

An Analysis of Current and Experimental Methods of Male Contraception

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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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STS Research Paper

Introduction

There were an estimated 85 million unintended pregnancies worldwide—roughly 40% of all pregnancies – in 2012 alone (Sedgh). While female birth control methods such as birth control pills, IUDs, and Plan B have been developed and shown to be effective in the last century, there has been no such progress for male contraceptives. The two primary methods for male birth control are the condom and the vasectomy, and both methods have been used for over a hundred years. Despite the progress in female contraceptives, unintended pregnancies remain a global problem – one that could be helped by the use and development of novel male birth control methods. Using the social construction of technology, the development of current and future male contraceptives will be analyzed in the context of social, economic, and political influences.

Methods

Current methods of male birth contraception, primarily being condoms and vasectomies, are examined in the remainder of the paper. The way each method works is first explored, and then, the following questions are answered: Is the method safe, effective, accessible, and reversible? The development and use are examined using SCOT. Next, new contraceptive techniques and how they work are investigated. For each of these new methods, the following questions are explored: would the method be safe, effective, accessible, and reversible? SCOT is used to explain which new methods might be used, what the barriers are to entry into the market and use, and how these might influence the development of novel contraceptives.

Male Contraception

Birth control aims to prevent pregnancy. Pregnancy occurs when the male reproductive cell, called sperm, attaches to and fertilizes the female reproductive cell, called an egg. Hence, the main goal of male birth control is to prevent the male sperm from reaching and fertilizing the female egg. Sperm is produced in the testes, the male reproductive organ, carried through a tube, called the vas deferens, to another tube called the urethra and finally out of the penis. Different male birth control methods seek to prevent pregnancy by addressing different parts of this pathway. Male birth control methods are generally divided into two categories: hormonal and non-hormonal.

Current male birth control methods are the condom and the vasectomy. A condom is a form of barrier protection where a latex covering is worn over the penis. Barrier methods have existed since the 15th century, and rubber condoms have been used for birth control since the 19th century (Madhy). Condoms entrap a fluid containing sperm and nutrients, called semen, and prevent it from reaching the egg. A vasectomy is a surgical procedure in which a section of the vas deferens is removed. Vasectomies were performed on canines as early as the 1820s and started to be used widely in men during World War II (Leavesley).

There are a number of male contraceptive techniques, both hormonal and non-hormonal, that have been or are currently being developed that are not on the market. Hormonal contraceptive methods work by lowering the amount of testosterone, the male sex hormone, in the testes. As testosterone is responsible for the production of sperm, a lower amount of testosterone in the testes can cause azoospermia, or a lack of sperm in the semen. Two non-marketed methods for hormonal male birth control are injectable testosterone enanthate and testosterone undecanoate (Patel). A non-hormonal experimental method of contraception that works similarly to a vasectomy, by occluding the vas deferens, is under development. In this

method, a gel made out of compounds called maleic anhydride and styrene is injected into the vas deferens and remains there for a period of roughly a year (Ansari).

Social Construction of Technology and Male Contraception

Use and development of contraceptive techniques is influenced by social, political, and economic factors. Social factors that can influence how and if a method of contraceptive is used could include pressure from friends, family, and/or religious groups. Political factors that hold influence could be education programs, policy on the adoption or rejection of a contraceptive, or other governmental programs. Finally, economic influences that can affect the use of contraception include the cost of the contraceptive or the cost of raising a child.

The social construction of technology, or SCOT, describes the idea that groups within society give a technology its meaning (Wright). Pinch and Bijker postulate that different groups hold different meanings on a given technology, and this influences the technologies' purpose and how it is used. SCOT can be used to investigate how factors influence how a technology has developed over time and can give insight into how upcoming technologies might be accepted or changed.

There are four major steps in the SCOT framework: interpretation, groups, closure and stabilization, and wider context. Interpretation focuses on the meaning that different stakeholders or groups relevant to the technology give to it. Some groups can view and use a technology in a different way than others. The stakeholders could be a company that manufactures the technology, its employees, or the users of the technology, among others. The closure and stabilization step of SCOT involves the acceptance of a technology by society and its relevant groups. Closure and stabilization is achieved when society views the technology as acceptable.

Finally, the wider context step explores the wide-ranging social, economic, and historical factors that influence a technology, its development, and its use.

Results and Discussion

Introduction

The following section will first explore what male contraception is, and what it seeks to accomplish. Next, it will address the current methods of contraception - vasectomies and condoms. It will look into what they are, how they work, and how they were developed. Finally, new methods of male birth control, both hormonal and non-hormonal methods, will be examined.

Male Contraception

As discussed previously, the goal of male contraceptives, and contraceptives generally, is to prevent the male reproductive cell, sperm, from reaching and fertilizing the female reproductive cell, the egg. Sperm is carried through the male reproductive tract from seminiferous tubules to the penis. Sperm is made in the testes of a man in the seminiferous tubules, a group of cells that collectively produce sperm. Sperm is moved out of the seminiferous tubules to the epididymis, a highly folded tube connected to the outside of the testicle inside the scrotum, where it matures until ejaculation. When ejaculation occurs, sperm travels from the epididymis, through a duct or tube called the vas deferens and into the ejaculatory duct. On this path, fluid with various nutrients such as sucrose is added to the sperm to produce the fluid called semen from structures such as the seminal vesicles and prostate gland. Semen then enters the urethra and leaves the body via the penis. Male contraceptives can be broken down in two broad categories: hormonal and non-hormonal methods. Hormonal methods seek to reduce sperm

levels in males by altering the level of testosterone, the male sex hormone. Non-hormonal methods seek to prevent egg fertilization without addressing hormone levels by stopping progress along this pathway.

Development of Current Methods

The two commonly used method of male contraception are not the result of recent innovation. In fact, both of these methods have been used for over a century. The vasectomy first was used on dogs in the late 19th century and was eventually used in human patients in the early 20th century. There is evidence that condoms were used as early as ancient Egypt, but the first evidence of their use was for both birth control and disease prevention in Renaissance France. In contrast, there have been significant advances in female contraception in the last century. Hormonal and non-hormonal female birth controls have been developed that are accessible, effective, and reversible. The two most common of these are “the pill,” a type of hormonal female birth control, and IUDs, or non-hormonal devices that are implanted in the uterus.

Analysis of Current Methods

Various problems of condoms include their ability to break, be punctured, or used improperly, and in comparison with other birth control methods, they have a high failure rate. In the perfect use condition the failure rate is roughly 2% (Trussell, 2011). However, the failure rate associated with use over a year has been shown to be between 13% (Trussell, 2011) and 18% (Sundaram, 2017). Common failure modes of condoms are incomplete use, which entails late application or early removal. Incomplete use was found to have a prevalence between 20%-60% (Sanders, 2012). Although damage to condom before use provides a failure mode, a study showed that 2.1%-11.2% of users opened condom packaging with a sharp tool and inspecting

condom for damage was neglected by 74.5% of male users (Sanders, 2012). Condoms provide a risk for failure when not used correctly or at all. Although there are extensive education programs for the use of condoms, incorrect use persists. Furthermore, a surveys and focus groups reported that barriers to condom use were the embarrassment of buying condoms and their cost (Morrison, 2016).

The vasectomy procedure is generally considered to be safe and an effective method of birth control. The one-year failure rate in the year following vasectomy is 0.15%. This failure rate is vastly better in comparison with other methods, a 15% failure rate for male condoms, 27% for withdrawal, 29% for spermicides, and 25% for periodic abstinence (Trussell). The main drawback to a vasectomy is that it is not easily reversible, especially for those who receive a vasectomy at less than 25 years old (Holman, 2000). Vasectomy reversal can result in a decrease in fertility, as conception rate at 12 months is around 50% for reversal and 80-85% in healthy couples (Holman, 2000). Another drawback is cost, as vasectomies can be expensive and not covered by insurance. The cost of a vasectomy is around \$1,000, a cost that is a large barrier for many. Furthermore, a vasectomy reversal is even more costly and usually not covered by insurance. A cost analysis of the vasectomy reversal found that the average initial cost of a vasectomy reversal was more than \$25,000 (Pavlovich).

Although vasectomies are an effective method of male contraception, they suffer from a lack of predictable reversibility and accessibility. As the procedure incurs a much greater upfront cost than other methods, like condoms or female birth control such as the pill, many who could benefit from the procedure are prevented from having it due to economic reasons. The cost could be rationalized for the case of a young adult, as he could incur the cost when he is young, and not have to purchase any other birth controls for the remainder of his life, pending no complications.

However, this argument is flawed if this young adult wishes to have a child at any point. If he does so, the huge cost of reversal negates the cost benefit of getting the procedure in the first place. Aside from the financial cost of a reversal procedure, there comes a risk that there cannot be a successful reversal of the vasectomy.

The shortcoming of these two methods are significant because they are the two most used methods of male contraception. The public and users could see the two technologies on the market and not think to look further. Advertisements are used by the companies that provide these technologies to reinforce the idea and public opinion that the technologies are adequate.

New Methods

There are a number of experimental birth control methods for males that have been explore or are being developed. These methods fall into two categories: hormonal and non-hormonal. Hormonal male birth controls generally work by injecting a form of testosterone, the male sex hormone, into the body from an outside source. The production of the male sex hormone testosterone begins in the brain where gonadotropin releasing hormone or GnRH is released. GnRH stimulates the release of two other hormones, luteinizing hormone or LH and follicle stimulating hormone or FSH. These two in turn stimulate the release of testosterone. This production of testosterone is regulated in the body via a negative feedback loop, meaning that when the body senses high testosterone levels, it signals to itself to stop the production of GnRH which in turn causes testosterone to stop being produced. When exogeneous, or foreign, testosterone is introduced into the body, the testes produce less testosterone. Production of sperm in the testes is dependent on testosterone being present, so the decrease in production of testosterone in the testes causes a decrease in production of sperm. Two experimental methods for hormonal male birth control are injectable testosterone enanthate and testosterone

undecanoate (Patel, 2019). Both compounds' goal is to induce azoospermia, or a lack of sperm in semen, in the user. They function by increasing the amount of exogenous testosterone which in turn results in FSH and LH production being suppressed, and together result in lower levels of testosterone in the testes and impairment of sperm production (Patel, 2019). Nieschlag demonstrated the ability for testosterone use to induce azoospermia, but he was unable to show consistent results (Nieschlag).

Although there has been large success in using hormonal birth control in women, the promise in using a hormonal birth control for male contraception is lacking. Despite the fact that the physiological mechanism of action works in theory, there are downsides to using hormones to regulate sperm production in practice. The first is that there are inconsistent results. The results could be as a result of the naturally varying levels of testosterone in men. In a case where two men, one with a naturally high level of testosterone and one with a naturally low level of testosterone, are given the same dose of a testosterone mimicking drug, the testosterone levels of the first man could increase but not significantly while the levels of the second could experience a much larger relative increase. The second downside of using hormonal birth control in men is the levels of the testosterone required are often associated with negative side effects. Large amounts of testosterone cause increased risk of prostate cancer and heart problems, among other things.

Non-hormonal experimental male birth control methods aim to either disable sperm or to occlude the vas deferens. One non-hormonal method is Adjudin, an anti-sperm compound that prevents spermatids from binding to Sertoli cells (Wang, 2021). Sertoli cells aid in the development of sperm cells, so Adjudin effectively prevents the sperm cells from developing. However, the margin between the efficacy and toxicity of Adjudin is narrow (Mruk, 2006).

Another non-hormonal method is a vas occlusive method, via a material called a hydrogel. A hydrogel is a porous material that is made of polymers, or long molecules, that cross-link and bond to one another. There are a huge number of materials that hydrogels are made up of, and one example of a hydrogel used for vas occlusion is a gel composed of a compound called maleic anhydride and styrene. The gel occludes the vas deferens and prevents sperm from traveling from the testes to the penis through the vas deferens, similar to a vasectomy. This method has been shown to fully inhibit fertility and to be reversible using a solution of sodium bicarbonate to dissolve the gel (Ansari, 2016). A hydrogel-based vas occlusive method seems to have promise for development and use. The vas deferens can be occluded using a hydrogel, accomplishing the same goal as a vasectomy, and importantly, the use of a hydrogel addresses the major drawback of using a vasectomy – reversibility.

Each of these upcoming methods of male contraception deal with barriers to entry. Because the male contraceptive industry has been dominated by two products, consumers could be wary of another. Furthermore, the development of these techniques can be very costly, and the scientists behind these projects incur great financial risk. Even more, their products must meet the time consuming and stringent requirement posed by the FDA.

These new methods of male contraception show the process of closure and stabilization. Both members of the medical and scientific community and users of male contraception have impacted the development of new methods. These new methods aim to be better than existing methods, and push towards closure and stabilization of male contraception. In order for these novel methods to be utilized by the public, the scientific community and manufacturers of the technologies need to educate the public, including patients and doctors, on the new methods as well as existing methods of birth control in order for them to be successful. Furthermore, the

methods likely need to be significantly better than current methods for the new methods to be adopted.

Limitations and Future Research

The greatest limitation for this paper is that there is no stabilization for future male contraceptive technologies. The market of male birth control will continue to see innovation and continue to shift as a result of social groups and their forces. The field will continue to explore different vas occlusive methods that work by blocking the passage of sperm using different methods and materials. These methods could take the form of another kind of hydrogel or even a clamp placed over the vas deferens. Hydrogels are large classification of materials, so there exists an opportunity to explore the efficacy of many different kinds of hydrogels, both synthetic and natural.

Conclusion

Although there have been two predominant technologies in male contraceptive market, these options are not necessarily adequate. Both the condom and vasectomy have their merit, but with their use come inherent downsides. Condoms lack efficacy in the long run and are often misused, despite extensive education programs promoting proper use. Vasectomies suffer from high cost, especially for reversals, and lack reversibility of other birth control methods. New methods are being developed that could address some of these downsides, and a vas occlusive hydrogel offers great promise in addressing efficacy and without sacrificing on revisability. However, there are many barriers to entry for the development and adoption of new methods.

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