CREATING AN *IN VITRO* MODEL OF THE VAS DEFERENS AND VALIDATING A VAS-OCCULSIVE CONTRACEPTIVE DELIVERY SYSTEM

THE BURDEN OF CONTRACEPTION: ANALYSIS OF SOCIAL AND TECHNICAL FACTORS THAT INFLUENCE CONTRACEPTIVE USE AND DEVELOPMENT

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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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CONTRACEPTIVE USE: AN OVERVIEW

Unplanned pregnancies make up almost half of pregnancies worldwide (UNFPA, 2022). As of 2022, nearly all of the burden of contraception falls on those with female reproductive systems. These options include birth control pills, hormonal and non-hormonal intrauterine devices (IUDs), hormonal rings and implants, and female sterilization (CDC, 2022). Contraceptive methods can be split into three overarching categories: traditional, short-acting, and long-acting methods. Traditional methods include withdrawal and cycle tracking, while short-acting methods describe methods that are taken or used daily, such as the pill, patch, or condoms. Long-acting methods can be further split into two categories, reversible or nonreversible. Creating long-acting reversible contraceptives (LARCs) is where much of current research is focused (Secura et al., 2010). Another important descriptor of contraception is whether or not the method largely relies on hormonal changes or suppression to be effective. Most methods are hormonal, but there are some exceptions, such as the copper IUD.

History of Contraceptive Development

The development of current contraceptive methods was heavily impacted by social and political factors. The birth control pill was the first contraceptive option besides the condom to be distributed widely by physicians for solely contraceptive use (Liao & Dollin, 2012). The human trials for the birth control pill became an infamous example of medical malpractice as the women participating in the trials were unaware this was a new medication. After the effectiveness of the pill was proven, it became an available option for married women. The sexual awakening of the 1960s also contributed to the dispersion of the pill, as women began to take control over their own reproductive health. In the 1980s, family planning became a norm for physicians to learn and to discuss with both married couples and single women. The success of

the pill also created a path for new and improved forms of contraception, like the IUD, implant, ring, patch, and more (ibid).

Male Contraceptive Methods

The only long-acting contraceptive method currently available to men is a vasectomy -- also referred to as male sterilization -- which accounts for a mere 2% of contraceptive methods used (United Nations, 2019). Additionally, nearly a third of men who have vasectomies reversed reported new fertility problems after the reversal procedure (Cleveland Clinic, n.d.). Only recently has research begun to focus on valid options for male contraception. As so many methods of contraception rely on hormonal changes, research has found the male hormone cycle more difficult to alter without causing severe side effects, partially due to its 24-hour cycle (Bridget Murray Law, 2011). Additionally, to attempt to suppress the production of sperm, testosterone levels must be lowered until the production of sperm reaches azoospermia (Khourdaji, et al., 2018), which is at most one million sperm per milliliter of semen, compared to the average of 15 to 200 million sperm per milliliter of semen (Spotlight, 2022). Despite the abundance of current research concerning male contraceptives, no method has reached the market in the United States. Further research will be conducted to investigate how social and medical factors have combined to leave the burden of contraception on women, and how the development of contraceptive options has been affected by these socio-technical elements. This will also relate to the development of male contraceptive methods, and why male contraception has not reached the market yet.

CREATING AN *IN VITRO* MODEL OF THE VAS DEFERENS AND VALIDATING A VAS-OCCULSIVE CONTRACEPTIVE DELIVERY SYSTEM

The intended purpose of my technical project is to create an anatomically accurate *in vitro* model of the male reproductive system and refine the delivery method of a male contraceptive device. This project is in partnership with a Charlottesville startup company, Contraline, who is developing a LARC by synthesizing a hydrogel that is injected into the vas deferens to block the flow of sperm to the rest of the reproductive system, creating a vas-occlusive device. ("Contraline," n.d.). This device is mainly marketed towards men in long term heterosexual relationships, but would provide effective and reversible contraception for any person with male anatomy who is looking to prevent a partner's pregnancy. The capstone project is focused on making practice models so that urologists may practice inserting the device before performing the procedure in the operating room. The procedure is performed in a similar manner to a vasectomy, which focuses on three main parts of the male anatomy, see Figure 1.

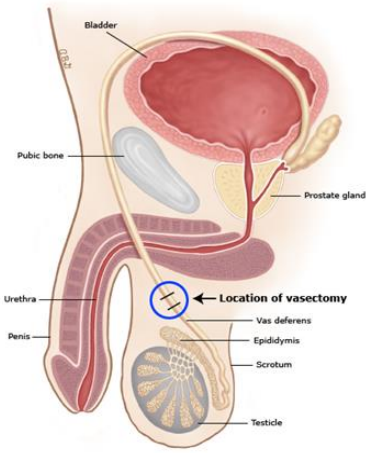

Figure 1. Diagram of the male anatomy, with location of scrotum, vas deferens, and typical vasectomy location shown. Image source: ("Anatomy of Vasectomy PI - UpToDate," n.d.)

The scrotum, which holds the testicles, also contains two spermatic cords that run from the interior abdominal wall into the scrotum. This spermatic cord contains a vessel called the vas deferens, which transports sperm to the rest of the male reproductive system (Gurung, Yetiskul, & Jialal, 2022). A vasectomy externalizes the spermatic cord from the scrotum before cutting the

vas deferens in order to stop sperm flow to the rest of the reproductive system ("Vasectomy - Mayo Clinic," n.d.). The main variation in the procedure performed by Contraline is that instead of cutting the vas deferens, a hydrogel is injected into the lumen (hollow channel) of the vas deferens. A urologist cannulates the vas deferens and must place the needle precisely inside the lumen. The hydrogel swells to the inner diameter of the lumen and acts as an obstruction so that sperm may not flow. After an estimated 3 years, the hydrogel will dissipate naturally and all fertility will resume without a further procedure ("Contraline," n.d.).

Our team has three phases we are working to complete. The first phase entails developing an anatomically correct model of the vas deferens. An anatomically accurate model requires not only the correct size of the vessel, but also must be synthesized from a material that is representative of the biomechanics of the vas deferens in a live human. One of the challenges of this phase is the biomechanical properties of the vas deferens is somewhat unknown, as it has not been studied in humans ("Vas Deferens (Ductus Deferens)," n.d.). Another challenge is that the wall of the vas deferens is incredibly thick relative to the lumen (Koslov & Andersson, 2013). The second phase involves developing a cannulation product that involves physical or chemical feedback that ensures the doctor is within the lumen of the vas deferens. As the walls of the vas deferens are incredibly thick, the lumen is small at an estimated 2 millimeters in diameter. This is a challenge for the urologists who perform the procedure since the target area is so small. We will use our model from the first phase to validate the device we create. The third phase involves getting feedback from urologists to iterate on our design and create a proof-of-concept model that incorporates all of our designs and work so far.

SOCIO-TECHNICAL FACTORS THAT INFLUENCE CONTRACEPTIVE USE AND DEVELOPMENT

A person's use of contraception – and which method they choose – is a decision which is heavily influenced by many social, political, and technical factors. The Social Construction of Technology (SCOT) is a theory based on the idea that people and societies are the ones who give meaning to technologies (Pinch & Bijker, 2008). Pinch and Bijker explain that technology's purpose can be redefined after it is created. The social circumstances at the time the technology is created influences how the technology is made, dispersed, and accepted. According to Pinch and Bijker, SCOT is a multidirectional view of how technology is used in that a technology is in no way deterministic. Different social groups have different uses and opinions on technologies, so therefore technologies can be used and accepted in different ways around the world (ibid).

The theory of SCOT applies directly to contraceptive choice because each contraceptive method has been shaped by its intended users. The most popular contraceptive method in any given geographical region is highly influenced by location, social atmosphere, and political leanings or limitations. This can lead to a disconnect between what the user's wants and needs are, and what is readily available to them (Wyatt et al., 2014). Political and economic factors have also been shown to influence contraceptive use, as these aspects contribute to controlling access, enforcing relevant laws, and promoting or impeding moral support of contraception (Sai, 1993). International organizations like the World Health Organization (WHO) and the United Nations (UN) have programs that provide contraceptive access to less developed countries, which have a direct impact on the surrounding economies. Additionally, in countries where children contribute to the household income, contraception is seen as unfavorable. Conversely, in countries where children do not contribute to household income, contraception is seen as a way for women to have autonomy, and a potential path out of poverty with less children to support. In a study conducted with data from Nigerian women ages fourteen to twenty-four, the impacts of

societal norms of the region were analyzed in how they affected contraceptive use ("Understanding How Social Norms Affect Modern Contraceptive Use," n.d.). Over 68% of these women has had at least one unintended pregnancy, and 64% of those women chose to end the pregnancy via abortion. The study aimed to determine whether social norms that discourage contraceptive use impacts the motivation to get contraception, or impacts the woman's ability to acquire the contraception. The women shared their socio-economic standing, relationship status, and past use of contraception. They were then asked a series of questions to help the interviewers determine what prevented contraceptive use. It was found that the ability to access contraception was a more impactful factor than the motivation to access them, meaning that these women felt their social norms prevented them from acquiring the contraception they needed. This study is a powerful example of how social factors influence the use and development of contraceptive methods.

RESEARCH METHOD

Thorough research will be conducted to answer the question: how have social and medical factors have combined to leave the burden of contraception on women, and how has the development of contraception options been affected by these socio-technical elements? Historically, women have carried an unfair portion of contraceptive responsibility, and the research guided by this question will unveil ways for future contraceptive methods to even this burden. It has been shown that communities can be strengthened through widespread contraceptive use (Sohn, 2020). The long-term effects of contraceptive use correlate with decreased maternal mortality rates, which leads to more women in the workforce and higher education. An extensive literature review will be performed to compile data concerning contraceptive use and development, as well as the social factors that influence these qualities.

Relevant peer reviewed articles and case studies will be gathered to provide evidence of contraceptive use, non-use, or development. Male contraceptive methods will also be discussed and researched.

CONCLUSION

Contraceptive non-use rates are as high as 40% in some countries, despite almost half of all pregnancies worldwide being unintended (Otim, 2020). With current technologies, men are unable to equally share the responsibility of contraception with their female counterparts. Uncovering reasons for current contraceptive use and success will allow male contraceptive technologies to be as effective and appealing as possible to their intended users. As pregnancy rates decrease, more women are able to succeed professionally, which leads to improved economies and communities. The future of male contraception depends on not just scientific advancements, but also the social factors that influence contraceptive use. The extensive research performed will provide a guide to what social factors influence a contraceptive method's success and widespread use, so that future development can align with these ideals.

REFERENCES

Anatomy of vasectomy PI - UpToDate. (n.d.). Retrieved October 28, 2022, from https://sso.uptodate.com/contents/image/print?imageKey=PI%2F

Contraception | CDC. (2022, October 19). Retrieved October 28, 2022, from https://www.cdc.gov/reproductivehealth/contraception/index.htm

Contraline. (n.d.-a). Retrieved October 28, 2022, from http://www.contraline.com/

Contraline. (n.d.-b). Retrieved October 28, 2022, from Male Contraceptive Initiative website: https://www.malecontraceptive.org/contraline.html

Gurung, P., Yetiskul, E., & Jialal, I. (2022). Physiology, Male Reproductive System. In *StatPearls*. Treasure Island (FL): StatPearls Publishing. Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK538429/

Hormones & desire. (n.d.). Retrieved October 28, 2022, from https://www.apa.org/monitor/2011/03/hormones

Khourdaji, I., Zillioux, J., Eisenfrats, K., Foley, D., & Smith, R. (2018). The future of male contraception: A fertile ground. *Translational Andrology and Urology*, *0*(0), S220-S22S235. https://doi.org/10.21037/tau.2018.03.23

Koslov, D., & Andersson, K.-E. (2013). Physiological and pharmacological aspects of the vas deferens—An update. *Frontiers in Pharmacology*, *4*. Retrieved from https://www.frontiersin.org/articles/10.3389/fphar.2013.00101

Liao, P. V., & Dollin, J. (2012). Half a century of the oral contraceptive pill. *Canadian Family Physician*, *58*(12), e757–e760.

Nearly half of all pregnancies are unintended—A global crisis, says new UNFPA report. (n.d.). Retrieved October 28, 2022, from United Nations Population Fund website:

https://www.unfpa.org/press/nearly-half-all-pregnancies-are-unintended-global-crisis-says-new-unfpa-report

Otim, J. (2020). Contraceptive nonuse among women in Uganda: A comparative assessment of predictors across regions. *BMC Women's Health*, *20*(1), 275. https://doi.org/10.1186/s12905-020-01148-6

Sai, F. T. (1993). Political and economic factors influencing contraceptive uptake. *British Medical Bulletin*, *49*(1), 200–209. https://doi.org/10.1093/oxfordjournals.bmb.a072598

Secura, G. M., Allsworth, J. E., Madden, T., Mullersman, J. L., & Peipert, J. F. (2010). The Contraceptive CHOICE Project: Reducing barriers to long-acting reversible contraception. *American Journal of Obstetrics and Gynecology*, *203*(2), 115.e1-115.e7. https://doi.org/10.1016/j.ajog.2010.04.017

Sohn, E. (2020). Strengthening society with contraception. *Nature*, *588*(7838), S162–S164. https://doi.org/10.1038/d41586-020-03530-8

Spotlight: One year and counting: Male birth control study reaches milestone | NICHD - Eunice Kennedy Shriver National Institute of Child Health and Human Development. (n.d.). Retrieved October 28, 2022, from https://www.nichd.nih.gov/newsroom/news/080222-NEST

Trevor J. Pinch & Wiebe Bijker. (2008). *The Social Construction of Facts and Artifacts*.

Understanding how social norms affect modern contraceptive use | BMC Public Health | Full Text. (n.d.). Retrieved October 28, 2022, from https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-11110-2

Vas deferens (ductus deferens). (n.d.). Retrieved October 28, 2022, from Kenhub website: https://www.kenhub.com/en/library/anatomy/vas-deferens

Vasectomy Reversal: Purpose, Procedure & Success Rate. (n.d.). Retrieved October 28, 2022, from Cleveland Clinic website: https://my.clevelandclinic.org/health/treatments/15459-vasectomy-reversal

Vasectomy—Mayo Clinic. (n.d.). Retrieved October 28, 2022, from https://www.mayoclinic.org/tests-procedures/vasectomy/about/pac-20384580

Wyatt, K. D., Anderson, R. T., Creedon, D., Montori, V. M., Bachman, J., Erwin, P., & LeBlanc, A. (2014). Women's values in contraceptive choice: A systematic review of relevant attributes included in decision aids. *BMC Women's Health*, *14*(1), 28. https://doi.org/10.1186/1472-6874-14-28