FASTTraCS

Enhancing University Support Structures for FemTech

About FastTraCS

FastTraCS, UNC-Chapel Hill's pioneering MedTech incubator, specializes in medical device and technology development through collaborative engineering. We bring together experts from across clinical disciplines to develop groundbreaking solutions aimed at improving patient care and enhancing community health outcomes.

About FemTech

FastTraCS is at the forefront of FemTech—a field dedicated to developing technological solutions that address unique unmet needs in women. Our work in women's health includes extensive expertise in Obstetrics & Gynecology and other specialties. Our actively growing portfolio aims to introduce breakthrough solutions that address critical needs. Our strong network of healthcare provider innovators and collaborators uniquely positions us to affect a meaningful change on the future of women's health.

UNC
SCHOOL OF MEDICINE
North Carolina Translational and Clinical Sciences Institute

CONTENTS

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Introduction

FemTech includes software, diagnostics, products, and services that address reproductive, pregnancy, nursing, and general health and wellness for women [1–5]. Pioneers in this field face a gauntlet of unique challenges in translating promising concepts into commercially viable, market-ready solutions despite immense potential to enhance quality of life, address healthcare disparities, and generate substantial socioeconomic benefits. These challenges contribute to the zero-growth seen in 510(k) device clearances over the last decade (Figure 1). The scope and complexity of needs within the domain of women's health introduces numerous barriers to innovation and translating concepts into clinical practice.

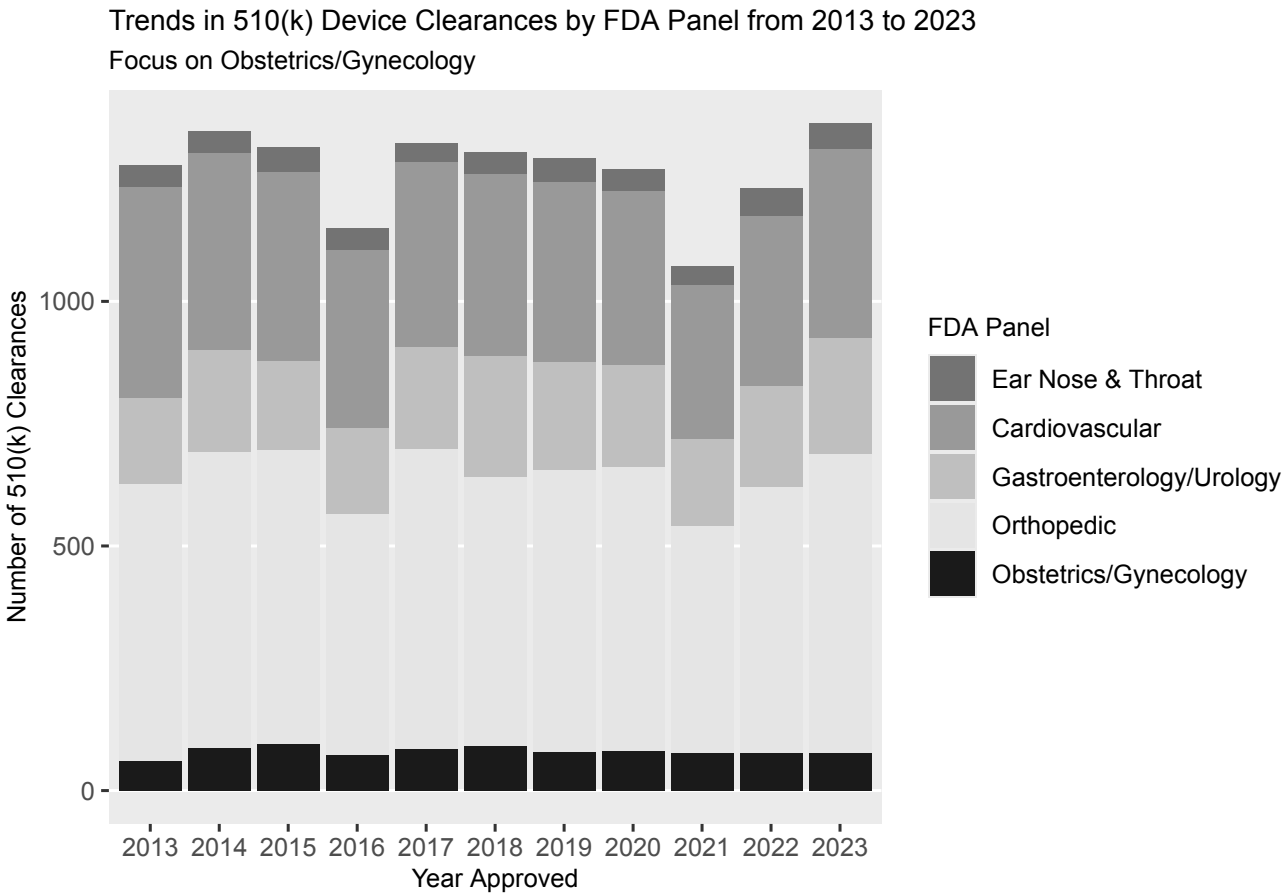

Figure 1. Stagnation in 510(k) Device Clearances for Obstetrics/Gynecology (2013–2023)
Compared to other clinical specialties, FDA 510(k) device clearances in Obstetrics/Gynecology have stagnated over the past decade, despite significant unmet needs and increasing opportunities for innovation in women's health. Data was sourced from OpenFDA (https://open.fda.gov).

We assembled stakeholders across multiple stages of the innovation process including designers, engineers, investors, entrepreneurs, and clinicians to better define these barriers, potential solutions, and leverage their expertise within a set of design thinking (DT) exercises [6] in October 2023. While this user-centered approach gained popularity in the 1960s, later becoming common in companies in consumer-oriented industries, DT integration within healthcare innovation is rarely utilized [7–14]. In contrast to other methodologies, DT is a flexible, iterative process that establishes a user-centered approach throughout the innovation spectrum, from identification of needs through to prototype development and testing [14,15].

Approach

This guided DT exercise was held as a single day event with fourteen experts in women's health, including clinicians, designers, biomedical engineers, health services researchers, and investors who were also associated with the university innovation community at the University of North Carolina at Chapel Hill (UNC-Chapel Hill). DT approaches were utilized to interactively brainstorm, define, and rank key barriers and potential solutions in FemTech innovation within the context of an academic healthcare system, leading to a specific focus on two central "sprint" questions: 1) What barriers currently exist to commercialize FemTech projects? and 2) What are specific programs or initiatives that would address these barriers? DT sessions culminated in anonymous ranking of ideas put forward by individual group members. Each stakeholder was provided with three votes with which to rank the importance of the responses. Participants could apply their votes (0-3) to any idea presented with total scores leading to rankings (max of 42 votes).

Results

Q1: What barriers currently exist to commercializing FemTech projects?

A scarcity of funding streams allocated to supporting FemTech innovations, particularly in early de-risking stages, was recognized as an overwhelming barrier by the group (43%; Table 1a). This

was also deemed to reflect a broader societal undervaluation and lack of prioritization to address unmet needs in women's health. Other highly ranked barriers included entrenched patriarchal structures, along with lack of clarity around institutional innovation regulations and pathways.

Q2: What are specific programs or initiatives that would address this lack of money/funding/investment barrier?

Participants were asked to brainstorm programs or initiatives to bridge funding gaps within FemTech, considering institutional and external resources. As before, solutions were proposed, voted on, and ranked (Table 1b). Directed internal funding for women's health was identified as the top initiative, with bridge or transition funding that would provide continuity of support through commercialization. A university-supported "generator" dedicated to FemTech technology development was also identified as a high priority.

Discussion

Translation of FemTech solutions from identified need through to a usable product comes with many barriers for both new and experienced innovators. The DT approach provides one avenue to integrate end-user and key stakeholder perspectives in the process of need finding as well as solution development. In our DT session, participants identified a range of barriers underscoring the complex landscape in which FemTech operates and highlighting the need for targeted strategies to foster conducive environments supportive of innovation and commercialization.

Innovation Navigation

Significant importance was placed on the need for a navigator focused on FemTech, serving as a conduit to identify and support women's health-related work across the university and healthcare system. For example, the navigator could foster a more integrated approach to innovation by introducing technologists to interested clinicians and potential investors. More broadly, greater transparency of innovation policies

(e.g., intellectual property assignment and royalty protocols) is needed. Additionally, university-sponsored events to generate creative solutions to specific women's health challenges, such as an 'ideathon', were highlighted as an opportunity to advance partnerships across the University and broader community. Funding was highlighted as a major limitation in innovation support. Since the DT event, several external funding mechanisms have been issued in 2024, including a national executive order for a historic new investment of $12 billion in funding for women's health research [16].

Advisory council and community building

The creation of a FemTech community advisory group to strategically guide FemTech innovation through the institution was also proposed. Meaningful community partnerships were noted as a critical area for growth, with the goal of fostering connections and building trust among patients, clinicians, researchers, and entrepreneurs, to align community-based identification of gaps and proposed solutions. This could be achieved by organizing open events sponsored by the University and in partnership with existing women's health groups (i.e., FemTech Focus), further encouraging collaborative investment at the cross-section of non-profit institutions and social enterprise sectors [17]. While stakeholder engagement has long been recognized in healthcare delivery, its implementation can pose significant challenges in terms of time, cost, and complexity, often resulting in stakeholders being relegated to superficial roles or token representation. More broadly, effective use of implementation science frameworks were recognized as an important component across the FemTech innovation life cycle.

While DT approaches are helping to identify barriers and potential solutions, it is essential to recognize that it is one tool of many and not sufficient to resolve drivers of FemTech success. While focused on institutional needs and barriers at UNC-Chapel Hill, we expect that these same barriers, and potential solutions to address them, extend to other academic and private health care systems. Broader communication and coordination of efforts across institutions could dramatically launch a thriving FemTech innovation ecosystem, with a transformative impact on culture, policies, and practices for women's health globally.

Table 1. Barriers and Potential Solutions to FemTech and Women's Health Innovation (N=42 votes total))		
1a. Barriers (Top 6)	**Votes n (%)**	**Details**
Insufficient Financial Resources	18 (43%)	• Funding and support are scarce, particularly during the initial discovery phases of FemTech projects. • Even when financial resources are available, a clear focus on directing these funds towards FemTech projects is absent, resulting in a failure to prioritize these areas. • Challenging reimbursement policies and disparities within private equity/venture capital investment pose significant challenges to commercialization.
Patriarchy and Lack of Trust	11 (26%)	• Historically, patriarchal structures within healthcare have marginalized the unique health needs of women, resulting in significant disparities. • Cultural and commercial undervaluation of women's well-being has contributed to a trust deficit among researchers, engineers, and entrepreneurs, further compounded by an insufficient emphasis on patient-centered research and translation.
Innovation Process Ambiguity	4 (10%)	• The pathway from conceptualization to commercialization in the institutional ecosystem remains complex, leaving innovators uncertain about what resources are needed, and when. • Uncertainty is compounded by lack of 'best practice' guidance to steer innovators' journey throughout various stages of development or technology.
Technology Translation	2 (4%)	• Innovative ideas may not always translate into a profitable business due to market misalignment or cost challenges. • A concept's clinical potential can often be overshadowed by its lack of commercial feasibility, particularly within women's health.
Safety Considerations	1 (2%)	• The development of new drugs and devices for women's health may be hindered due to difficulty in designing and assessing safety for specific sub-populations of women, especially among pregnant women which is deemed very high risk.
Time Management	1 (2%)	• The learning curve associated with innovation and entrepreneurship significantly slows down the pace of innovation. • Aspiring faculty, staff and students must navigate a complex web of regulations and business strategy, which can be time-consuming and often detracts from the core focus on technology development and translational research. • This barrier can delay the translation of promising FemTech ideas into market-ready solutions that can benefit women's health.

1b. Solutions (Top 5)	Votes n (%)	Details
Directed funding/ bridge funding	9 (21%)	• Need finding identified specific women's health funding as a top initiative, acknowledging the importance of leveraging technology to improve access to healthcare, enhance diagnostics and treatment options, and empower women to take control of their health. • Showcasing, and securing investments from those who have successfully navigated FemTech product development could serve as a beacon for new ventures. • A model for this approach, Arch Grants, was highlighted as an impactful leader in targeted venture philanthropy [18]. • Interim bridge funding to acknowledge the achievements within institutional FemTech sector—ensure the continued development and progression of projects toward commercial viability.
FemTech Generator	5 (11%)	• Internal development of a concept or innovation generator aimed at addressing needs and challenges within the women's healthcare industry. This could encompass a wide range of activities, from brainstorming sessions and innovation workshops to software algorithms and automated tools designed to identify gaps in healthcare services or opportunities for improvement. • Funded by available mechanisms such as SBIRs and STTRs • Would require significant institutional support, with a designated portion of UNC or UNC Health's budget earmarked for FemTech projects.
Marketing support	5 (11%)	• Leverage strategic marketing to cast a spotlight on the funding shortfalls in FemTech and women's health, while also rallying a community of advocates to initiate a movement for change. • Engage with development support and explore crowdsourcing platforms to tap into philanthropic streams and public contributions, broadening the financial foundation for innovation in this vital field.
Public & Investor Education	4 (10%)	• Close the knowledge gap through educational outreach to funders, dissemination, and sponsored events and conferences. • Development of educational channels and content for a wide audience to raise awareness and understanding in areas of high unmet need.
Need demonstration	3 (7%)	• The demand for innovative solutions and devices in the FemTech domain is pressing. It is essential to magnify this need to spur action among both the creators of these technologies and the consumers who will benefit from them.

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