Barriers to Long-Term, Semi-Permanent Male Contraceptives and Male Involvement in Reproductive Health

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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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Introduction

When the question, "How many people in the world use birth control" is searched in Google, the top responses all mention women and their birth control use (Figure 1). But the search was about *people* who use birth control, not only women. World Health Organization states that among the 1.9 billion women of reproductive age (15-49 years) in the world (in 2021), 1.1 billion women have a need or a desire for family planning, 874 million are using modern contraceptives, and 164 million have an unmet need for contraception (*Family Planning/Contraception Methods*, n.d.). Men are nowhere to be mentioned. Men are not

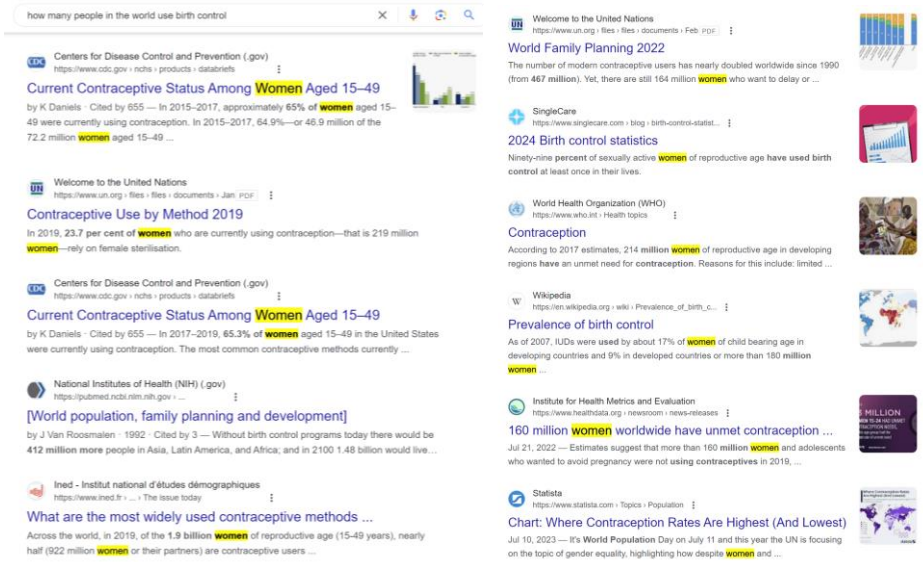

Figure 1. Google Search "How many people in the world use birth control"

considered in today's media as users of birth control. To get an understanding of where this disparity comes from, it is important to start with the question "what is birth control?". Birth control is defined as the use of medication, devices, or surgery to prevent pregnancy. The word 'women' is absent from this definition despite the historical and modern connotation. Perhaps a more fitting definition is: "…surgery *for women* to prevent *their own* pregnancies." Contraline, Inc., a biotechnology company from Charlottesville, VA is trying to change this narrative that

birth control is only for women. They are developing the first non-hormonal, long-acting, reversible contraceptive (LARC) meant for men, known as ADAM. This paper will explore why there is a necessity for a non-hormonal LARC for men, like Contraline's ADAM, which draws much-needed attention to the lack of male "representation" in reproductive health.

Background

The Origins of Contraception

Contraception first began in its most mundane form as condoms, developed in ancient societies using animal bladders or intestines, with the first rubber condom produced in 1855. Margaret Sanger opened the first birth control clinic in 1916, and in 1920, she stated that birth control is simply a means of weeding out those who are unfit and preventing the birth of "defectives." Over ten years later, after Sanger organized support for the research of birth control pills, the first oral contraceptive, Enovid, was made, a combination of progesterone and estrogen. Since then, dozens of new LARCs for women have been created, such as intrauterine devices and Norplant, a small set of soft tubes implanted under the skin that release levonorgestrel ("A Brief History of Birth Control," n.d.). To be considered a LARC, it must be able to provide long-term pregnancy protection after one use, implantation, etc. The length of protection depends upon the form of contraceptive but can range anywhere from three to ten years.

Contraceptives continued into the late 90s and early 2000s with the approval of two emergency contraceptives that can be used after intercourse to prevent pregnancy, Preven and Plan B. LARCs continued to become a popular choice in contraception with the creation of Mirena, a levonorgestrel-releasing IUD, a hormonal patch called Ortho Evra, and a single-rod implant named Implanon ("A Brief History of Birth Control," n.d.). Despite all of these advances

in the realm of birth control, 100 years later, there is still yet to be a long-term, semi-permanent choice for men.

The Inventory of Male Contraceptives

On the current open market, the only recognized method of long-term contraception for men is the vasectomy. Vasectomies are surgeries that cut off the supply of sperm to your semen and are technically reversible. However, multiple factors determine the viability of a reversal, such as the time passed since the reversal, and the age at which the vasectomy occurred. Reversals also do not guarantee fertility. If the vasectomy is reversed in three to five years, 88 percent of patients achieve sperm in the semen but only have an average pregnancy rate of 53 percent (*Vasectomy Reversal*, n.d.). Beyond this timeline, fertility continues to decrease, with success rates of 40% to as low as 25% (Fuchs, n.d.). While condoms are technically male contraceptives, they are not considered LARCs. They are a one-time-use contraceptive, considered a barrier method, similar to dental dams, sponges, and cervical caps (*Birth Control*, n.d.).

Even though female contraception began in the early 1900s, male contraception trials did not begin until the 1970s. National Institutes of Health (NIH) began male hormonal contraceptive clinical trials using testosterone enanthate, a testosterone replacement typically used in male hypogonadism (Wang et al., 2016). Since the 70s, a few more methods of male contraception have "hit the market" but have not broken into the mainstream. The first are testosterone injections. Testosterone prevents the release of follicle-stimulating hormone, which is the pituitary hormone responsible for sperm production (*Infertility in Men*, n.d.). These injections taken weekly or monthly reduce sperm counts, preventing pregnancy. The second is an NES/T gel, a Nestorone (NES), and testosterone (T) combination gel that is applied to the skin

daily. Nestorone is a non-androgenic form of progestin that stops sperm production (*NES/T Gel*, n.d.). Another method of male contraceptive is a testosterone and Gonadotropin Releasing Hormone (GnRH) antagonist injection. GnRH antagonist works by competitively binding to receptors and reduces follicle-stimulating hormones and luteinizing hormones, another hormone responsible for fertility, to undetectable levels (*Update on Male Hormonal Contraception - Giulia Gava, Maria Cristina Meriggiola, 2019*, n.d.). The last of the male contraceptives is the hormonal male pill. This pill contains dimethandrolone undecanoate, a testosterone-like medication that can be taken orally, rather than injected and is effective at stopping sperm production (*Male Birth Control: 8 Options in the Pipeline*, n.d.) The newest male contraceptive is not on the market yet. It is an injectable, non-hormonal hydrogel that works by occluding the vas deferens, the tube in the male reproductive tract where sperm travels. It could be considered the first set-and-forget male contraceptive: ADAM by Contraline, Inc.

Sociotechnical Framework Methodology

Two sociotechnical frameworks will be used in tandem to explain the barriers to male contraceptives and male involvement in contraceptive uptake: cultural lag and technological momentum. Cultural lag is described as a sociological phenomenon that occurs when advancements in material culture evolve and change rapidly, while non-material culture resists change and remains fixed for longer periods of time (*3.3C*, 2018). In other words, scientific advancements in technology occur at a faster rate than changes in social norms, values, and institutions. Technological momentum proposes that for societies to accept a technological system, it must first align with social context and goals. The last stage of technological momentum is the standardization of an application that is continuing to move forward and is difficult to replace (Hughes, 1983). Both have importance in this paper as the barriers to male

contraceptives stem from a place of misunderstanding between the scientific realm and the social realm. Not only is the scientific realm moving faster than the social realm, but the social realm is resistant to change, refusing to move. Male birth control is meeting resistance to society as the "norms" of female birth control continue to develop and solidify.

Cultural Lag

Sociologist William F. Ogburn coined the term "cultural lag" in 1922 in his paper "Social Change with Respect to Culture and Original Nature." His theory suggests that a period of maladjustment occurs when the non-material culture is struggling to adapt to the new material culture conditions (*3.3C*, 2018). His most classic example of cultural lag is the amount of time society took to adapt to the speed of the automobile in 1964. It took much more time for the social institutions and the building of roads to adapt to the speed at which faster cars were being produced (*Cultural Lag*, n.d.). Cars travelled much faster than horses and older cars the roads at the time were made for.

It is important to note that "cultural lag" does not necessarily mean that one part now lags behind the other. It does not mean that one type of culture fails to adjust to change. It is more of a "future shock" as Alvin Toffler says, which refers to the stress and disorientation induced by society on individuals by "[subjection] to too much change in too short of a time" (*Cultural Lag*, n.d.). Future shock suggests that there must be a balance somewhere between the pace of environmental change and the pace of human response, which progresses much slower.

Technological Momentum

It used to be widely believed that technological development was determined by the advancement of knowledge which then determined how society was organized, which means that

technology is a product of the way humans act and live, and it is impossible to control (*Momentum: A Concept in Technology Studies*, n.d.), until a historian of technology proposed a new idea. The term "technological momentum" comes from Thomas P. Hughes who described a metaphor of momentum to describe how technological systems are made and become stable. As systems emerge, they begin to be relatively flexible, but over time, they become more stable, beyond human control (*Technological Momentum*, n.d.). Momentum is described as the product of an object's mass and speed. The more momentum an object has, the more difficult it is to slow it down. According to Hughes, when speaking of emerging technologies, the "mass" of the technology can be represented by the structure of the system which includes the businesses committed to the development and commercialization of the technology, and the design standards and regulations. The "speed" is understood to be the pace of the development of the technology. A new technology can "pick up speed" when progress is evident and other individuals or companies jump on to further drive development.

Discussion

A Hole in the Industry

The lack of long-term, reversible contraceptives for men is a result of the barriers blocking this form of contraception as well as the barriers inhibiting male involvement in the growth of long-term contraceptives. NPR has noted that a barrier to the development of hormonal male contraceptives is the complexity of the male reproductive tract. Women typically release one or two eggs per month, requiring only the regulation of hormones during this period. Men, however, can produce millions of sperm per day, and a single ejaculation contains 15 million sperm per milliliter of semen (Barber & Muraskin, 2022). Regulating the count of sperm

to reliably prevent pregnancy would require constant manipulation of male hormones, which can become an issue of safety, but also one of ethics. The hormonal methods of male birth control mentioned prior contain testosterone as well as progestin, a form of progesterone that plays a role in the menstrual cycle in women (Chung-Lun Wang, 2022). While progesterone is beneficial for men in reducing stress and helps balance the body, excessive progesterone can wreak havoc on the body causing estrogen dominance (Lam & Lam, n.d.). Estrogen dominance can result in the feminization of men as well as erectile dysfunction, prostate enlargement, and increased risk of prostate cancer (Figure 2). Thus, even though a hormonal male birth control such as this can

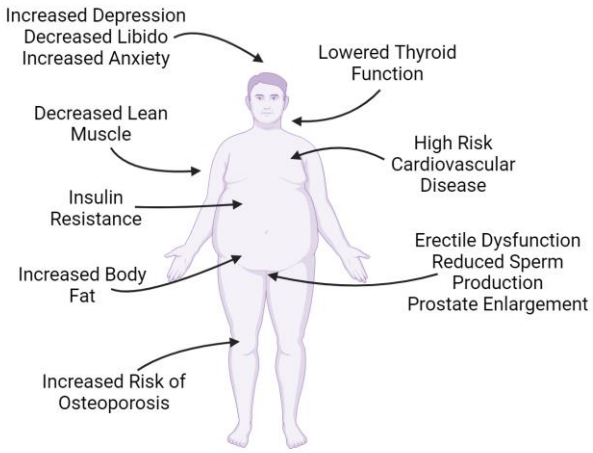

Figure 2. Side effects of estrogen dominance in men

suppress sperm production, it can also have some potential negative long-term side effects, especially with the state of masculinity.

Traditional or hegemonic masculinity is defined as a set of masculine norms that accentuate expressions of masculinity that invoke men's power, dominance and privilege over women and other men. Toxic masculinity aligns with the ideas of hegemonic masculinity but enforces a restriction in behavior based upon traditional gender roles that augment the existing

power structures strongly favoring men (Chatmon, 2020). This form of masculinity is deeply rooted in contraception and reproductive health. It is important to first note some sobering statistics on mental health. Men are more likely to die by suicide than woman, accounting for almost 75%. Men are less likely to seek help for mental health issues, with only 35% of men seeking help compared to 58% of women. While women are more likely to be diagnosed with depression and anxiety, men are more likely to struggle with it (Hospital, n.d.). Toxic masculinity has stifled the development of male reproductive health and male contraception. Since contraception is not used to treat a disease, it is imperative that the side effects of contraception are minimal and short-term in order to be acceptable to the target population (Plana, 2015), for men that is. Along with the possibility of estrogen dominance, many male hormonal birth controls cause depression. This occurs in female hormonal birth controls as well; however, depression has become somewhat normalized in female reproductive health. Men often deny having depression because they learn early on that acknowledging emotional pain is a sign of weakness and find it shameful (Schlossberger, 2021). Thus, many clinical trials for male contraceptives with the depression side effect cause concern from the general population and are terminated. With male birth control being so novel, there have not been many studies on the long-term effects of contraceptive methods due to the limited amount of research. The lack of research leads to a lack of acceptability of male contraception. But acceptability only comes with studies and research, creating an endless loop.

Men are not Involved

BMC Public Health investigated the lack of men involved in their reproductive health as well as the reproductive health regarding family planning, citing reluctance and shamefulness, as well as overall misperceptions (Roudsari et al., 2023), due to the institutionalization of

reproductive health as women's health. Understanding these barriers to male reproductive health will allow companies to better approach these issues and break into the male contraceptive market. Due to the idea that family planning and pregnancies are for women, there is an inadequate amount of family education targeted at men. The lack of awareness for men in reproductive services leads to a lack of training and a lack of encouragement to participate. The reluctance of women to involve men is also a cause for concern. Some women prefer to attend health centers alone or learn about reproductive health alone due to issues such as feminine embarrassment, fear of the partner, and the ignorance of men to the situation at hand. Most family planning services and reproductive health services are perceived as not being welcoming to men as patients or as partners simply due to the infrastructure of these services (Hardee et al., 2017). The policies, services, and hours of operation opposingly target men, and the health care workers cannot counsel men on contraception.

One significant factor contributing to the absence of men is the gap in men's and boys' access to reproductive information and services, causing a vast separation between male and female knowledge of contraceptives and access. A quote that well expresses the concerns of men in family planning is "how had we expected them [men] to participate when we neither shared information nor provided them with accessible services?" (Piet-Pelon, 1999). Though some men have the mentality that reproductive health is not for them, not all men feel that way, in fact, 58.2% of men are interested in learning about their reproductive health and fertility (Daumler et al., 2016). Adolescent boys want to be informed about their sexual lives, contraceptive options, and sexually transmitted infection (STI) prevention, but they have extremely limited options on where to get reputable information. Young men often turn to unfiltered media and other young men, yielding less than accurate results (Hardee et al., 2017). Part of this issue comes from the

intrinsic thoughts that pregnancy responsibility lies solely with the girl and her parents, and none with the boys. Since men have no control over the pregnancy situation, is it not their responsibility? This is a question that is far from being answered in the public eye. If it is made to be their responsibility as well, more family planning services and information would be geared toward men. This plays into the endless loop dynamic: men do not get involved because of a lack of awareness, and some women do not want men to be involved because they are unaware. Similarly, men are uninformed because there is a lack of resources and resources are lacking. After all, there is not an upward trend in informed men.

Unsung Heroes

What are the names of the doctors who specialize in female reproductive health and the ones who specialize in male reproductive health? The ones that specialize in female reproductive health immediately come to mind—gynecologists and obstetricians. Those that specialize in male reproductive health, however, are less likely to be well-known—andrologists. Andrologists are a type of urologist who typically treat male-factor infertility (MFI), sexual dysfunction, and cancers of the reproductive tract (Mulawkar et al., 2021). Andrologists have been placed in the background of reproductive health for men with the rise of assisted reproductive techniques (ARTs) such as intrauterine insemination, *in vitro* fertilization (IVF), and intracytoplasmic sperm injection (ICSI). Most ARTs are managed by gynecologists, which means that MFI is also managed by gynecologists, who may not have the necessary clinical skills or training to perform these evaluations. Most often, the only required skill set is a laboratory science or technology degree, excluding important specified training in the field. ARTs were never required to face rigorous safety testing before clinical use, unlike most other therapies and procedures in

medicine. These techniques allow a large number of patients to undergo treatments without understanding the root of their infertility or the long-term risks to their offspring (Alukal & Lamb, 2008). If these facilities are not required to perform testing, clinicians and other workers should be required to understand and share the dangers of assisted reproduction. This is where an andrologist could fit in.

Andrology is slowly disappearing. Doctors are needed less and less to specialize in sectors such as men's reproductive health. Furthermore, ICSI has changed the way male infertility is being treated. It is characterized by the direct injection of a single healthy sperm into a mature egg (Figure 3). Before, andrologists would examine patients' reproductive tracts and determine the cause of infertility, whether it be erectile dysfunction, or obstructive or nonobstructive azoospermia (no sperm in the ejaculate). Now, IVF and ICSI are being used as a

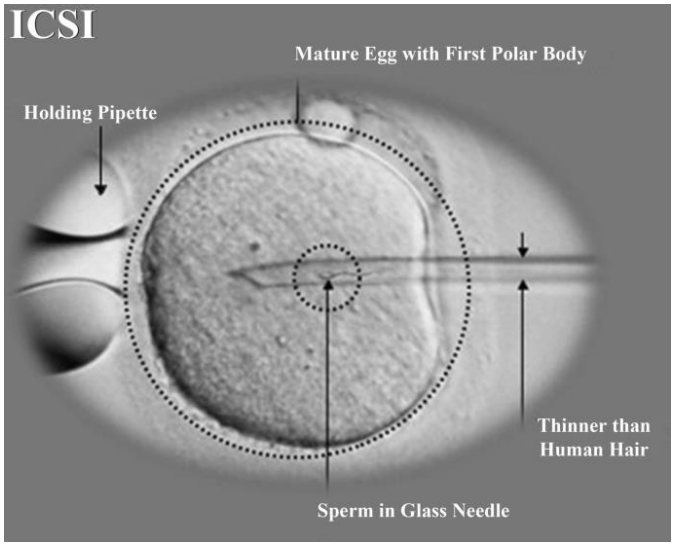

Figure 3. ICSI process of assisted reproduction (Mori, 2016)

treatment and examination for severe MFI. These assistive techniques only treat infertility at its surface, instead of determining the underlying cause. In addition, diagnostic processes of male patients and partners usually only begin after embryo development or implantation failure

(Cannarella et al., 2023), far too late in the process for men to be willing to find treatments. If the causes of infertility are curable, such as anti-sperm antibodies, varicoceles, infections, etc., treatment should be pursued. Only andrologists can do this; they are the ones with the proper knowledge and skills to manage the complexity of the male reproductive tract in regard to fertility.

Impact of ADAM

ADAM by Contraline has the potential to change the course of contraceptives. Men will have a place in reproductive health. With the introduction of a male contraceptive that does not have hormonal side effects, it eliminates the barriers surrounding hegemonic masculinity and vulnerability, specifically emotional pain as a sign of weakness. ADAM has no adverse side effects, meaning no chemically induced depression or anxiety, weight gain, muscle loss, or any other factors contributing to masculinity. ADAM also opens up the conversation for men to learn more about their own reproductive health. One of the reasons women are so well informed is due to the abundance of contraceptives on the market. With the introduction of ADAM, men, too, will have contraceptives on the market, meriting a discussion in schools and healthcare.

Future Work

The battle for male reproductive visibility is far from over. Creating a non-hormonal contraceptive for men is only the beginning. There are still barriers to break in getting it into the mainstream. Even with all of the promotion and education on male contraceptives, it still requires the willingness of men to participate. There may no longer be barriers of lack of knowledge, or adverse side effects, etc., but it is a two-way street. Men have to want to participate, only half do, and that is not something that can simply be fixed with a new

contraceptive. The next step is to get ADAM released publicly, then marketing is key. Men need to be made aware of family planning from a young age, so the stigma surrounding it never develops, as well as understanding his own reproductive health, more than simply where sperm comes from, and how it is expelled, but the way that it functions, the problems that can occur, as well as where and when to seek help. Andrology, not just urology, needs to be better understood and better explored in science, bringing it back to the forefront. Each of these goals will take work, and it will not happen in an instant, but as long as society moves forward instead of backward, male reproductive health will achieve the same consideration as females.

Conclusion

While the contraceptive world has grown significantly over the last fifty years, there is still a long way to go. There are far too many barriers blocking men from participating in their own reproductive health, as well as too many barriers blocking companies to aid in men's participation in reproductive health. This problem is not one that can be fixed in a day with a male contraceptive gifted in a neat little bow. This problem is systemic. It is deeply rooted in the minds of consumers, engineers, and companies, alike. Coming back to the idea of cultural lag, society is stuck in the past and present. Reproductive technology is continuing to move forward, but society does not. There is too much change in too short a time, fifty years. The world is simply not ready. But it needs to be ready; technology is.

Resources

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