NAVIGATING BARRIERS IN MALE FERTILITY CONTROL

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By

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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According to the United Nations Population Fund (UNFPA), around 121 million unintended pregnancies are recorded each year – indicating a global crisis (2022). The global sexual health agency reported "profound consequences for societies, women, and girls" resulting from the family planning crisis, with over 45% of unintended pregnancies ending in unsafe abortions sometimes causing maternal death (para. 2). Worldwide, this crisis is attributed to a variety of factors including gender inequality, sexual violence, and a lack of effective contraceptive options for women and men alike. University of Virginia researchers Khourdaji et al. (2018) argue that the rapid increase in the Earth's population calls for more effective methods of contraception, and while there are numerous contraceptive choices for women, the researchers conclude that "methods of contraception for the male partner are limited to condoms and vasectomy" (Abstract section). The currently used methods of male contraception are inadequate amidst a global crisis, as condoms have a failure rate of 3%, and vasectomies are less utilized due to their low chance of reversibility.

But why should managing fertility fall solely on women? The idea that family planning is distinctly a woman's job serves as an antithesis to the following research, as well the motivation behind it. With male contraception methods that are wholly lacking in efficacy, there is a great need for a solid male contraceptive with the standards of efficacy and use like female birth control or an IUD. This STS research paper seeks to answer the question of what currently stands as obstacles in the field of male fertility control (MFC) through analysis with the Social Construction of Technology (SCOT) concept. First developed by Wiebe Bijker and Trevor Pinch in 1984 (Bijker, Hughes, and Pinch, 1987; Bijker and Pinch, 1984; Kline & Pinch, 1999), the Social Construction of Technology examines changing relationships between social groups revolving around the engineer of a novel technology.

An end to the unintended pregnancy crisis can be identified through examining male fertility control worldwide including current initiatives in production, societal attitudes towards male contraception, and overall strategy in sexual education. The loosely coupled technical research aims to provide a solution to the slow development of a contraceptive on the engineering side, combining organ-on-a-chip systems with integrated detection of bioluminescence. This tactic has the potential to model the reproductive system more accurately than traditional cell culture and animal models, and could lead to better discoveries in drug development (Wu, 2020). Together, this research provides a holistic answer to the lagging development of a male contraceptive and a framework for the successful implementation of a novel contraceptive through analysis with the SCOT concept.

RECOGNIZING CURRENT ISSUES IN DEVELOPMENT

Research pertaining to male birth control has been conducted for years, targeting many different aspects of the male reproductive system to induce azoospermia – a condition in which there is no sperm in the ejaculate. The following section examines both technical roadblocks and their subsequent effects on investments in contraception production, as well as legislative hurdles.

CHALLENGES IN BIOMEDICAL RESEARCH

At the forefront of the movement to develop a male contraceptive are hormonal methods – contraception that aims to suppress the production of sperm by interrupting "a naturally occurring hormonal feedback loop, the hypothalamic pituitary-gonadal (HPG) axis" (Abbe et al., 2020, Mechanisms of Male Contraception section). Researchers Abbe et al. (2020) describe

formulations using androgen and progestin as having shown promising efficacy and reversibility, but clinical trials are plagued by prominent side effects including decreased sexual libido and severe depression. Clinical trials for an injectable hormonal contraceptive for men was stopped prematurely in 2016, as it involved drastic changes in mood and sexual desire in the participants. Cases involved an overdose on paracetamol, a tachycardia with paroxysmal atrial fibrillation, and a suicide that the researchers deemed unrelated to the contraceptive (Behre et al., 2016). A contraceptive has to be used in order to be effective, and these findings suggest that a hormonal male birth control does not present itself as the most attractive option for men despite being the most researched method in controlling male fertility.

There are millions of male sex cells produced daily by the average man, each capable of inducing pregnancy. According to clinical researcher William Bremner (2012), it is increasingly difficult to suppress all of the spermatozoa "compared to the relative ease of preventing the production of one ovum a month in the female" (para. 6). Another challenge to translational research in MFC refers to the physical structure of the male reproductive system. Bremner continues to write that the blood-testis barrier blocks easy access to the testicles where the production of sperm from the primordial germ cells occurs, also known as the seminiferous tubules. The blood-testis barrier is a physical wall between the blood vessels and seminiferous tubules that prevent the delivery of large molecules in a treatment from reaching cells. Due to the aforementioned complications, the development of an oral male contraceptive is riddled with biological barriers that conflict with the time and money spent on producing a male birth control pill.

LEGISLATION AND RISK TO INVESTMENT

On June 24, 2022, the U.S Supreme Court reversed the decision made in the landmark case *Roe v. Wade*, effectively declaring that the constitutional right to abortion no longer exists (Totenberg and McCammon, 2022). According to Stacy Weiner (2022) with the Association of American Medical Doctors, the recent change in legislation has sparked a wave of interest in male contraceptive initiatives. While this uptick in curiosity can bring about increased work in the field and attention from investors, the pressure could result in incomplete and rushed research.

There is a lack of financial motivation to invest in the development of a novel male contraceptive. Although the market is estimated at $4 billion, the time and effort spent to develop the technology is not worth the amount of money that will be spent (Cima, 2015). The long amount of time needed to produce contraceptives and put them through trial "increases the risk of an investment" (A Modern History of Contraception section). The side effects caused by male contraceptives in development also pose a liability risk to pharmaceutical companies, stifling funding prospects from potential investors.

Why invest in contraception instead of something like cancer research? This question is posed by Elaine Lissner (2015), director of male birth control manufacturer the Parsemeus Foundation, as she claims that you can kill someone with the side effects of cancer treatment "but still cost them an arm and a leg" (A Modern history of Contraception section). This is indicative of a moral obstacle that stands in the way of male fertility control, as investors find it easier to ethically justify funding research that works to save a life rather than to suppress one.

In the development of a novel male contraceptive, it is imperative for the engineer to consider all parties involved in the process to allow for the product's successful implementation.

The current scope of social groups contributing to the MFC field is depicted in Figure 1 through the lens of the Social Construction of Technology framework, as the engineer at the center of the novel technology is influenced by social groups that provide a prospective into the development of the technology. In turn, the product designed by the engineer has an impact on the social groups that affect it, ultimately mirroring their interests. For a male contraceptive to be effective in its implementation, the concerns of all actors involved in the development process must be taken into consideration.

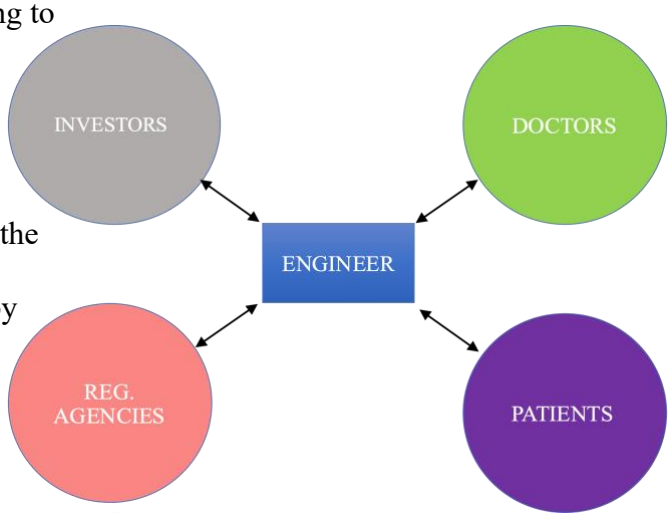

Figure 1: Male Contraceptive SCOT Model. The engineer in this model is tasked with considering the concerns and interests of social groups involved in the design process. (Muhammad, 2022)

IDENTIFYING VARYING PERSPECTIVES TOWARDS MALE FERTILITY CONTROL

The desires and attitudes of men towards male contraception largely differ regarding geographical area and religion. The next section recognizes the diverse perspectives of men across the world, identifying patriarchal factors that serve as a root cause. Traditional moral and religious values long held by people lead to deep chasms in global sexual education across countries, ultimately blocking the conversation of a novel male contraceptive.

CULTURAL, RELIGIOUS, AND GEOGRAPHICAL DIFFERENCES

The lagging development of a solid male contraceptive is compounded with wildly varying perspectives on its need and potential use. Published in 2005, German health researchers Heinemann et al. conducted a multinational survey of men and women to gauge their perspectives on MFC. The authors found "a more 'paternalistic' view which may be particularly present in Latin American society" (Discussion section, para. 4) with 8-12% of men stating that they alone would make the decision to use male contraceptives. In addition to this, Heinemann et al. cite that the majority of Muslims and Buddhists would not try a new method of male fertility control (MFC) compared to Christians, indicating a diverse geographical and cultural shift in attitudes toward MFC. These results suggest a patriarchal standard of women being primary child caretakers and upholding the sole responsibility of family planning, an idea shared by Journalist Raizel Joleigh of the Male Contraceptive Initiative (2020) that modern society has socialized some women into believing they should "have to bear the fruit of their actions" (A Matter of Trust section, para. 1).

Kim et al. (2022) attempt to frame the deep chasm in attitudes pertaining to MFC using a social network through a study conducted in Benin, Nigeria. The authors find innate gender roles and power imbalances sustaining socioeconomic boundaries that contribute to the family planning crisis, such as men not wanting to seem less masculine as a result of having less children and women afraid of being labeled as promiscuous by the community. Furthermore, writer for *The Guardian* Moira Donegan (2019) argues that many men are against male contraception options like condoms and vasectomies, either because of the diminishing of pleasure for them or the fear that "the procedure will inhibit their bodies' ability to create and absorb testosterone, rendering them effeminate" (para. 10). Coupled with the results of the study

conducted by Kim et al., an ingrained stigma around sexual reproduction - reinforced by gender roles - is visible in global societies.

A GENERAL LACK OF SEXUAL EDUCATION

Moral and religious values sometimes reinforce sexual taboos, leading to unwanted conception and the possible result of sexually transmitted diseases. Sexual education initiatives work to remedy the unintended pregnancy crisis and bolster sexual autonomy, but largely differ between countries. According to The Encyclopedia of World Problems and Human Potential (n.d), sexual education for young people in Europe ranges from compulsory to nonexistent. Research shows "a lack of preparation" as children enter puberty (Incidence section). A study performed by the United Nations Educational, Scientific, and Cultural Organization (UNESCO) in 2012 identified legislation in 28 Asian countries pertaining to sexual education, finding only 15 to have a full set of policies related to the subject. Of those 15, only Bangladesh, the Philippines, and Vietnam have laws that manage population and reproductive health. Andrea Casey (2021) with Next GenerAsian cites reasons like objectification and religion as responsible for inadequate sexual education.

A lack of sexual education instilled in youth is directly related to the limited use of contraception in a given geographical area. In a 2019 report by the United Nations, contraception use and methods were shown to vary wildly across countries. Prevalence was revealed to be 60% in Eastern and South-Eastern Asia, 49% in Latin America, and less than 30% in Sub-Saharan Africa. In contrast, U.S researchers Kimberly Daniels and Joyce Abma with the CDC (2017) reported that 81.7% of unmarried men used any method of contraception in their last sexual encounter, from condoms to vasectomies. This data has implications relating to culture and

global health care that are imperative for an engineer of a novel male contraceptive to consider in the design process. In Figure 2, the SCOT model is updated to include both culture and health care, as both are social groups that undoubtedly have an effect on how a male birth control would be received. All of these social groups, including the newly added groups, are also influenced by the technology created. A concrete male contraceptive could redefine interpretations of family planning and fertility control worldwide.

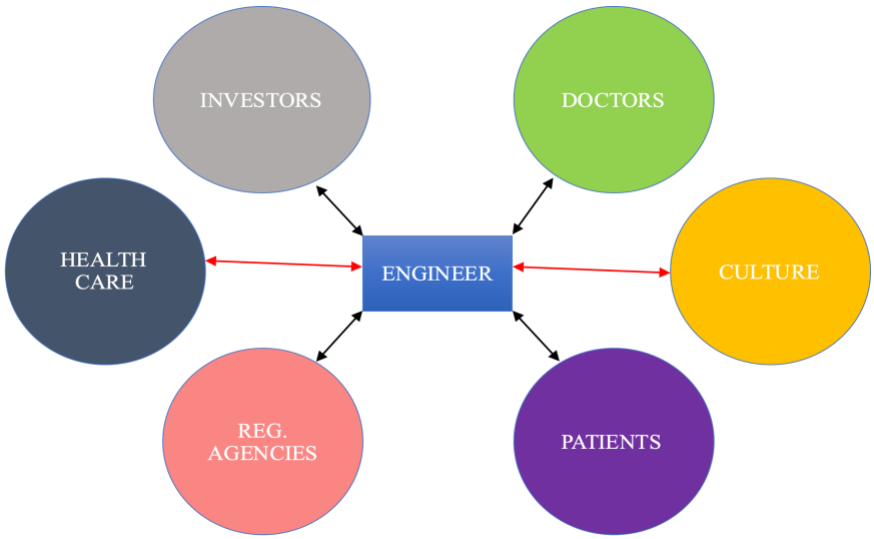

Figure 2: Updated Male Contraceptive SCOT Model. The engineer in this model is tasked with considering the concerns and interests of social groups involved in the design process. In contrast to Figure 1, the engineer is responsible for health care and considerations regarding global cultures. These social groups also influence the technology being developed. (Muhammad, 2022)

A PLAN FOR MALE FERTILITY CONTROL

My research shows that the answer to the slow development of a concrete male contraceptive is multifaceted. Factors including a lack of sexual education, ultimately fueled by a chasm in values shared across countries, compounded with legislative pressure and challenges in translational research bar the progression of managing male fertility. It is futile to change the

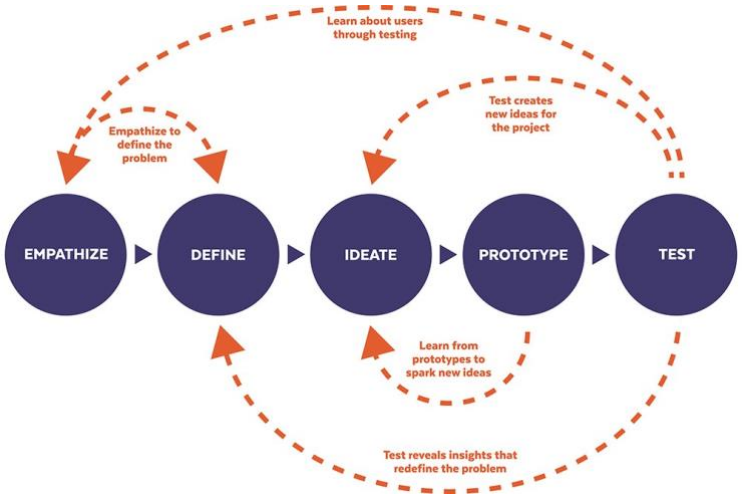

Figure 3: Human centered design (HCD) process. This process first involves a holistic understanding of a particular problem, empathizing with it and correctly defining the issue. Each step in the process provides feedback to a future or previous step, establishing interconnectedness the entire way. (Vahdat et al., 2020)

long held and generational opinions of people regarding family planning, but it is possible for engineers to work alongside the social groups involved in the development process to deliver a novel treatment in the midst of a global crisis. My research will include a framework for the successful implementation of a male contraceptive using the human-centered design model (HCD) as depicted in Figure 3, a five-step design process described by researchers Vahdat et al. (2020) that can facilitate discussion around technology implementation, eventually leading to a collaborative brainstorming of solutions. The HCD model's use in the global health sector has been implemented to use social innovation to improve health outcomes. Along with the novel technical idea, this research provides an avenue to ending the family planning crisis and establish male contraception as a more attainable option than it is currently.

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