The Fetal State of Male Contraception

Social, Economic and Structural Hurdles of Development

Master Thesis Summary · Ophelia Wach · Technical University Munich

"When you say male contraception, people are like 'oh, that's an interesting thing'.
You have to put 'male' in front of it for them to understand that you don't mean the 'normal' contraception …"

— Expert on Male Contraception, Thesis Interview 1

Why Male Contraception?

Universal access is key.

Universal access to reproductive and contraceptive health care is a consistent challenge.

Contraceptive choice is limited for men.

Whilst there is a broad spectrum of methods for women to prevent conception, contraceptive choice for men is limited to condoms and vasectomies.

Vasectomies and condoms are not enough.

As vasectomies are designed to be irreversible, and condoms fail 13 percent of the time in typical use, the contemporary contraceptive method mix is considered inadequate.

No new methods have become available.

Still, in over fifty years of male contraceptive research, no new methods have been released to market.

The „fetal state“ of male contraception

Technology development is in early stage.

There are large knowledge gaps, especially in non-hormonal contraception. Since space and funding for research are strongly limited, there is only little opportunity to explore promising targets for male contraception.

There is no commercial market developed yet.

Despite potential for large revenue, the market for male contraception is practically non-existent. Contraceptives are known for high failure rates in development, there is a threat of litigation and skepticism regarding acceptability. This renders investments high risk and hinders market development.

Men are not considered in their full reproductive capacity.

Male contraception is perceived as rather exceptional. Decades of reproductive health care targeting women as primary users of contraception established gendered norms and habits that disadvantage male patients and male contraceptive usage.

Economic Factors

There is a general lack of funding.

“You can have someone do all of these studies that regulatory bodies are going to find important, but it's crazy expensive. (…) So funding is always a challenge.”

— Expert on Male Contraception, Thesis Interview 1

Private funding is abysmal.

“[T]he male birth control market is massive. It is billions upon billions of dollars.(…) I think there is a very real market here with real returns for investors. What we have in front of us is creating an entirely brand-new market and there's very little amount of money in the world that's worth that.”

— Expert on Male Contraception, Thesis Interview 3

Governments have little interest to invest.

“[O]verpopulation or control of population is not the problem at all here. (…). That's why it's not a priority. I got a grant (…) [b]ut if you take a big picture, you see that most of the funds goes to other areas.”

— Expert on Male Contraception, Thesis Interview 8

Social Factors

Women are considered responsible for reproductive health.

“I mean, it's a thing for a girl to go to a gynecologist as a young girl for a first appointment, right? There's nothing close to that on the male side, like it would never cross a father's mind or parents' mind, or even this teenager's mind to do it.”

— Expert on Male Contraception, Thesis Interview 7

The standards for contraceptives are high.

“Because there are relative unknowns and there haven't been products like this before they are also setting the bar very high to say like, well, we got to be sure about this.”

— Expert on Male Contraception, Thesis Interview 1

Structural Factors

Regulatory requirements are unclear.

"[Y]ou do not know what the federal agency wants to see before its approval. Is it like female matter or is it different?"

— Expert on Male Contraception, Thesis Interview 4

There is no medical infrastructure for male contraceptives.

"[O]ur whole commercial infrastructure is geared toward women. Men do not go to the gynecologist. But those are the kind of doctors that we go to where we (…) have an existing sales force."

— Expert on Male Contraception, Thesis Interview 9

Data and knowledge about male reproduction is incomplete.

"And they [scientific organizations] always express concern about testicular contraception because there's not enough research on the topic. (…) The point is that research is precisely what we're trying to do at the moment."

— Expert on Male Contraception, Thesis Interview 7

Medical trials need to consider two reproductive bodies.

"[Y]ou have to enroll with female partners.(…) You have to have cycle tracking, a whole bunch of things that make a clinical trial big and hard."

— Expert on Male Contraception, Thesis Interview 1

How to overcome these hurdles? Starting points

- ✓ Raise awareness for contraceptive counseling for people who produce sperm.
- ✓ Create medical centers for male reproductive health to build expertise on contraception and offer training to medical personnel.
- ✓ Ensure that current contraceptive options (vasectomies, condoms) are covered by public health insurance to strengthen access to male contraceptives already today.
- ✓ Form public-private partnerships to de-risk investment in contraceptive development.

> *"I think that more male partners stepping up and telling their stories about their involvement in reproduction, their roles as reproductive beings is important. I want men telling their abortion stories."*
>
> — Expert on Male Contraception, Thesis Interview 1

“I would like to have all the possibilities. The natural possibility and the big artificial possibility and the sure method and insecure method, the very dangerous method and very safe method. Because I'm sure during my way of life I'm not the same. (…) The line is very personal.”

— Expert on Male Contraception, Thesis Interview 5

Outlook

Promising Male Contraceptives In Development*

- NEST/T: a transdermal gel that is applied to the shoulders daily and contains the hormones *Nestosterone* and *Testosterone*. It is in stage 2b clinical trial to test the efficacy of the gel to temporarily inhibit sperm production. Preliminary results in seventeen locations worldwide are promising, raising hopes for a stage 3 trial.

- DMAU: an intramuscular injection of the hormone Dimethandrolone undecanoate. DMAU has been tested and well tolerated for a period of 28 days in form of a daily oral pill. It is in consideration for long-term studies (stage 1).

- EP055: non-hormonal oral pill that disables the protein EPPIN. EPPIN resides at the surface of sperm and is responsible for the movement of sperm post ejaculation (motility). Animal studies of EP055 have shown high efficacy with low adverse effects, paving the way for in-human studies in the upcoming years.

- Thermal Methods: aim to increase the temperature of the scrotum to inhibit the production of sperm (spermato-genesis). E.g. contraceptive underwear and rings that place the testes close to the body; testes baths. Research is in early stages.

*status quo as of September 2023

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