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FOGSI Modern Approaches to Maternal Health Initiatives

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CHAPTER 11

FemTech: The Concept of Maternal/ Female Healthcare through Technology

Rohan Palshektar, Hrishikesh D Pai, Manisha Nandi

INTRODUCTION

The core concept of FemTech is to give women what they often lack for their health, sexuality, and empowerment.

In the year 2013, the term "FemTech" was coined in Germany by the Danish founder of Clue, Ida Tin, a tracking app for ovulation and period. FemTech (or "female technology") is an umbrella term dedicated to digital health technologies, addressing women's health such as fertility solutions, services, products, and software. It includes mobile tracking apps for periods and fertility, monitoring devices for reproductive health issues, fertility, pregnancy, and nursing, self-help applications to address the concerns associated with general health and wellness, women-centric solutions, and proactive approaches to menopause.[1]

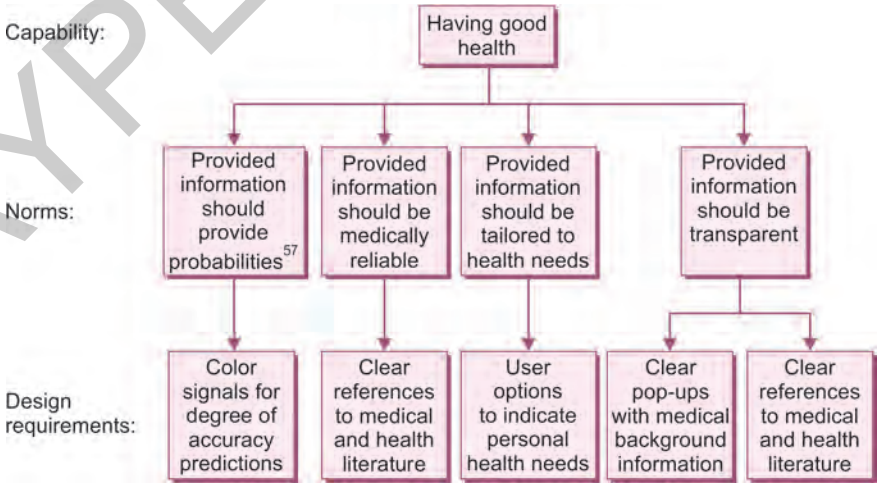
OPTIMAL HEALTH AND CHALLENGES

One of the major challenges for the FemTech structures is to educate the users.[2]

The potentiality of good health is *represented by the capability grading* **(Flowchart 1)**.

The capacity to ensure command over individual environmental factors, and thereby

Flowchart 1: Capability grading.



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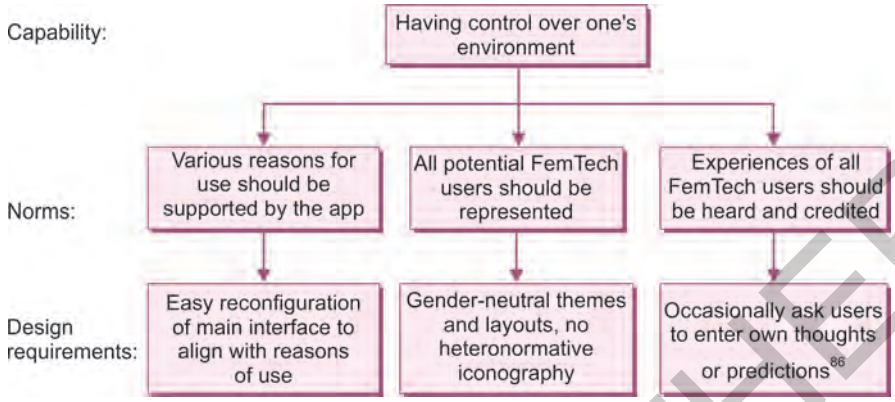
Flowchart 2: Capability hierarchy.



mitigation of the associated epistemic injustice and gender stereotyping is *represented by a capability hierarchy* **(Flowchart 2)**.

IMPORTANCE OF FEMTECH

There are several reasons FemTech has become important in present life. These are mentioned as follows:

- *Progress in medical awareness and delivery systems:* Virtual clinics, direct online consumer prescription over phone using video and audio services, and innovative physical clinics.
- *Promotion for self-care:* The availability of free and subscribed healthcare trackers/apps, at-home diagnostics, and wearable and affordable electronic chips help women get their personal body parameters.
- *Communication/presentation/awareness and advertisements of stigmatized topics:* The female menses and the use of disposable sanitary pads and products, pregnancy testing kits, diagnostics tests, etc. have been shown through advertisements by the companies at prime time to commercialize these products and target the female audience.
- *Delivers culturally sensitive and tailored care:* The designing of the products and services to marginalized groups, including African and Asian women, women in underdeveloped/developed countries, and lesbian, gay, bisexual, transgender, and questioning (or queer) (LGBTQ) populations.
- *Better suited to understanding the needs of women:* The FemTech companies are mainly recognized and supervised by women, hence they can better understand women's needs and problems.
- *Moderates the gender discrimination in technology management:* This enhances job opportunity for educated women in various fields and eliminate gender discrimination.

PERSONALIZED MEDICINE AND PRECISION MEDICINE

Till date, medicines had been manufactured in the same manner for everyone, with no regards to the age, sex, and racial identity of the individuals. Recently, it has been well established that all the above factors have a very crucial role to play toward the effectiveness of medical therapies, because

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every individual reacts in a considerably different way to treatment. Due to the novel advancements in genetic research in the past few decades, it is now established that the future will be based on the principles of precision medicine, an individual approach to each patient. Targeted therapies will be selected based on genetic tests and by identification of specific biomarkers.

A woman's health is cyclical when in balance. According to the Celtic lore, *trinity* knot (*triqueta*), a woman's life is represented in three prominent phases: The maiden, mother, and the crone; and all these three stages are characterized by specific health transitions. The basic biological alterations influence the very microscopic compositions of a woman's body. An ideal approach to health for all these three stages of a woman's life could predict and help in the prevention of diseases. In the same manner, *precision health* promises to offer personalized, and woman-specific personal health education, lifestyle modification coaching, and primary detection of disease to help in mitigating the outcomes of various diseases occurring all through the life of a female. This, however, contrasts with the concept of *precision medicine*, a focus on the unique microbiological targets for the diagnosis and treatment of the diseases that affect the outcome after the onset of the disease **(Fig. 1)**.

With the emergence of the FemTech market, the diagnostic tools which utilize the body fluids (urine, breast milk, and saliva) can monitor hormone levels, nutritional status, and detect diseases (malignancies and endometriosis) **(Fig. 2)**.

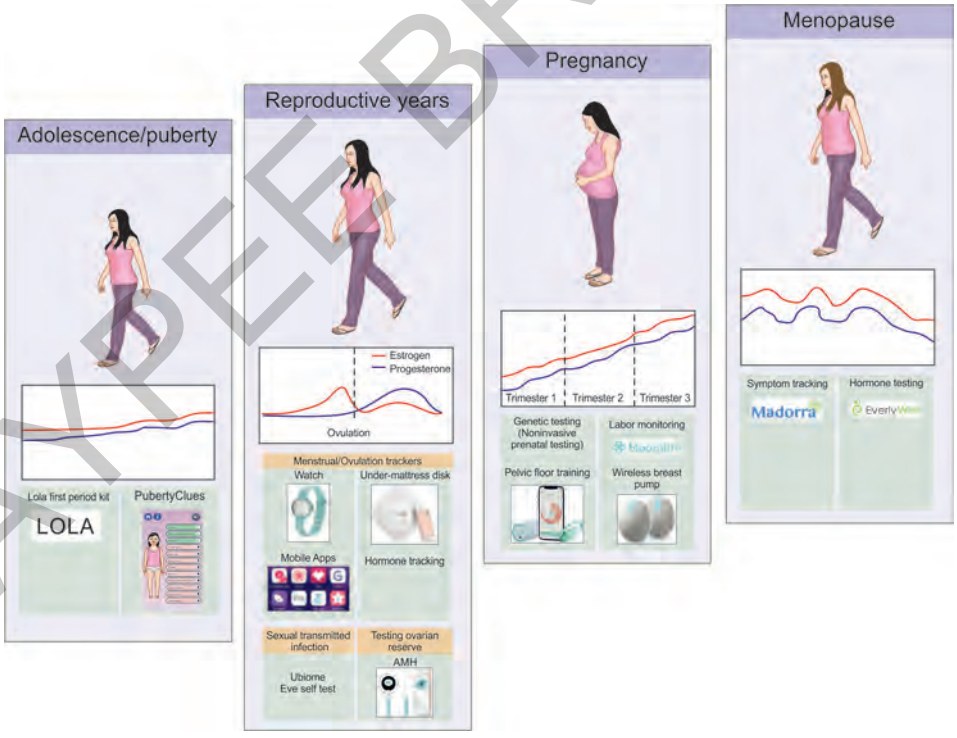

Fig. 1: The emerging new technologies and tests: Role in different age groups.[3]
(AMH: anti-Müllerian hormone)

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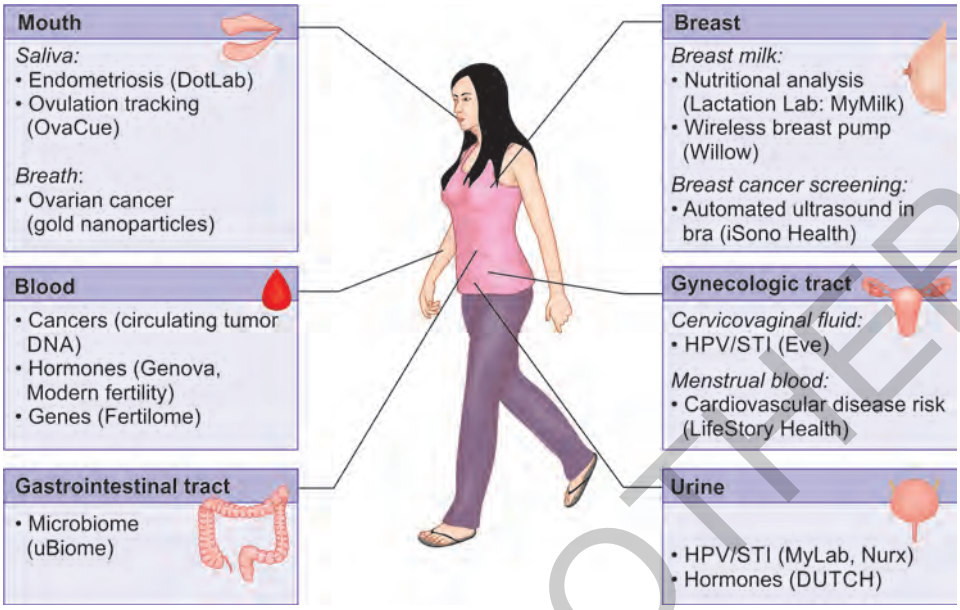

Fig. 2: The emerging new technologies and tests by anatomic site.[3]

MENSTRUAL HEALTH

A recent study evaluated 14 different mobile apps and reported that mNFP, Lily, and the Lady Cycle, in accordance with the Sensiplan method, consistently can help in the determination of the accurate fertile window of a woman. The authors emphasized that in order to enhance the accuracy of tracking, women wanting to avoid or achieve pregnancy should also be able to detect the fundamental signs of fertility. Generally speaking, recent studies have reported that these applications have a rate of failure of 5% and 1% for typical users and perfect users, respectively, that makes these comparable to other methods of family planning; for example, the contraceptive pills, vaginal rings, and the other fertility awareness method (FAM)-based techniques. However, these apps are less effective with irregular cycles, miscalculations of fertility window, and inconsistent use. Even though these apps allow tracking of symptoms, dates of menstruation, and intercourse, only few of them provide an insight to aid in the identification of the potential health issues. Hence, in the future, associating and linking symptoms from patient database can enable clinicians to identify the potential markers for health issues earlier.

With a clear background of pharmacogenetics, the concept of personalized contraceptives is in the range of vision. For instance, one study published recently stated that women who are carriers of cytochrome P3A7*1C variant (adult expression of CYP3A7) have a faster metabolism of the steroids in the body. In 25% of these females with the variant, there was a fall below the threshold for ovulatory suppression in the levels of etonogestrel—which means despite the use of the contraceptive implant women were still able to conceive. Hence, pharmacogenetic tests are now being offered for oral contraceptives in certified laboratories. The potential implications on the future recommendations

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on contraception can help personalize the choice and dose of oral contraceptives.

SEXUALLY TRANSMITTED INFECTIONS

Despite decades of decrease in the incidence, at present the rates of gonorrhea and syphilis are increasing. Subfertility owing to chlamydia infection is also frequent even with advanced diagnostic tests [nucleic acid amplification test (NAAT)]; it is mostly due to the difficulties that exist in getting proper access to the tests. Addressing the problem, various self-testing methods have come into existence to improve the accessibility and application of sexually transmitted disease (STD) tests. A recent study on the accuracy of clinician and self-collected samples has reported sufficient analysis on the agreement with comparability of the results. Recent publications support that through these approaches, testing and identification of patients at risk are possible and convenient. For instance, mobile technologies can be used for notifying sexual partners exposed to STDs, hence the population at risk can be notified and screened.

ENDOMETRIOSIS

At present endometriosis is diagnosed based on clinical symptoms and findings of clinical examination, ultrasonography, and magnetic resonance imaging (MRI); no specific feature or biomarkers are accessible to provide with a definitive diagnosis of the disease in the absence of histological reports obtained via surgical interventions. The saliva testing is a noninvasive method for detection of microRNAs, which has shown to have a correlation with the disease. A new company called DotLab has commercialized this concept.

FERTILITY AND PREGNANCY

Planning the Future: Follicle Tracking and Ovarian Reserve

In modern times as more couples plan to conceive at older ages, the demand for predicting the fertile window increases. A woman's ovarian reserve is evaluated by measuring the serum biomarkers which aids in detecting the functions of the somatic cells present in the follicles. The hormone marker anti-Müllerian hormone (AMH) correlates with the ovarian follicles and tends to decrease throughout the reproductive phase of a woman. However, it accounts to be the most common "fertility test". Home-based tests for AMH, estradiol (E2), follicle-stimulating hormone (FSH), luteinizing hormone (LH), prolactin, testosterone, and thyroid-stimulating hormone (TSH) have been offered by new companies. The results are added to graphs that overlay by age the average risk in a "fertility timeline".

ARTIFICIAL INTELLIGENCE IN FERTILITY TREATMENT

Predictive modeling forms the background for artificial intelligence (AI): Age, menstrual cycles, serum AMH, polycystic ovarian disease (PCOD), and antral follicular count are taken into consideration. Several studies have reported that the above factors can help in reducing the rate of cycle cancellations and ovarian hyperstimulation syndrome (OHSS), hence, aid in cost-effective treatment. Another way of reducing cost is with preimplantation genetic testing (PGT). The primary disadvantages with PGT are the impending uncertainty regarding mosaic results, cost factor, and concerns that the entire embryo cannot be represented by trophectoderm biopsy. AI has the potential to answer these challenges in assisted reproductive technology (ART). Moreover, selecting embryos

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via AI will aid in reducing the expenses by optimizing laboratory performance, reduction of failed cycles by avoiding the transfer of embryos that have a lesser possibility of implantation, and hence a shorter time to achieve a successful pregnancy. There will also be cost savings with the lesser number of consumables used and manual labor staff hours. With the increase in the accuracy of the AI systems, it will uncover newer determinants of fertility, growth in the predictive ability, and minimize patient dropouts due to financial fatigue.[4]

In future, women can have access to add-ons such as external ultrasound and blood testing hardware, to allow 3D automated follicular monitoring and home-based blood tests. This information would be forwarded to the clinics and analyzed with the help of AI. Analyzing data from numerous cycles to enable "machine learning" can pave the way for individualized adjustment of the dosage of gonadotropins, administered via subcutaneous administration systems like the insulin pump.

Future of Molecular Testing and Identifying Women-specific Diseases

As researchers continue to comprehend the microbiological mechanisms of various illnesses, certain companies are providing genomic tests to provide a link to the single nucleotide variants of diseases such as endometriosis, polycystic ovary syndrome (PCOS), unexplained infertility, OHSS, and recurrent pregnancy loss (RPL). The implications for detecting single nucleotide variants remain unclear owing to the contribution of environmental factors and epigenetics involved in the process of development of a disease. For instance, studies have reported single nucleotide variants in association with pelvic endometriosis, but the etiological mutations are not necessary for the evolution and detection of the disease process.[3]

PREGNANCY PREDICTION

Currently, kits/apps help in detecting the presence of modifiable risk factors of preterm delivery using algorithms and digital data of patients. When any risk is detected, the app informs the medical unit and sends modifiable schemes to aid in minimizing the risk which may go unaddressed. The available home pregnancy kits are very reliable with an accuracy of 99% for detecting pregnancy. Digital devices using sensors to change color and determine the lines for "pregnant" or not on their screens are also available.[1]

Pregnancy apps include features like:

- Weekly notes about the size of a baby in utero
- Tips for what might be going on with the pregnancy
- Preparation checklist
- Contraction counter for when the big day finally arrives

MENOPAUSE

Bone mineral density (BMD), breast and endometrial cancer, and the cardiovascular system are influenced by the early onset of menopause. Hormonal assays using saliva can be used to detect (estrogen, AMH, and FSH) for hormonal changes. The onset of menopause with a focus on AMH levels has also been explored, however, the accuracy of serum AMH for predicting early menopause remains finite and restricted in clinical practice. New technologies and mobile apps that offer insight into the biophysical changes of menopause are now made available. For instance, mobile apps provide education, symptom trackers, and peer support.

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In addition, a noninvasive method has been developed for the treatment of vaginal dryness to alleviate sexual dysfunction and loss of libido. Currently, there are lack of specific scientific tests for managing menopause. There needs to more focus of resources for developing tests.

TOPICS THROUGHOUT WOMEN'S LIFECYCLES

Cardiovascular Disease

With the loss of protection from the effect of E2 in the initial stages of menopause, women have a 30% increased risk of cardiovascular disease (CVD). The Women's Ischemia Syndrome Evaluation reported that an angiogram can give a normal report, but menopause is related to microvascular changes and leads to CVD in the long run. Emerging biomarkers can help in the stratification of the risk factors and improve the diagnostic testing methods allowing for accurate detection of CVD. For instance, a new technology helps in the detection of the modified proteins in a woman's menstrual blood for risk stratification and CVD detection. Wearable technologies are also being developed such as electrocardiogram (ECG) devices in smartwatches and a bra to monitor for CVD and hypertension. Rigorous scientific studies are required for the assessment of the predictive value and accuracy of these new technologies.

Obesity

The sex-specific high-risk factors are hormone changes, pregnancy, and menopause. Generally, serum E2 fluctuations cause downregulation of metabolism and satiety-regulating hormones such as leptin, cholecystokinin, and peptide YY. The serum progesterone levels also play a role in increasing the energy intake. Female-specific cloud-based systems are available to link data (metabolic, reproductive, and vascular health) and laboratory data along with lifestyle modifications for the management of health and well-being of patients. Nuanced data, which comprises metabolomics, microbiomics, proteomics, and genomics, also offers an actionable intelligence when applied in part to form a precision healthcare management program.

Cancers

Precision medicine is applicable for the assessment of risk factors and for the detection of malignancies. Home-based tests are available that evaluate the predictive factors of genetic malignancies. For instance, color genomics provides at-home saliva testing with the use of a 30-gene panel for ovarian, breast, pancreatic, melanoma, colorectal, endometrial, and gastrointestinal malignancies (BAP1, ATM, CHEK2, PTEN, MLH1/2, MSH6, POLE, PMS2, TP53, and STK11). While these genes are detected in specific malignancies, the functional risks of the genetic alterations before the detection of malignancies are still unclear.

Cervical Cancer

Human papillomavirus (HPV) infection is the causative factor for 99% of squamous cell carcinomas and testing for the virus forms an integral part of the screening protocols. Detecting high-risk HPV and cervical intraepithelial neoplasia (CIN) may help in the prevention and progression of invasive cancers. The recent recommendations apply cytology and high-risk HPV testing in combination. Newer technologies offer home self-testing for HPV to improve participation in the screening protocols. Self-sample collecting devices are being used in the United States of America (USA) and Canada. Testing with links

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to the healthcare unit and counseling services will be required to explain the implications of active infection for clinical management.

Breast Cancer

Hormone receptors: Estrogen receptor (ER) and progesterone receptor (PR) are applied to characterize the malignancy types. Recently, HER2 testing has been used for predicting the response of a drug targeted at Herceptin. New classifications based on multigene panels can help in predicting the potential benefits of chemotherapy in the different risk groups. Options in precision medicine are now focused on early detection of breast malignancies. Biennial mammograms between the ages of 50 and 74 years are recommended by the United States Preventive Services Task Force, but only 70% of the population abide by this. Self-examination is not recommended compared to radiological surveillance. Several companies are developing adaptive screening mammography for designing bras that will perform a screening. This new technology is yet to be available for clinical application but can provide an effective screening technology option.

Ovarian Cancer

Ovarian cancers are notoriously difficult in terms of detection as often the physical symptoms present late. Moreover, CA125, the most common biomarker, is not very accurate and can be raised in benign diseases such as endometriosis, fibroids, and several traumatic conditions. Researchers are looking for ideal and innovative noninvasive technologies for the detection of ovarian malignancies at early stages. A group of researchers from Israel have developed breath sensors that apply molecularly modified nanoparticles made of gold that provide a specific nanoparticle spatial configuration while interacting with specific organic volatile compounds. This device has an accuracy of 82% for the detection of cancer; irrespective of confounding factors like tobacco use other and comorbidities. Urine biomarkers are being explored for ovarian carcinomas: HE4 and Bcl-2, to differentiate between malignant and benign tumors. The overall treatment response, benefits, and mortality are not yet ascertained, but utilizing urine is a favorable body fluid due to easy access and has a less complex protein matrix than blood. While urine testing might hold promise as it is noninvasive, challenges exist about the hormonal and environmental influences that might alter the fluid integrity.

Mental Health

Women have specific hormonal and physiologic alterations that lead them toward depression during pregnancy, the postpartum period, and menopause. With a significant burden of mental health issues amongst women, more clinical skills and resources are required to meet these essential needs. Virtual and online mental health support is being developed. Mobile apps are now available for depression, stress, meditation, and eating disorders. The University of North Carolina at Chapel Hill has come up with a mobile app for postpartum depression in their recent study program.

Alzheimer's Disease

Cognitive impairments and progressive dementia are the hallmarks of Alzheimer's disease (AD) and 70% of the population affected by AD are women. Moreover, both women and men can be carriers of the apolipoprotein E (APOE) ε4 allele: The main gene for the disease, women experience a rapid loss of physical functioning and memory loss when they are the carriers.

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Mobile apps and tracking devices have been developed to offer caregivers' data related to the location of the patients and integrated sensors for fall detection with even links to emergency service providers.

POTENTIAL LONG-TERM BENEFITS OF IMPLEMENTING PRECISION MEDICINE

The potential long-term benefits of implementing precision medicine include:

- Wider adoption of collecting patients' genetic and other molecular information as part of routine medical care
- Improved ability to predict which treatments will work best for specific patients
- Better understanding of the underlying mechanisms by which various diseases occur
- Improved approaches to preventing, diagnosing, and treating a wide range of diseases
- Better integration of electronic health records in patient care, which will allow doctors and researchers to access medical data more easily

FEMTECH PRODUCTS

As the FemTech industry is growing in India, the available products for women are listed in **Table 1**.[5]

FEMTECH: MORAL IMPLICATIONS

The women of the house take part in majority of the decisions related to the family's health issues. The healthcare systems related to women's products is still very small,

TABLE 1: Available FemTech tests.

S. No.	*Name of company*	*Detail of app/device developed*
1.	OKY	The first period tracking app with personalized monthly trackers and calendars, tips, and period information; it is girl-centric and managed through a gamified design
2.	Clue	Menstrual and reproductive health of women
3.	Glow	Ovulation, pregnancy, and women's reproductive health
4.	Ava	Tracks and predicts ovulation and woman's fertile time period
5.	Natural cycles	Women's fertility status
6.	Bonzun	A custom-made in vitro fertilization (IVF) app developed to achieve the goal of fertility management
7.	Bloomlife	Rent wearable devices so that pregnant women and doctors can handle the complications related to pregnancy in a better way
8.	Coroflo	Monitors the flow of milk to the baby of a breastfeeding mother
9.	Apricity	Online clinic for women to discuss and help women to improve their chances of conceiving a child
10.	Thennai Scan	Designs cost-efficient, accurate, and remote devices to screen for early detection of breast cancer using a small thermal camera and smartphone
11.	Niramai	Detects early breast cancer in an effective and safe manner using disruptive artificial intelligence algorithm
12.	Skin health	App to predict relationship between skin health and the menstrual cycle

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as it focuses on a specialized field with less investors. Moreover, FemTech companies need data security with individual information.[6] FemTech has emerging technologies for menstrual cycle information, sexual activity, pregnancy status, and cancer-related data. However, these companies are not regulated by the law. There are ethical issues related to the misuse of personalized data as many of the applications are not registered. There are chances of cyberattack and most of these technologies cannot provide replacement to the treatment by a healthcare professional. Still FemTech has been very useful and offers more in the field of new technologies for awareness and treatment of female health issues.

CONCLUSION

With the advent of a plethora of newer technologies in the FemTech space for women, it has the potential to make an impact on the improvement of women's health. Limits to these technologies include unbiased clinical trials and actual application trials, high device costs, and limited data on accuracy. Additionally, technical and regulatory challenges may act as the present challenges for proper clinical implementation. However, these new technologies and devices might offer great opportunities for the provision of accessibility to testing and education specifically among the marginalized populations. There is a greater possibility to proceed with linking these newer methods to conventional clinical practice for the improvement of health-related outcomes and the challenges faced by women all through their lifetime.

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Modern Approaches to Maternal Health Initiatives

The book *Modern Approaches to Maternal Health Initiatives* by FOGSI intends to focus on modern approaches to maternal health initiatives. The first section, Health Policies and Strategies, includes chapters on preconception health care, guidelines for quality antenatal care, midwife-led obstetric care, audits in maternal health, perinatal mental health, and violence against women, among other topics.

The second section, Newer Technologies and Treatments, focuses on FemTech (the notion of maternal/female health care through technology), PPH armamentarium, skill laboratories and simulators, preeclampsia biomarkers, e-learning, and improvements in fetal treatments, among other things.



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