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Source: *Biology of Reproduction*, 103(2) : 167-175

Published By: Society for the Study of Reproduction

URL: <https://doi.org/10.1093/biolre/ioaa086>

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Contraceptive Special Issue

The role of team science in the future of male contraception[†]

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[†]**Grant Support:** This work was supported through the generosity of public donations made to Male Contraceptive Initiative.

Received 15 February 2020; Revised 19 May 2020; Accepted 21 May 2020

Abstract

Efforts to develop a male contraceptive method beyond condoms and vasectomy have been on-going for nearly 70 years. During this time, there have been ebbs and modest flows of resources available to support product development, but not at a level sufficient to carry research efforts through to market. The small community of researchers that have continued to pursue the development of male contraceptives is comprised of dedicated scientists who have a great deal of knowledge and experience to offer. While collaboration has been an organic outcome of limited resources, competing research objectives and geographically diverse locations have made consistent and sustained progress challenging, particularly for those working in the earliest stages of developing nonhormonal, reversible male contraceptive methods. While the past decade has seen an increase in funding to the field, the levels are still modest when placed in the context of actual costs to bring products to market. In addition, there are challenges still to be identified given that there is no regulatory precedent for these products. These challenges present an excellent use case for the application of design-thinking or human centered design, as a means of generating novel solutions. By engaging those with deep technical expertise in the field of male contraception as well as thought leaders from other fields of practice, design-thinking offers an opportunity to identify potential strategies, including nontraditional approaches, capable of driving the product development process forward, in a faster and more efficient manner.

Summary sentence

An organizational framework that engages and supports researchers and demonstrates appreciable collaborative outputs will result in a faster path to market for nonhormonal, reversible male contraceptive products.

Key words: contraception, human reproduction, male sexual function, reproductive behavior.

Introduction

Male contraceptive initiative (MCI), established as a 501(c)3 in 2014, is led by a mission to facilitate the research and development of male contraceptives for people around the world and to build awareness among researchers, donors, and the general public about the demand for and status of novel male contraceptive methods.

While initially focused on advocacy and awareness building, MCI has matured into a leading funder of the research and development of nonhormonal, reversible male contraception (NHRMC), providing more than \$3 million in grant funding since 2017.

With best-case scenario leads in the NHRMC pipeline still over a decade away from market, MCI views its role as one of outreach,

facilitation, and advocacy; serving multiple stakeholders includes researchers, potential product champions, and transitional and transitional change agents who will play a critical role in bridging awareness between the current generation and future end-users of NHRMC products. The overarching goal of these efforts is to facilitate efficiency in current product development processes as well as to proactively predict and mitigate down-stream challenges.

One of the biggest challenges facing the field of NHRMC is the limited availability of funding. While leads in male contraceptive product development have been pursued since the 1930s, many of the traditional avenues of funding for contraceptive R&D have historically focused on developing and improving existing female-targeted methods. This prioritization made sense historically, given the disproportionate burden of an unintended pregnancy, biological and otherwise, that falls upon women. However, the past two decades has seen a renewed interest and growing vocal support for the development of more male contraceptive methods [1, 2]. A consumer research study published by MCI in 2019 indicated that a minimum of 17 million men in the USA alone are seeking contraceptive options, beyond condoms and vasectomy, that fit their lifestyle and relationship status [3]. This desire, fueled by additional concerns regarding the impact of population growth on the environment and social inequities, including links between unintended pregnancy, poverty, and poor health among disadvantaged populations [4], has primed the contraceptive ecosystem to move to a second phase of development. This second phase continues to address the needs of women by expanding and improving upon existing methods while also considering the role of male methods, the needs of men, and their engagement in reproductive health. Indeed, the very nature of gender as a binary concept is being challenged in our current society, calling for a more inclusive view of issues associated with reproductive health [5] that could be supported through a more diverse method mix.

An environment of limited funding, while challenging, does have its benefits. The need for working with limited resources has fostered an intimate research community built on decades of collaboration and partnerships. This sense of community is what compelled MCI to explore how we might expand upon and organize a cooperative practice, a collective that would foster an efficient pace through the product development process with diversity in research concepts and resulting products while also demonstrating a compelling case to contemporary philanthropists and impact investors. This team science approach has been well demonstrated and reported in the literature for the ability to “enhance biomedical research motivation” [6] and for the potential to result in greater productivity and scientific impact while producing more innovative products [7].

To explore the feasibility of developing such a collaborative, MCI looked to harness the power of design-thinking, or human-centered design (HCD), an approach to problem solving that is “constructive, experiential, and rooted in the needs and context of end-users of a product or service to develop novel solutions” [8]. The use of HCD in the global health sector has been an increasing practice over the past decade as a means of improving population-level health outcomes through social innovation [9].

In support of this effort, MCI engaged IDEO, a global design firm that works to advance the practice of HCD across industries from health to technology, to lead an ideation workshop that would facilitate independent thinking as a means of identifying challenges and opportunities in the development of NHRMC.

Given that male contraception is a field with broad, reaching challenges that require a thoughtful cross-disciplinary approach,

Table 1. Overview of expertise across workshop participants.

Area of expertise	# of participants
Blockchain	1
Business design	1
Clinical research	5
Contraceptive research/scientists	18
Engineering	3
Film making	1
Individuals w/ venture capital experience	9
IP law	1
MPT	2
Potential investors	4
Product design	9
Public health	4
Regulatory	2

Note: Some individuals are included in two or more categories.

the 30 workshop attendees represented the NHRMC clinical and laboratory research communities as well as thought leaders from three different continents, representing 11 interdisciplinary fields (Table 1).

Materials and methods

HCD is a solutions-based problem solving methodology rooted in empathizing with individuals most closely affected by a particular challenge. The approach utilizes qualitative and quantitative research methodologies to understand the lives, needs, and aspirations of those who are intended to be served by the design, identifying challenges and working to reposition them as opportunities. The intention is to first develop a holistic understanding of a challenge before collaboratively designing potential interventions to address it (Figure 1).

While HCD is most frequently viewed as a tool to better understand customers for whom a product is being designed, in this situation, MCI viewed HCD as a means of facilitating discussion. The goal was to allow the NHRMC research community to connect through the process of identifying the challenges facing their product development efforts and working together to brainstorm potential solutions. By viewing the research community as customers of resources such as funding and advocacy efforts, MCI would be better positioned to build an effective strategy for supporting the needs of the field.

Of note, only those researchers currently working in the earliest stages of NHRMC were included in the ideation event. This decision was made given that the vast majority of products currently in development for NHRMC are in the earliest stages of product development, discovery, or lead optimization. These leads are also almost exclusively anticipated to qualify as drug products under US Food and Drug Administration regulatory classification. Therefore, they have commonalities in their development process as well as in the associated issues and challenges they will face.

The iterative approach at the core of HCD allowed the participants to work together, building shared empathy as they identified existing challenges, concerns for potential challenges further in the development process, and gaps in knowledge that need to be

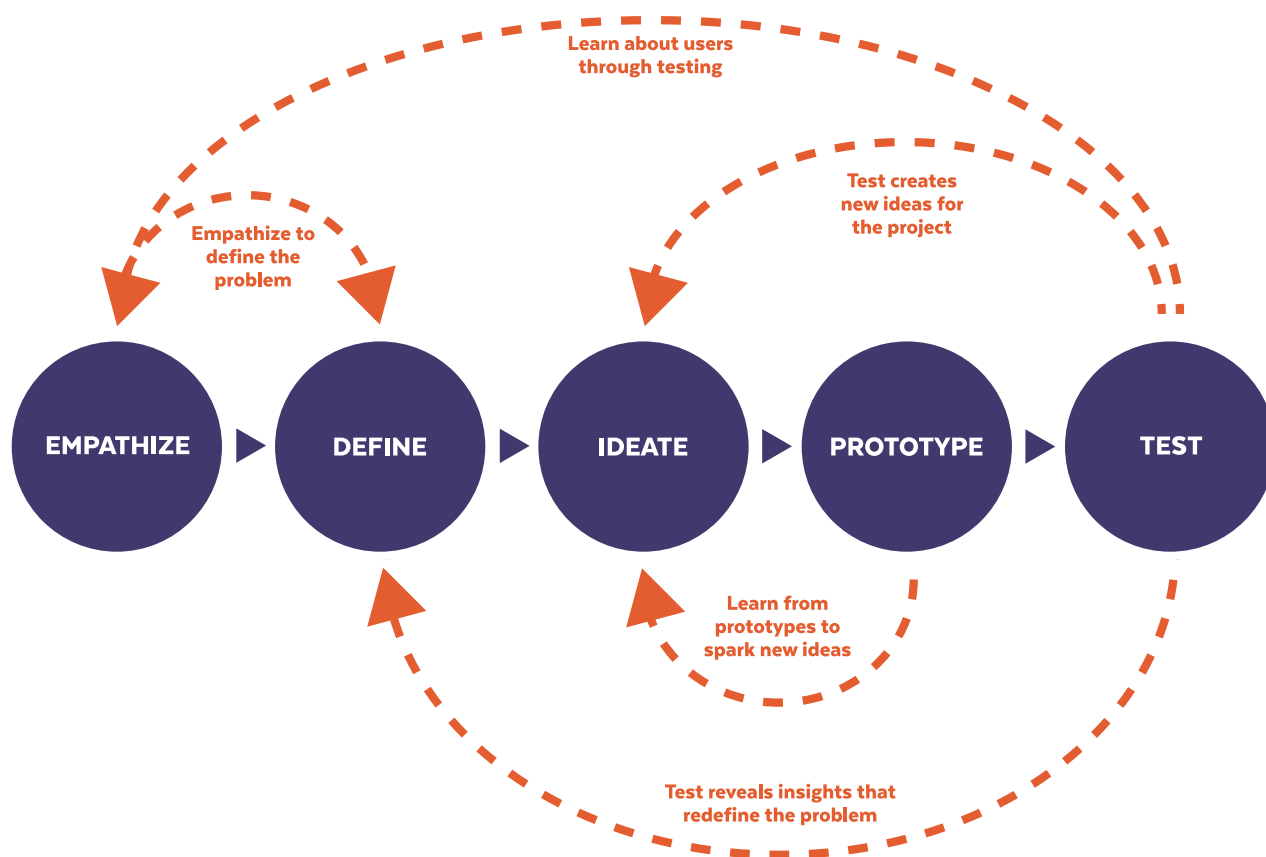


Figure 1. Design-thinking/human-centered design process.

addressed. The first activity of the event focused on reviewing the product development pathway, or “Journey to Market”. This activity asked participants to locate where they and their work currently reside along the development pathway and to list the challenges and gaps in knowledge that they believe need to be addressed across the various stages. This activity was followed by a centering exercise, entitled “North Star” where the participants worked to identify their individual goals as well as a collective purpose in the context of developing NHRMCs. Focusing on these identified purpose(s) of the work, or North Stars, the participants were able to move on to identify key stakeholders related to successfully achieving their goals.

With challenges and stakeholders identified, the participants shifted to the process of brainstorming through ideation and prototyping, developing what is considered the cornerstone of the HCD process—the “How Might We” (HMW) question. The process of developing HMW questions encourages participants to reframe their challenges as opportunities, with a simple three-part question: (1) “How” sets the stage for exploration and assumes that a solution is possible. (2) “Might” encourages ambiguity and optimism, implying that there are likely many viable solutions, not just one, thus allowing participants to consider nonconventional solutions. Finally, (3) “We” emphasizes that solutions will require many voices and experiences, and reinforces the need for collaboration. Setting the stage through HMW questions allowed participants to seamlessly transition through developing approaches or concepts, to answering the questions, and ultimately identifying solutions to the challenges identified. An imperative of this stage of the workshop was to

encourage an environment with freedom from judgment to allow unconstrained ideas to flow freely. It is this freedom that allows participants to consider what they really want “without the constraints of technology or materials” [10] during this early stage of the process.

Concepts, or prototype solutions, were rapidly generated with the assistance of a worksheet that led participants through a brief process of detailing a general overview of their concept, the value proposition, and any additional information or design aspects that would further illustrate their vision. Concepts were then presented to the group and then refined based on patterns identified and various opportunities for combination.

Finally, participants completed a platform canvas exercise to depict what a collaborative relationship would look like between MCI and “someone like them”, with groups forming organically based on how participants associated their primary relationship with MCI: as basic scientists, applied scientists, entrepreneurs, regulators, etc. Key questions were posed to each MCI + partner diad (e.g., MCI + scientists) to address the needs, offerings, benefits associated with the relationship, and hopes and fears of each partner in the context of the relationship.

Interspersed throughout the HCD activities was carefully curated roundtable discussions with nonparticipant experts related to leading products to market, building a collaborative platform, and a field trip to explore concepts of masculinity.

Following completion of the third day of the ideation workshop, MCI and IDEO staff worked together to synthesize the results of the workshop and identify next steps (Figure 2).

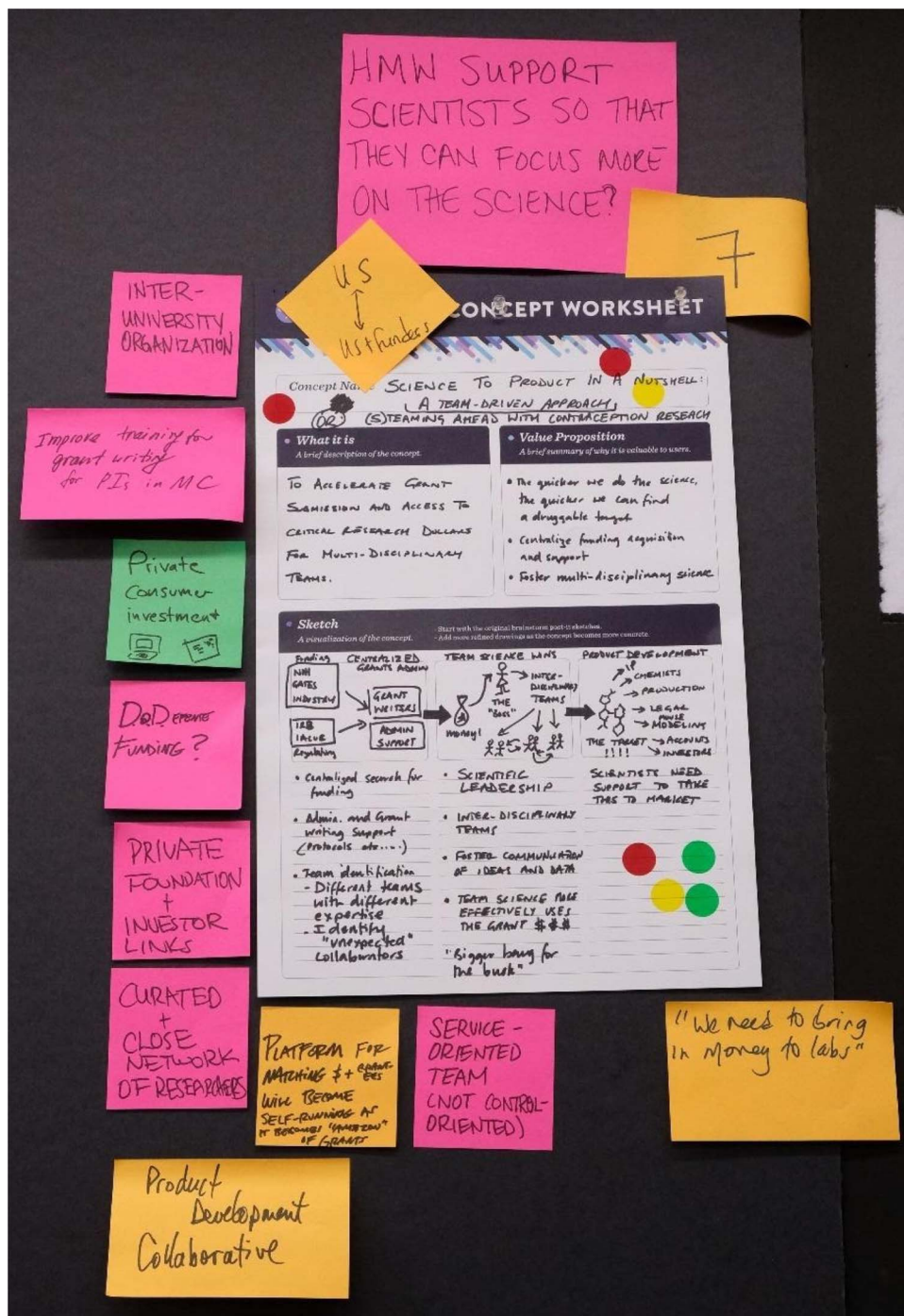


Figure 2. Result of HCD process, including HMW question, concept worksheet, and stakeholders.

Results

Day 1: looking in

Journey to market and challenge identification. It is reasonable to anticipate in any workshop setting that time will be required for participants to “warm up” before deep engagement can be experienced. However, the initial discussion of the drug development pathway quickly became an engaging and animated discussion. The first immediate outcome of this discussion was the understand-

ing that the concept of product development as a linear pathway is misrepresentative of the actual process. Participants coined the term “swirling vortex” as a more accurate visual representation of the process, where each step forward is, indeed, dependent upon the previous step, but also where steps often require iteration and feedback loops that can transition efforts back to previous steps. This reframing has resulted in the development of a swirling vortex model based on input from workshop participants (Figure 3).

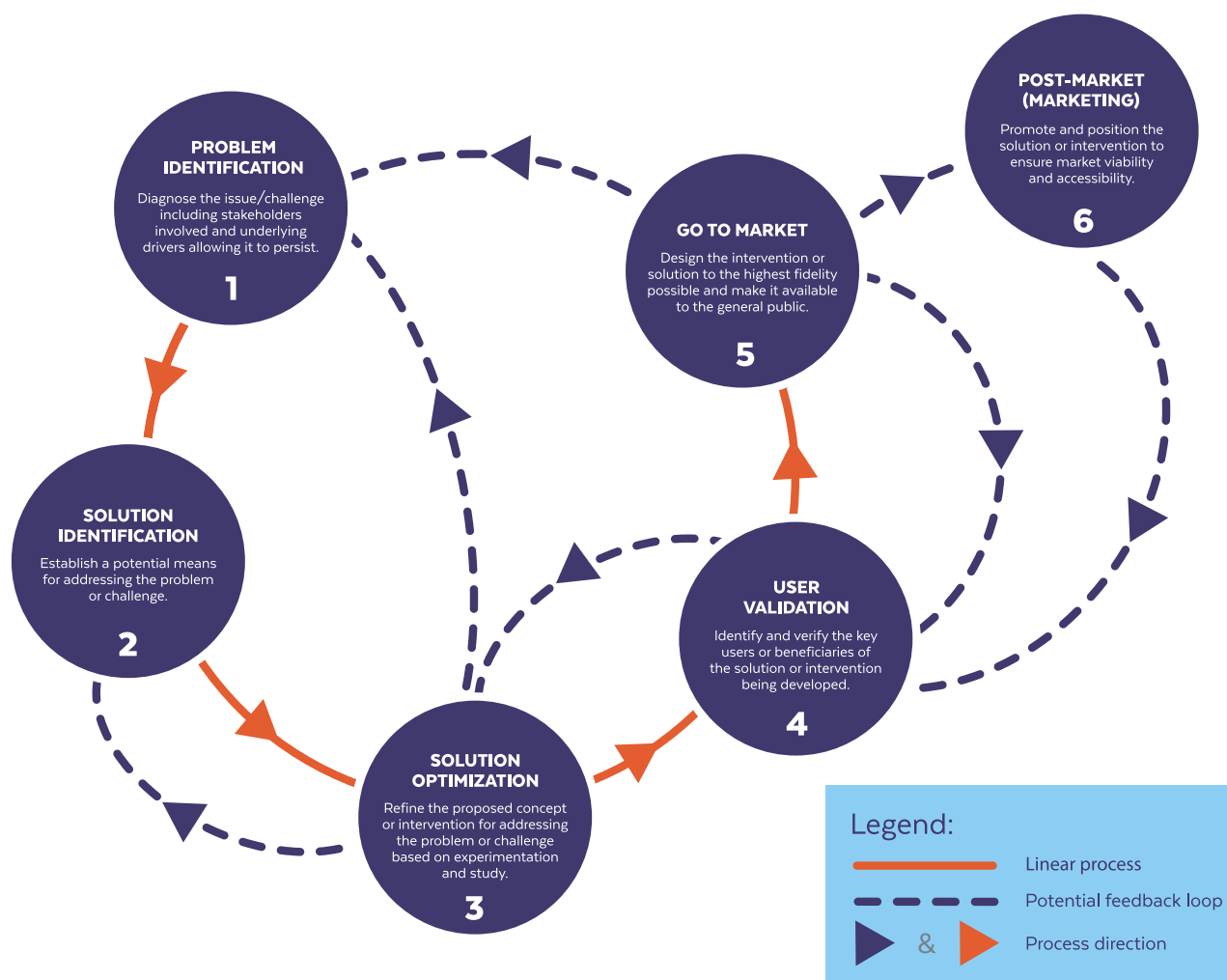


Figure 3. Swirling vortex.

In all, participants identified hundreds of challenges in this first exercise. Challenges were grouped into categories addressing the following key themes:

- Advancing basic science to promote male contraceptive development, including gaining a deeper understanding of the basic biology related to the blood-testis-barrier (BTB) in an effort to address challenges in developing formulations with targets located within the BTB.
- Anticipating and clarifying potential regulatory challenges given that no predecessor product for male contraception has been through review by a stringent regulatory authority.
- Understanding the challenges of building a business around a novel male contraceptive product, and raising capital to support development.
- Understanding the desires of men as they relate to contraceptive products.
- Connecting with distribution and provider networks.
- Addressing social stigmas that may impact the uptake of methods when they reach the market, including the fact that contraception has historically been viewed as a female responsibility.

North stars. In this exercise, designed to identify key stakeholders that influence the development and success of NHRMCs, workshop participants identified 25 individual, organizational, and ecological stakeholders as potential sources of guidance for development efforts. These 25 were clustered based on related aspects. For example, funders, donors, and investors were grouped into a general category of investors. Priority stakeholder groups were then identified through a voting exercise where participants chose the most important stakeholders to them as well as the stakeholders that they viewed as being the most critical to facilitating the path to market. The resulting vote clusters clearly identified the selection of users and investors, respectively, as the key stakeholders in these two areas. Following these clusters was environmental groups and pharmaceutical companies, respectively.

Field trip: transformation + masculinity. A key theme that emerged early on in the workshop was the need to understand and communicate an environment where contraception, beyond condoms and vasectomy, is not viewed exclusively as a feminine concept.

To build upon this anticipated point of discussion, a field trip was coordinated to observe the work of performance artist, Monique Jenkinson, a cisgender woman who takes on the drag queen persona Fauxnique as a means of exploration across the spectrum of gender. Monique led participants through a series of exercises to explore their individual concepts of masculinity and femininity through movement and a pile sorting activity to gather social perceptions of masculinity and femininity. These concepts were then discussed freely as Monique transformed into her alter ego, Fauxnique.

The activity was designed to integrate heavily into the concept of empathy as a foundation of HCD. Participants were able to work through a process of shedding social constraints related to contraception as a gendered issue, allowing remaining workshop discussion and activities to focus on the concept of NHRMC as a means of addressing unintended pregnancy, more broadly.

Day 2: building

How might we. Following the first roundtable discussion, focused on the process of taking products to market, participants started the process of reframing the challenges identified on Day 1 as opportunities using the HMW approach. The result was the development of 10 questions that became the foundation for the remaining workshop activities. They are provided below in no particular order.

How Might We ...

- ...create a support system for scientists so they can focus more on science?
- ...align funders and grantees with shared goals and assessment to facilitate funding?
- ...separate social concepts of masculinity and virility?
- ...connect scientists and investors around male contraception?
- ...position male contraceptives within the context of great and safe sex?
- ...help funders and investors to understand the return on investment (ROI) across various male contraceptive opportunities?
- ...facilitate a concept of asynchronous, attributable team science?
- ...create and share a strategic vision for moving forward with male contraception?
- ...give male contraceptive advocates the quantitative and qualitative evidence they need to prioritize male contraception among key stakeholders and funders?
- ...help everyone in the male contraceptive community to understand the lives, motivations, and aspirations of target audiences?

Concept development. Building upon the HMW activity, participants were asked to develop prototype concepts detailing approaches to address the HMW questions. Initial rough concepts were developed and presented to workshop participants. Small groups were then assembled to revise some of the more promising concepts, applying an iterative approach to improving upon the initial drafts by adding additional or refined content. A total of 10 concepts made it to this stage as outlined below. Concepts ranged from utilizing social media and mobile applications to engage target users and gather information about their preferences, to communications

campaigns to increase awareness and build demand. They include the following:

(1) Communications/advocacy

- Developing a common suite of messages to present a unified statement of vision for NHRMC between organizations and across investors, donors, and other stakeholder groups.
- Developing a communications campaign that presents individual stories describing the motivations of men and their partners who wish to use NHRMC.
- Using social media to identify opportunities to share product prototype characteristics with potential users to obtain their input.
- Engaging mass media and pop culture channels to model male contraception as an aspirational social concept.
- Developing an app that utilizes gamification as a way of confirming contraceptive use by both partners.

(2) Product development

- Applying aspects of successful models of product development extrapolated from other therapeutic areas such as vaccine and rare disease research.

(3) Funding landscape

- Developing a centralized means of administering grants related to NHRMC to accelerate submissions and increase access to limited research funding for multidisciplinary teams.
- Reaching a new ecosystem of investors and donors by promoting evidence and developing a business case demonstrating the high-impact and ROI potential offered by reducing the number of unintended pregnancies globally. Specifically, participants identified the need to better promote the secondary impact that contraception offers by addressing critical social and health outcomes, including reduced infant and maternal mortality rates, improved educational outcomes for girls, better economic outcomes for families, and decrease in environmental impact and resource demands.

(4) Operational

- Connecting and aligning the NHRMC community of researchers, allowing them to share goals and resources, thus promoting wider access to state-of-the-art facilities and expertise for the field.
- Expanding MCI to become a global coordinating center for NHRMC stakeholders, connecting researchers, concepts, investors, and advocates to expedite the time to market for NHRMC products.

Day 3: moving forward

Collaborative design: platform canvas. The needs, experience, and offerings of workshop participants varied considerably. Similarly, the value offered by MCI varies by participant based on their fields of practice, proximity to NHRMC product development, and other factors. The final activity, following the second roundtable discussion on building a collaborative platform, provided participants an opportunity to close out their workshop experience by developing a platform canvas. This activity asked users to reflect upon the needs, offerings, and benefits associated with the groups with whom

Table 2. Focus areas and identified needs.

Focus areas (priorities in bold text)

- Collaboration/support system for scientists^a
- **Solution identification**
- **Solution optimization**
- **Cultural stigma and taboo**
- User validation
- Go to market strategy
- In-market strategy

Identified needs (priorities in bold text)

- Connect NHRMC scientists + investors
- Facilitate “Team Science”
- **Create and share a strategic vision for moving forward with NHRMC**
- **Give NHRMC advocates the evidence they need to get NHRMC prioritized among funders**
- Help funders + investors understand ROI for NHRMC opportunities
- Build alignment between funders + scientists through shared goals and assessments to facilitate funding
- Support scientists so that they can focus more on the science
- Help the NHRMC community better understand the preferences, lives, and attitudes of target audiences
- Separate masculinity and virility
- Position NHRMC within the context of great and safe sex

^aNotes: Three overlapping themes (problem identification, collaboration, and new business mindset) were merged into the single category of collaboration/support system for scientists).

unique attributes, a common theme was the need for an organized, central ecosystem for the field. This ecosystem would not only provide support and advocacy for the research community but also serve as a representative for the field, demonstrating an alignment in vision and path as a means of offering a more compelling investment case across a pipeline of products versus smaller scale individual projects.

Day 4: synthesis

The final day of the event consisted of a postworkshop synthesis exercise conducted by MCI and IDEO. Through this synthesis, seven focus areas were identified as needing to be addressed by the NHRMC research and development community. Four of these focus areas were identified as priority areas with a total of 10 specific needs identified (Table 2). These needs were further narrowed down to four priority needs, including:

- Connect NHRMC scientists + investors.
- Facilitate team science.
- Create and share a strategic vision for moving forward with NHRMC.
- Give NHRMC advocates the evidence they need to get NHRMC prioritized among funders.

Discussion

The opportunity to assemble a group of multidisciplinary experts to focus on the challenges associated with one specific field of practice over the course of 3 uninterrupted days was a privilege and opportunity that is not lost on the staff of MCI. Scientific research tends to be an isolated practice, particularly for those working across different institutions and countries across the globe. The willingness of these individuals to dedicate their time to this exercise, based on a methodology that was new to many of them, is a testament to the dedication of the NHRMC community. Coming together to create a sense of community, a shared agenda, and a vision for the field is extraordinarily rare and important. It is

the hope of MCI that, by using the group’s collective strengths and knowledge to identify potential solutions to their challenges, there is also a greater awareness among the participants of the true potential that they hold both as individuals and as a collective.

In an effort to continue the momentum established during the workshop and to promote continued engagement from the team science community, a final list of three requests were presented for participants:

- Continue to engage with the community in an open and collaborative manner.
- Share experiences/learnings/documents via communication channels that are useful to others in the community (within comfortable limits with respect to proprietary information).
- Share what has not worked, including study results that produced undesired findings. These lessons often are not shared through peer review but can be more useful than knowing what did work.

Encouraged by the results of the workshop, MCI has made establishing the framework and facilitating the community that is “team science” a priority in 2020 and looks forward to supporting the continued pursuit of a research ecosystem that reflects the spirit of meaningful collaboration established by those who contributed to this event.

Acknowledgments

We would like to thank the following individuals and acknowledge their contributions to the success of this workshop:

(1) Ideation participants

- Akash Bakshi, CEO and Co-Founder, YourChoice Therapeutics.
- Mark Barone, Senior Scientist, Population Council.
- Kathryn Carpenter, University of North Carolina at Chapel Hill, Gillings School of Global Public Health/MCI Summer Fellow.

- Paula Cohen, Professor of Genetics, Cornell University College of Veterinary Medicine.
- Simon Cook, Co-Founder and Chief Technology Officer, Eudaemon Technologies.
- Aaron Crapster, Principle Scientist, Vibliome Therapeutics/Male Contraceptive Initiative Fellow.
- Jason Cross, Co-Founder and Chief Strategy Officer, Rymedi.
- Patricia Cuasnicú, Senior Scientific Researcher, National Research Council (CONICET).
- Pamon Forouhar, Rapid Evaluator, X, the moonshot factory.
- Liliya Gabalev, Graduate Student Instructor, UC Berkeley/Male Contraceptive Initiative Fellow.
- Gunda Georg, Professor and Medicinal Chemistry Department Head, University of Minnesota.
- Robert Goodwin, CEO, Vibliome Therapeutics.
- Robert Gorkin, Co-Founder and External Research Manager, Imagine Intelligent Materials Ltd.
- Bethany Young Holt, Executive Director and Founder, CAMI Health and Initiative for MPTs.
- Sabrina Martucci, Johnson President and CEO, Daré Bioscience.
- Jennifer Kiang, Senior Manager, Daré Bioscience.
- Polina Lishko, Assistant Professor of Cell and Developmental Biology, University of California, Berkely.
- Elaine Lissner, Founder, Parsemus Foundation.
- Nadja Mannowetz, Co-Founder and Chief Science Officer, YourChoice Therapeutics.
- Connie Moreadith, Public Health Consultant.
- Debbie O'Brien, Board Member, Male Contraceptive Initiative.
- Stasia Obremsky, Strategy Director, Rhia Ventures.
- Stephen Palmer, Director of Lead Discovery and Development, Center for Drug Discovery, Baylor College of Medicine.
- Lisa Rarick, RAR Consulting.
- Gianni Renda, Deputy Chair, Dept. of Architectural and Industrial Design Swinburne University of Technology.
- Joel Segre, Early Pipeline Strategy Lead, X, the moonshot factory.
- Iana Simeonov, Digital Health Strategy Consultant.
- David Sokal, Co-Founder and Board Chair, Male Contraceptive Initiative.
- Pablo Visconti, Associate Professor, University of Massachusetts.
- Wei Yan, Foundations Professor of Physiology and Cell Biology University of Nevada, Reno.
- Kevin Whaley, CEO, Mapp Biopharmaceutical, Inc.

(2) IDEO staff

- Caricia Catalani, Dr.PH, M.P.H, Director of Design for Health and Design Research, IDEO.
- Dav Rauch, Director of Product Development, IDEO.
- Sebastian Sanne, M.S., Senior Design Lead and Business Designer, IDEO.
- Veronica Lin, Senior Resourcing Coordinator, IDEO.

(3) Special contributors

- Monique Jenkinson, Multi-Genre Performing Artist.
- Shalu Umpathy, Managing Director and Director of Partnerships, IDEO.org.
- Ridhi Arun, Program Coordinator, IDEO.org.
- Becca Carroll, Portfolio Lead, Last Mile Money, IDEO CoLab.
- Christine Winoto, Founder and Director, UCSF Rosenman Institute; Deputy Director, QB3; Founder and Partner, MedTech Venture Partners.
- Sherya Mehta, Co-Founder and CTO, Zenflow.
- Dennis Boyle, Partner and Founding Member, IDEO.

We would also like to thank Dan Johnston, PhD, Chief, Contraception Research Branch, and our colleagues at the Eunice Kennedy Shriver National Institute of Child Health and Human Development for their continued collaboration and for allowing us to participate in their 2019 Contraceptive Development Meeting held at Baylor College of Medicine in Houston, TX.

Conflict of interest

The authors have declared that no conflict of interest exists.

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