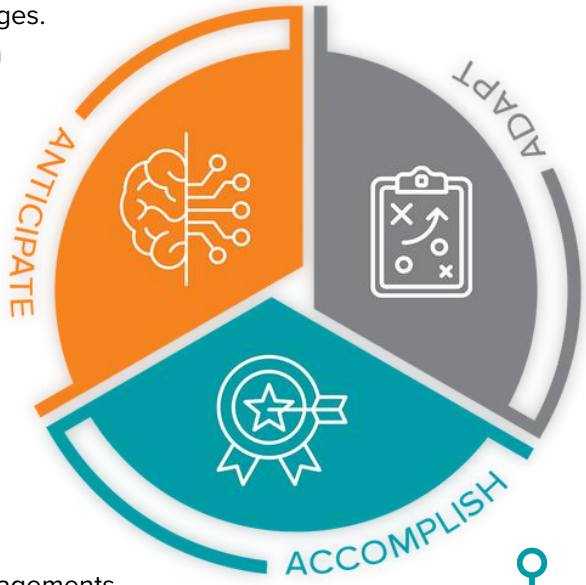
PM360 Elite 100 — 2023 Winner

Our 360° Approach to Access™

Tranforming the Traditional

We have reimagined the traditional approach by applying a market access lens across the entire product development lifecycle - from clinical to commercialization, launch through post-launch. Our unique approach to access fits into any phase of development, while navigating the medical, legal and regulatory requirements at each.

In an ever-changing market access landscape, we take a proactive stance, anticipating future opportunities and identifying potential challenges. Our distinctive process integrates the market access lens early in development and extends throughout the launch strategy, utilizing landscape analyses and strategic scenario planning to craft a dynamic market access plan.



We specialize in adapting market access plans, tailoring stakeholder-specific messaging to enhance the value proposition based on access opportunities and challenges. Our customized tactical plans, combined with strategic workshops, simplify the value story, creating compelling customer selling propositions.

As a comprehensive agency, we go beyond creating tools and tactics. We equip field teams with adapted tactical plans through a series of strategic workshops, ensuring effective customer engagements. Our proprietary training methodology goes a step further, simulating real-world customer interactions and empowering teams to communicate unique value stories.

This complete view ensures comprehensive, tailored strategies across market access stakeholders.

Our 360° Approach to Access™ involves anticipating challenges, adapting strategic plans, and accomplishing access through wraparound engagement.

Contact PFG MedComm to learn more: hello@pfgmed.com

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