FASTTraCS

Unmet Needs in Reproductive Endocrinology & Infertility

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.

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CONTENTS

Acknowledgements 3

Introduction 4

Approach 6

Results 6

Discussion 6

Table 1: Unmet Needs 11

References 13

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Introduction

Reproductive Endocrinology and Infertility (REI) faces a unique set of challenges, from intricacies of hormonal treatment protocols to the complexities of patient care pathways. UNC Fertility, like many growing infertility clinics, needs to bridge these gaps not only to enhance clinical outcomes, but also to improve patient experience and operational efficiency

The practice of in vitro fertilization (IVF) has experienced remarkable innovation over nearly five decades since the birth of the first IVF baby, evolving from a groundbreaking experimental procedure in 1978 into a cornerstone of modern reproductive medicine [1]. Early attempts at IVF were characterized by modest success rates—challenged by low implantation efficiencies, high rates of multiple pregnancies, and complications like ovarian hyperstimulation syndrome. However, progress through innovation has reshaped the landscape of fertility treatment [2].

Advancements in laboratory techniques have been particularly transformative. The development of specialized, stage-specific culture media has improved the in vitro environment, significantly enhancing embryo development and implantation rates. The introduction of blastocyst transfer, combined with refined methods for controlled ovarian stimulation, has not only increased the efficiency of IVF but also minimized risks associated with multiple gestations.

Additionally, improvements in oocyte and embryo cryopreservation, particularly through vitrification, have expanded reproductive options for patients facing infertility due to age-related decline or medical treatments such as chemotherapy. These advances have paved the way for more personalized and less invasive treatment protocols. Collectively, the innovations of the past four decades have not only enhanced clinical outcomes but have also spurred the development of emerging technologies in reproductive genetics and individualized treatment strategies, ensuring that IVF remains at the forefront of reproductive innovation.

As of 2025, there are roughly 500 reproductive medicine clinics in the US [3]. Academic medical centers remain highly ranked

in the US, and include the Weill Cornell Medicine Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine, Duke Fertility Center, Columbia University Fertility Center and UNC Fertility [4]. In recent years, private clinics have increasingly gained traction. These promise affordability, innovative care delivery and add-on services (e.g. comprehensive chromosome screening (CCS)). Examples include Boston IVF (https://www.bostonivf.com/), Kindbody (https://kindbody.com/) and CNY Fertility (https://www.cnyfertility.com/).

With national IVF volumes steadily increasing and U.S. birth rates now below population replacement thresholds, fertility care has become a public health priority. Recent data from the Society for Assisted Reproductive Technology (SART) underscore this trend: in 2023, more than 432,000 IVF cycles were performed across 371 SART member clinics—up from 389,993 in 2022—leading to the birth of 95,860 babies, or 2.6% of all U.S. births. This reflects both rising demand and improving outcomes in assisted reproductive technologies [5]. These gains are occurring alongside expanded insurance coverage in select employment sectors and greater public awareness due to national discourse around reproductive health. Together, these factors emphasize the urgent need to optimize and innovate within fertility care delivery to meet growing patient demand and ensure equitable access to high-quality, effective treatment.

Even with advancements in technology and availability of treatment centers, challenges remain . Couples seeking IVF treatment experience significant drop-out rates (est. 10-50%), mainly due to physical or psychological burden of treatment [6]. In the US, the cost of IVF treatment is significant; though notably in countries with universal health care, drop-out rates remain high, estimated up to 25% [7].

Here we describe a facilitated Design Thinking session convened with key stakeholders from UNC Fertility, including clinicians, nurses, and administrative staff. The session was structured around rapid ideation techniques designed to surface unmet needs in a time-efficient and collaborative manner. Participants engaged in various activities like creative warmups, individual brainstorming, thematic clustering and rank voting to identify

the most salient issues. This human-centered approach not only highlights critical pain points within the current REI workflows but also creates an opportunity for novel, needed and innovative solutions.

Approach

A 90-minute lunchtime session followed a structured, yet fast-paced agenda tailored to rapidly uncover and prioritize unmet needs in REI. After a brief overview and warm-up exercise, 13 participants were presented with the central prompt: "**What unmet needs are most pressing for REI providers and patients?**" Working independently, each attendee noted as many needs as possible within a five-minute window, then selected the most compelling one(s) to share with the group. Subsequently, attendees voted (with each participant receiving three votes) to identify needs they felt passionate about addressing. Though the workshop also introduced solution-generation activities—such as "Crazy Eights "—this whitepaper focuses on the need identification process, forming a foundation for further ideation and potential innovations within Assisted Reproductive Technologies (ART).

Results

Table 1 summarizes the outcomes of the voting exercise on unmet needs at UNC Fertility. Participants distributed a total of 39 votes among a range of issues that impact both patient care and clinical operations. Among the highest-ranked challenges were those related to the burden of multiple daily injections, limited clinical space, and the shortcomings of the current electronic medical record system. Each of these three needs received 6 votes, accounting for 15% of the total votes. This strong endorsement reflects the critical need for streamlined treatment protocols or innovative drug delivery solutions to reduce the frequency of injections, as well as the call for redesigned physical spaces that optimize workflow and enhance patient comfort. Similarly, participants underscored the necessity for a more integrated and user-friendly electronic medical record (EMR) system that supports the unique workflow of UNC Fertility, particularly in light of limitations associated with a non-Epic EMR system.

Other notable priorities included the need to improve ultrasound quality for patients with higher body mass indices, which received 5 votes (13%), and the need for better statistical tracking and data management systems, which garnered 4 votes (10%). Additional concerns, such as the high cost of fertility treatments and limited access to remote ultrasound evaluations, each received 3 votes (8%), emphasizing the importance of making care more accessible and affordable.

While some needs—specifically, the requirement for a medication tracker, more customizable ovulation induction (OI) stimulation templates, guidance for donor sperm selection, and the processes for creating or updating intraoperative flowsheets and medication customization during cycles—received 0 votes, these issues were still selected as the "best" individually generated ideas by some participants. Their inclusion in Table 1 highlights that, although they did not resonate as strongly overall, they remain areas of concern for stakeholders.

Discussion

The results of the Design Thinking session underscored three critical challenges within the REI Division at UNC Fertility: The need to streamline complex medication management protocols to reduce the burden of daily injections, the urgent requirement for optimizing physical space to improve workflow and patient care, and the limitations of the current electronic medical record system. These issues, each with significant implications for clinical efficiency and patient outcomes, form the cornerstone for targeted innovation in practice.

The need for reducing multiple daily injections emerged as one of the top priorities, reflecting the significant burden placed on fertility patients during hormone treatment protocols. Frequent injections not only increase patient discomfort but also introduce a range of specific challenges. Patients are required to manage multiple medications, in some cases three distinct injections on a strict regimen, each requiring precise dosing and scheduling over a defined duration—a critical factor that can significantly impact egg development and release. Inadequate management can lead to suboptimal outcomes, resulting in wasted time, effort, and financial resources.

Figure 1. Gonal-f, a common IVF medication containing follicle-stimulating hormone (FSH)

Gonal-f contains lyophilized follitropin alfa, used for controlled ovarian stimulation. Patients must reconstitute with sterile water using the included syringe and adequately mix solution. Administration is subcutaneous using small gauge needle. Proper dosing requires precise measurement based on individualized stimulation protocols.

In one qualitative study involving clinicians and IVF patients from the UK, US, and France, patients reported significantly higher levels of stress from daily hormone injections than clinicians anticipated. Notably, many clinicians were unaware that patients frequently believed they had made dosing or administration errors during controlled ovarian stimulation (COS), underscoring a critical gap in provider understanding of the patient experience [8].

Managing injections is complicated by requirements such as proper refrigeration, reconstitution process , and the need for accurate site selection. Patient education is essential to navigate these challenges, yet many women (disproportionally to men) experience significant needle-related anxiety, or trypanophobia, with estimated rates from 10-30% [9,10]. Addressing this need could involve the development of innovative drug delivery devices—such as long-acting injectables, wearable infusion systems, or simplified auto-injectors—and the redesign of treatment protocols to reduce injection frequency, thereby improving adherence and overall treatment outcomes.

Equally pressing is the issue of inadequate physical space that may occur in IVF clinics. This underscores the challenges that arise from limited office and patient room availability, which can disrupt workflow, reduce efficiency, and negatively affect the

patient experience. Optimizing clinical space is critical not only for ensuring that patients receive timely and private care but also for supporting the interdisciplinary collaboration essential for innovative care delivery. Redesigning or expanding existing facilities to better accommodate both administrative functions and clinical services may yield substantial improvements in operational efficiency and patient outcomes.

The third highly ranked need is related to EMR systems—arguably the most pervasive pain point experienced by healthcare providers. Participants noted that not being on UNC's Epic system and the constraints of the existing UNC Fertility EMR create significant barriers to seamless communication, documentation, and overall clinical workflow. A more integrated, user-friendly EMR system could facilitate better information sharing between providers and patients, reduce administrative burden, and ultimately support a more streamlined care process. While Epic is one of the major EMR providers, other specialized products exists such as eIVF (https://eivf.org/) and MediTEX IVF (https://www.ivf.software/) and BabySentry (https://www.babysentry.com/). Migrating to new EMR infrastructure is not only a technical challenge but also costly, considerations around cost-effectiveness and provider satisfaction are essential.

Together, these three top priorities—streamlining treatment protocols to reduce daily injections, optimizing physical space, and upgrading the EMR system—can be viewed as generalizable challenges in healthcare that seeks to enhance both patient experience and clinical efficiency. Addressing these challenges will require distinct approaches as each solution space is quite different. For example, optimizing clinic space would require significant capital, construction/engineering partners and a human-centered design philosophy to achieve an improved patient and provider experience.

This Design Thinking session highlighted that frequent medication administration, suboptimal physical space, and pervasive EMR limitations remain difficult problems to solve. These needs not only affect clinical efficiency and patient outcomes but also present significant opportunities for innovation in ART and IVF. Moving forward, potential solutions

should be assessed against measurable and concrete prospective outcomes. For instance, how might improve clinic space that boosts patient flow by 10% or 25% affect outcomes? If a new EMR system were implemented, how would provider satisfaction rates shift?

Such challenges are all too common in the dynamic and complex world of healthcare. Through white papers like this, these issues become better understood and characterized. All too often, important topics in healthcare go unaddressed due to lack of awareness, bias, or the perception that they are too niche.

Policy and the Future of Access to Fertility Care

Recent political discourse has elevated national awareness and urgency around reproductive care, particularly regarding access to assisted reproductive technologies (ART) such as in vitro fertilization (IVF). This increased visibility has catalyzed legislative and policy-level actions across multiple sectors, underscoring a broader recognition that fertility care is not a niche service but a vital component of reproductive health.

One major development is California's passage of SB 729, a landmark bill requiring large-group health plans and disability insurance policies to cover the diagnosis and treatment of infertility, including IVF services. This positions California as a leader in expanding insurance access to ART, with potential to influence legislation in other states [11].

Further spotlighting the issue, President Trump's executive order on February 18, 2025, directed the Assistant to the President for Domestic Policy to develop policy recommendations aimed at reducing IVF-related out-of-pocket expenses and insurance barriers. Although the executive order itself does not enact immediate changes, it initiates a 90-day policy development process that could result in lower-cost access to IVF—a treatment that can currently cost patients $12,000 to $25,000 per cycle. The order also reaffirms IVF as a safe and effective medical intervention, a point emphasized by clinical leaders and professional organizations in response to broader political discussions around reproductive health [12].

Together, these developments reflect a shifting policy landscape that increasingly acknowledges the importance of fertility care. For the field of reproductive medicine, this is both a challenge and an opportunity: a call to accelerate innovation in clinical delivery, technology, and patient experience to meet growing demand while navigating evolving policy frameworks.

Table 1. Unmet Needs in Reproductive Endocrinology and Infertility (n=39 votes total)		
Unmet Needs	**Votes n (%)**	**Need Statement**
Multiple injections per day	6 (15%)	Fertility patients undergoing hormone treatments often face the burden of administering multiple injections each day. There is a need for either streamlined treatment protocols or innovative drug delivery devices that reduce injection frequency and minimize discomfort, ultimately improving patient adherence and overall treatment experience.
Limited clinic space	6 (15%)	Fertility clinics require optimally designed physical spaces that balance efficiency with patient comfort and privacy. Limited office and treatment room space can hinder workflow and negatively impact the patient experience, indicating a need for space optimization or redesign.
Better EMR System for providers and patients	6 (15%)	The current electronic medical record systems do not fully meet the specialized needs of fertility clinics. Specifically, not being on UNC's Epic system and the limitations of the UNC Fertility EMR highlight a need for a more integrated, user-friendly system that enhances communication between providers and patients, streamlines clinical documentation, and supports the unique workflow of fertility care.
Ultrasound quality with obese patients	5 (13%)	Standard ultrasound equipment often falls short in providing high-quality imaging for patients with higher body mass index (BMI), potentially compromising diagnostic accuracy. There is a need for enhanced ultrasound technologies or protocols specifically tailored to improve image quality in obese fertility patients.
Better data management	4 (10%)	Effective decision-making in fertility care is hampered by inadequate data management systems. There is a need for improved statistical tracking and data management tools that can capture, analyze, and report treatment outcomes, thereby enabling providers to optimize protocols and improve patient care.
More affordable care	3 (8%)	The high cost of fertility treatments remains a significant barrier for many patients. There is a need for solutions that drive down costs or improve financing options, making fertility care more accessible and reducing the financial burden on patients.
Remote ultrasound evaluations	3 (8%)	Limited access to expert ultrasound evaluations, especially for patients in remote or underserved areas, can delay diagnosis and treatment. There is a need for remote ultrasound evaluation capabilities that facilitate timely expert assessments without the necessity for in-person visits.

Table 1. Unmet Needs in Reproductive Endocrinology and Infertility (n=39 votes total)		
Unmet Needs	**Votes n (%)**	**Need Statement**
Medication tracking for correct dose administration	1 (3%)	Accurate medication dosing is critical in fertility treatments, yet patients may struggle with tracking their medications. There is a need for a reliable medication tracking system that confirms when the correct dose is administered and monitors remaining supplies to support effective treatment management.
Ovulation induction (OI) template flexibility	1 (3%)	Current OI templates are not sufficiently customizable, limiting their utility in individualizing treatment protocols. There is a need for more adaptable and user-friendly OI stim sheet templates that allow clinicians to tailor treatment plans to each patient's unique requirements.
Guidance on donor sperm selection	0 (0%)	Patients considering donor sperm options often face confusion during the selection process. There is a need for enhanced guidance—possibly through dedicated counseling, additional appointments or artificial intelligence—to help these patients navigate donor selection more confidently and make informed decisions.
Creating / updating Intraoperative flowsheets	0 (0%)	The process for creating and updating intraoperative flowsheets can be inefficient and error-prone. There is a need for streamlined digital tools or templates that simplify documentation and ensure that flowsheets remain current and accurate throughout the treatment cycle.
Medication customization during cycles	0 (0%)	Fertility treatments require personalized medication dosing that adjusts to patient responses during a cycle. There is a need for flexible dosing systems or protocols that allow for real-time customization, improving treatment efficacy and reducing side effects.

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