Innovation in reproductive medicine: time to reimagine and redesign

Over that past 5 years, the use of the word "innovation" has exponentially increased. The word innovation comes from the Latin word innovare, and the modern usage refers to "a novel change, experimental variation or an alteration made to an existing product, idea, or field." To successfully innovate, one must think creatively and outside the box to generate new ideas that typically result in incremental enhancements on existing processes. The expanding field of innovation has developed validated techniques for testing these ideas, such as performing rapid cycles of experimentation and evaluation, and then implementing the ideas that succeed and moving past those that fail (1). This latter and perhaps most challenging task requires innovators to be forward-thinking, open-minded, and collaborative.

Globalization has made corporations more aware of fierce marketplace competition. This means that businesses need to be nimble and adapt to a constantly changing and fast-paced environment. Innovations are most apparent—and have been exceedingly successful—in fields that intersect with technology, such as online shopping, travel reservations, and door-to-door deliveries. Why then have some innovations been termed as disruptive? This term, first coined by Clayton Christensen (2) in 1995, describes a significant change: *disruptive innovations* can make expensive or sophisticated businesses. The classic examples of disruptive innovation include the impact of low-cost digital cameras on film cameras, availability of ridesharing services on taxicabs, and effect of online book sales on corner book stores.

HOW BROAD IS THE SCOPE OF INNOVATION IN HEALTHCARE

Both *management and process innovation* can streamline healthcare delivery, enhancing our ability to offer value-based care and a seamless patient experience. We have also witnessed tremendous growth in *service and product innovation*; the latter includes direct-to-consumer (D2C) health applications and wearable devices that improve the customer experience. Over the past several decades, we are using increasingly more medical devices within our homes. Thermometers, weighing scales, blood pressure monitors, glucose monitoring devices, and more recently, pulse oximeters, and electrocardiography were all exclusively used in physician offices and hospitals; however, now they can be wirelessly connected from our homes and even from our wrists to our physicians. The ease and success of home monitoring have led to the development of disruptive innovations in healthcare, such as home polysomnography and portable ultrasound devices. For example, a handheld ultrasound connected to a wireless smartphone at home can, in several cases, substitute for the larger sophisticated machines in diagnostic centers or hospitals. The impact of these product innovations is far-reaching because they make testing affordable and even accessible in remote parts of the world. How will such disruptive innovations impact practice patterns of healthcare professionals? It is evident that these devices will not replace healthcare providers. However, in selected cases, these devices can assist physicians in prioritizing or even reducing their workload and thereby shorten the time to diagnosis. For example, artificial intelligence-augmented algorithms can support physicians by performing preliminary interpretations of radiographic or pathology images. As implementation of innovations—incremental or radical—lead to redesigning of our care delivery models, physicians and health systems will both need to be prepared for uncertainty and accept change.

HAS INVESTMENT IN FemTech INCREASED OVER THE PAST DECADE?

The word "FemTech," coined in 2016 by Danish entrepreneur Ida Tin, refers to *technology-based innovation* specifically for women's health that includes diagnostics, medical devices, software, therapeutics, and consumer products and services. For example, commonly known FemTech products include applications and wearable devices that track menstrual cycles, predict fertility windows, and even monitor Kegel exercises. Innovations such as wireless maternal uterine and fetal heart rate monitoring have the potential to disrupt current practice patterns in obstetrics while extending care to low-resource settings. Even though *FemTech innovations* target women all over the world, investment in FemTech was $<5\%$ of all health technology funding in 2020 (3). Projections for this decade, however, are soaring; specifically, fertility-related services are targeted to be high yield. Entrepreneurs are capitalizing on the growing demand for fertility services resulting from delayed childbearing, wider acceptance of the use of donor gametes and embryos, and improved employer-based and state-mandated fertility insurance benefits in the United States. With this increased demand has come the awareness of several pain points in the delivery of fertility services and, thereby, opportunities for innovation. How will investment in FemTech impact the delivery of fertility care?

INCREASE D2C FERTILITY DIAGNOSTICS

To alleviate the anxiety and stress associated with infertility, several companies offer D2C tests that measure reproductive hormones and evaluate semen parameters. Some start-ups are also evaluating the feasibility of using portable ultrasounds for fertility assessments in the comfort of patients' homes. The high demand for at-home testing indicates a market for evaluating fertility potential even before a person meets the definition of infertility. This raises a valid question: why does an individual need to attempt pregnancy for 6–12 months before a physician evaluates their fertility status (4)? If patients can be offered screening for conditions with lower prevalence during the reproductive years, such as thyroid dysfunction and diabetes, surely there is an opportunity to offer fertility evaluation to those who desire it. To further improve the customer experience, several D2C companies provide the option to use health spending account dollars,

join support groups, and schedule virtual visits with a fertility nurse. On a cautionary note, as D2C product innovation expands, it is imperative that companies are transparent regarding the diagnostic accuracy of their tests. This is critical because overdiagnosis can result in both additional testing and medical overuse, resulting in increased patient stress and anxiety. Furthermore, as at-home tests cannot replace evaluation by healthcare professionals, robust algorithms need to be in place for counseling patients regarding their results. Although the proponents of these technologies argue that they increase awareness, empower patients, and could shorten the time to receiving therapy, it is noteworthy that the cost-effectiveness of these products is unclear.

CHANGE MODELS OF CARE DELIVERY

The coronavirus disease 2019 pandemic has resulted in several physician groups pivoting to telehealth to deliver a range of fertility services, such as counseling patients, providing educational information, and even signing consents. This modality of care delivery has been well received by our patients because it decreases the overall burden associated with multivisit and time-sensitive fertility treatments. At Penn Fertility Care, we implemented an innovative model of care delivery called Fast Track to Fertility to improve patient access and shorten the time to initiate treatment. In this model, a nurse practitioner conducts a virtual visit with a new patient to obtain a detailed history, review past records, and order diagnostic tests. Because of the complex and menstrual cycle-linked testing algorithms, we developed an artificial intelligence-augmented semiautomated chatbot. This texting platform sends reminders regarding next steps, provides information related to diagnostic tests, and engages in 2-way conversations using natural language processing. In addition to decreasing the time to completing the workup, this hybrid model can decrease messages in the patient portal and increase patient satisfaction. Moreover, this process innovation has improved job satisfaction for our nurse practitioners because they are now able to work at the top of their license. The availability of all results at the consultation visit also enhances the physician and patient experience because it allows them to engage in a focused discussion regarding treatment options.

INCREASE AUTOMATION IN THE IN VITRO FERTILIZATION LABORATORY

In our field, the in vitro fertilization (IVF) laboratory has been the site of most product innovations. Of these, low-cost intravaginal IVF culture systems have the potential to bring fertility treatments to underresourced parts of the world. As the demand for IVF services continues to expand, advances such as iris recognition at microscopes and workstations and radio frequency identification tagging of receptacles holding gametes and embryos show great promise to decrease the risk of liability and burnout in clinical embryologists (5). In addition, deep learning models trained with high-quality embryo image data derived from time-lapse videography could inexpensively automate parts of the embryo grading process. The successful implementation of automation in various IVF laboratory processes will improve work efficiencies, provide high-quality patient care, and meet the increased demand for IVF services.

I anticipate that during this decade, the number and scope of innovations in reproductive medicine will continue to increase. How can we all participate and contribute to these waves of innovation? Here are a few highlights I have learned during my firsthand experience with healthcare innovation. The framework for testing innovations in healthcare delivery includes defining and gaining insight into a problem and then intentionally exploring a broad range of solutions and performing rapid cycles to either validate or invalidate your proposed solutions (1). Defining a problem includes an in-depth contextual inquiry to see old problems with a new lens to reframe the question and design new solutions. While performing rapid cycles to test these solutions, one can apply newer methods such as vapor test, fake front ends, or fake back ends to test critical assumptions quickly and at low costs (1). This approach differs markedly from methodologies used to answer a research question in the laboratory and from experimental designs used to assess the efficacy of clinical interventions. In our field, we have a unique opportunity to leverage technology because our reproductive-age patients (typically millennials) readily embrace technology-based innovations, and we need to respond to their expectation that healthcare will be as seamless and efficient as other industries. We must contribute to different types of innovations (e.g., *management*, *process*, *service*, and *product*) from the outset, as early participation will allow us to anticipate changes, ensure fairness, and address biases. All of us at the front lines of healthcare delivery are acutely aware of challenges and pain points impacting the system and, therefore, can provide the best ideas for innovation. Furthermore, it is imperative that we invest in and support innovations that create frictionless workflows for the well-being of both our patients and all healthcare providers.

Anuja Dokras, M.D., Ph.D.
Women's Health Center for Clinical Innovation, Department of Obstetrics and Gynecology, University of Pennsylvania, Philadelphia, Pennsylvania

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