NOVEL CONTRACEPTIVE OPTIONS FOR MEN

INNOVATING TO EXPAND REPRODUCTIVE AUTONOMY FOR ALL

DSW
Deutsche Stiftung Weltbevölkerung

youth can

The unmet need for better contraceptive options

The only two contraceptive methods that are currently available for men are condoms, an on-demand option, and vasectomy, a permanent method of sterilisation. Condoms, alongside the risky approach of 'withdrawal', make up about 26% of worldwide contraceptive use[1].

Unmet need for contraception is a ubiquitous global health challenge and leads to approximately 121 million unintended pregnancies each year, equating to roughly half of all pregnancies. **257 million women have an unmet need for contraception globally**[2], with many citing side effects and health concerns as reasons for not using contraception. With the current, ageing array of female-led contraceptive options (largely rejigged versions of the hormone-based breakthroughs of the 1950s), the field is ripe for the development of novel contraceptives for all genders.

While contraceptive information and services are fundamental to the health and human rights of all individuals[3], **the very limited options available to men clearly fall far short of meeting their contraceptive needs**; across ages, relationship status, and reproductive intentions.

*The use of women and men in this document is done with recognition of diversity, and is inclusive of sex as a biological variable and gender as a social and structural variable across the life course.

1 https://www.unfpa.org/sites/default/files/pub-pdf/EN_SWP22%20report_0.pdf
2 https://www.who.int/health-topics/contraception#tab=tab_1
3 https://www.who.int/health-topics/contraception#tab=tab_1

Multiple reports in Belgium, including the latest State of Women's Health Report [5] have called for greater support for the development of male contraceptives, recognising the need for innovation. In 2025, Germany launched a research funding call on 'reproductive health, contraceptives for all genders' [6], with similar calls to action echoed in the United Kingdom [7].

With a growing global need for novel contraceptive options for all genders, the EU and its Member States should step up cooperation for contraceptive innovation, including with the private sector, not only to improve health outcomes but also to lead in a field ripe for scientific breakthroughs, social impact, and long-term return on investment.

4 https://www.bpas-campaigns.org/wp-content/uploads/2025/03/BPAS-Contraception-Report-March-2025.pdf
5 https://www.sciensano.be/en/biblio/womens-health-report-belgium-2024
6 https://www.bmbf.de/SharedDocs/Bekanntmachungen/DE/2025/01/2025-01-13-bekanntmachung-verhuetungsmittelforschung.html
7 https://www.ec-ec.org/wp-content/uploads/2025/03/BPAS-Contraception-Re-Imagined-The-Unfinished-Revolution-MARCH2025.pdf

Embracing opportunity

It is clear that current contraceptive choices are not meeting people's needs, yet there is a persistent lack of interest and under-investment in the research and innovation (R&I) of novel methods. **The totality of global funding for contraceptive and multi-purpose technologies (MPTs) R&I amounted to only 125 million EUR in 2023 - a five-year low.**[8]

There has been no funding for contraceptive technology development from the EU budget since 2021, despite European developers being involved in the development of 19% of all contraceptive products in the R&I pipeline, including 20 products in discovery and 17 products in clinical development[9]. Given the geopolitical changes afoot, the EU and its Member States are well positioned to support ongoing efforts across the continent to meet the global demand for novel contraceptives.

The EU should increase its investment in contraceptive R&I, through existing initiatives under Horizon Europe, the future framework programme, and broader upcoming R&I and external action instruments.

There has been no funding from the EU budget since **2021**

In 2023, the global contraceptive market-size was valued at around **30 B USD**[10]

The market growth rate is estimated to be **5.92%** from 2024 to 2030[10]

8 For reference, while difficult to calculate, the median cost of bringing a single new drug to market is estimated to be within the range of 1-2+ Billion USD.

9 https://cdn.impactglobalhealth.org/media/European-market-analysis.pdf

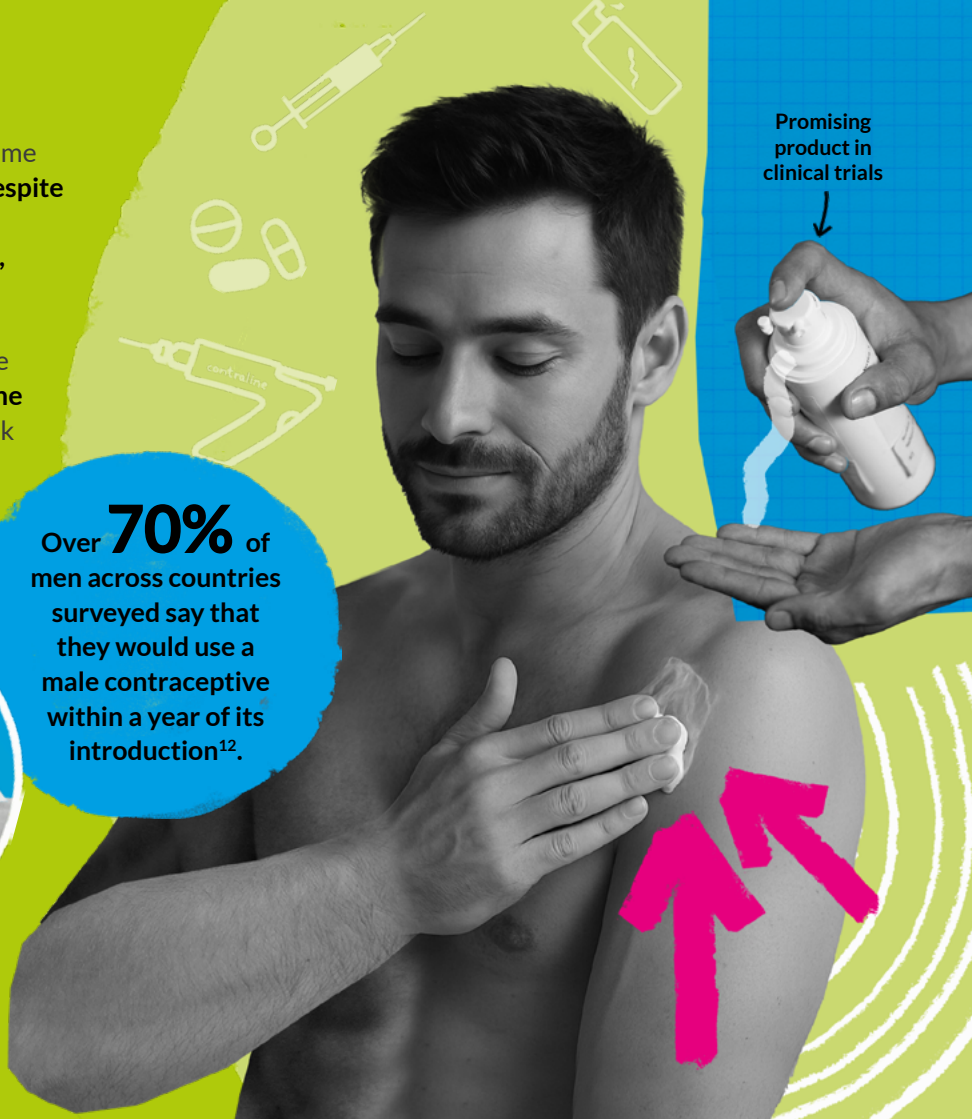
10 https://www.grandviewresearch.com/industry-analysis/contraceptives-market

What is in the pipeline?

Male contraceptives are not a novel concept: some have been in development since the 1960s[11]. **Despite the dire funding situation, sustained research efforts, predominantly in the field of academia, biotech and not for profit pharmaceuticals, have advanced promising candidates through the pipeline.** However, many of these innovative candidates are still **years away from reaching the market** and being in the hands of those who seek expanded contraceptive choice.

Promising product in clinical trials

Over **70%** of men across countries surveyed say that they would use a male contraceptive within a year of its introduction[12].



Promising product in clinical trials

11 https://pmc.ncbi.nlm.nih.gov/articles/PMC10759220/
12 https://www.malecontraceptive.org/market-research.html

MALE CONTRACEPTION R&I PIPELINE* *(selected examples)*

DISCOVERY

PRE-CLINICAL

Typical success rate entering the pre-clinical stage is 4%

ANDRO-SWITCH[13]

- Thermal ring to place around the penis and scrotum
- Medical device, minimally invasive, reversible
- Prevents sperm production
- Developed by Thoreme

Entering clinical trials in the coming years

PLAN A[14]

- Hydrogel polymer injected into the vas deferens
- Medical device, minimally invasive, reversible
- Prevents sperm transport
- Developed by NEXT Life Sciences

Hoping to get to clinical trials in 2025/2026

sAC inhibitors[15]

- On-demand pill
- Non-invasive, reversible
- Prevents sperm motility
- Developed by Sacyl Pharmaceuticals

Hoping to start clinical trials in 2025

PHASE I CLINICAL

Typical success rate entering the clinical stage is 13%

ADAM[16]

- Hydrogel inserted into the vas deferens
- Medical device, minimally invasive, reversible
- Prevents sperm transport
- Developed by Contraline

Moving forward to Phase II

YCT-529[17]

- Daily pill
- Non-invasive, reversible
- Prevents sperm production
- Developed by Your Choice Therapeutics

Entering Phase II in 2025

PHASE II CLINICAL

NES/T Gel[18]

- Gel to be rubbed on shoulders and the upper arm
- Non-invasive, reversible
- Suppresses sperm creation
- Developed by the Population Council **

Completed Phase IIb

PHASE III CLINICAL

Hormonal

Non-hormonal

*Adapted with the permission of *NewGenContraception*[19], with the contribution of the Male Contraceptive Initiative.[20]
**In collaboration with the Eunice Kennedy Shriver National Institute of Child Health and Human Development. Contraline has exercised its option to exclusively license NES/T from the Population Council, with negotiations ongoing.

> See footnotes on next page

What are the barriers to the development of novel technologies?

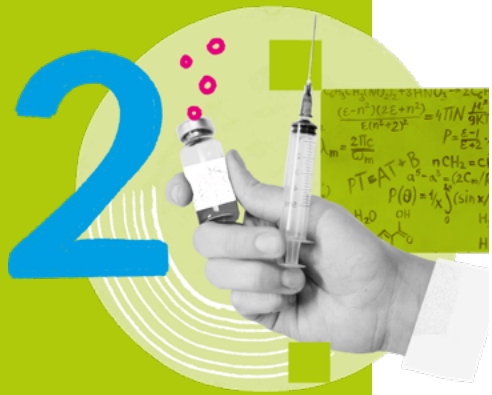
The R&I process includes several stages, each of which is designed to move an initial idea from a concept to a final product, and ultimately to approval and availability. On average, this takes 12 years, but can be much longer in areas where there is **chronic underinvestment, as is the case for contraceptive R&I**, which leads to a stop-start journey through the pipeline.

BASIC SCIENCE

Largely due to a historic neglect of women's health; social, scientific and political factors have limited resource allocation in this field of research, with the basic biology of human reproduction still poorly understood.

The EU and its Member States should increase investments in the research of the basic biology of human reproduction, to identify and validate new targets, and support the development of animal or replacement models, such as organoids or organs on a chip. This would benefit not only the contraceptive field, but also broader areas of health research, such as infertility or reproductive cancers.

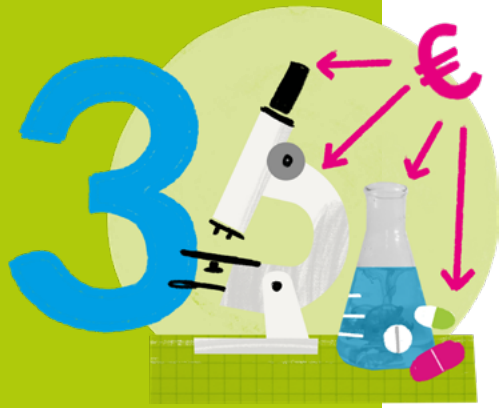
13 https://thoreme.com/en/
14 https://www.planaformen.com/
15 https://www.sacylpharma.com/
16 https://www.contraline.com/product/
17 https://www.yourchoicetx.com/
18 https://popcouncil.org/project/nestorone-testosterone-transdermal-gel-for-male-contraception/
19 https://newgencontraception.org/learn/contraceptive-rd/
20 https://www.malecontraceptive.org/



TRANSLATING RESEARCH INTO INNOVATION

Traversing the so-called 'valley of death', the gap between early stage research, funded predominantly via public and philanthropic funding, and later stage clinical trials that are often undertaken by, or in collaboration with the private sector[21] is challenging across all areas of biomedical research.

The EU should explore launching an accelerator programme (similar to the former Innovative Medicine Initiative's (IMI) AMR Accelerator[22]) to encourage cross-sectoral collaboration to enhance target identification and validation efforts, and bridge academic and industrial activities, including the increasingly active biotech sector.



INCENTIVISING

A significant increase in private sector investment in contraceptive R&I will be needed to translate new targets into a robust early stage pipeline and support their advancement through later stage clinical trials, registration, and ultimately into the hands of end-users.

The EU and Member States should explore the introduction of incentives to ensure attractive markets with rewards for innovation and mobilise increased investment and research activity in the field of novel contraceptives[23].

21 https://www.malecontraceptive.org/blog/male-birth-control-where-is-it
22 https://www.ihi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/future-topics/IndicativeText_AMRAccelerator_TBDrugDevelopment.pdf
23 https://igvm-iefh.belgium.be/sites/default/files/media/documents/200%20-%20La%20contraception%20en%20Belgique.pdf

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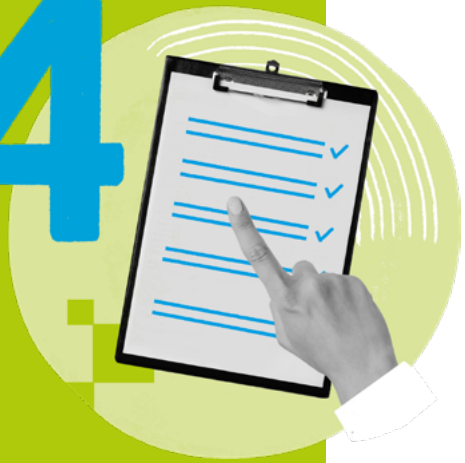

REGULATORY BARRIERS

The lack of approval guidelines for the development of contraceptive methods for men from regulatory authorities such as **the European Medicines Agency (EMA)** creates uncertainty and risk for researchers, developers, and investors. The pathway to approval is unclear and developers do not know what standards (e.g. for safety, efficacy) a technology must meet to gain approval. This ambiguity can lead to delays, rejections, or demands for additional (and costly) studies. Guidance for non-hormonal contraceptive development for women would also benefit from an update.

The EMA and other European regulators, together with global counterparts, should jointly evaluate the contraceptive and MPT landscape and develop approval guidelines that will inform developers and ensure the advancement and registration of safe and effective products. This should include a new medical-ethical assessment that balances the shared risk and responsibility of contraception, and considers a new endpoint for efficacy, based on established WHO thresholds for sperm concentration.

Over half, and in some countries up to 86% of female partners surveyed expressed trust in their male counterparts to be responsible for taking birth control[24].

24 https://www.malecontraceptive.org/imr-results.html#trust

Why expand reproductive choice for all?

Women have historically been the target for contraceptive development, and today, they still carry a **disproportionate burden for preventing unintended pregnancies,** facing physical, financial, and sometimes psychological consequences as well as the 'mental load' it creates[25].

This imbalance is a reflection of deep-rooted gender norms that position pregnancy prevention as a woman's responsibility.

Improving and innovating on the existing methods for women and introducing novel methods for men could broaden contraceptive choices for all[26]. It would **enable men to take a more active, intentional role in fertility and birth control,** thus gaining further agency in their reproductive lives and contributing to greater equality. In contexts where women face legal, cultural, financial or logistical barriers to accessing contraception or safe abortion, novel methods for men could offer couples who seek to space or limit births an expanded range of **shared contraceptive strategies**.

Funders, agenda setters, and researchers should centre efforts for novel contraceptive development on end user needs and preferences, including ease of use, protection against STIs, reversibility and user control[27].

25 https://www.brusselstimes.com/belgium/1582894/contraception-use-remains-mental-burden-on-women-study-shows

26 https://pmc.ncbi.nlm.nih.gov/articles/PMC10759220/

27 https://www.malecontraceptive.org/uploads/1/3/1/9/131958006/mci_consumerresearchstudy.pdfconsumerresearchstudy.pdf

28 https://onlinelibrary.wiley.com/doi/10.1111/andr.13726

29 https://mpts101.org/

Fit for (multi)purpose

Currently, the condom is the only approved multipurpose prevention technology (MPT) – a method of contraception that offers protection against both unintended pregnancies and HIV and other sexually transmitted infections (STIs), such as human papilloma virus (HPV), chlamydia or Hepatitis B. After form, protection from STIs is the most important criteria established by men when considering preferred characteristics for novel contraceptives[28]. However, most of the novel contraceptives currently being researched are not MPTs, despite their huge potential for public health impact and cost-saving. Lack of investment and regulatory barriers serve as significant obstacles to the development of MPTs, however, promising candidates are advancing through the pipeline[29].

Important sociocultural considerations

The introduction of novel male contraceptives raises a number of sociocultural and ethical considerations, including bodily autonomy, trust, and gender dynamics. **The broadening of contraceptive options for men should be seen as complementary to expanding contraceptive choices for women.** Just as women deserve full control over their reproductive choices, so too should men in order to expand, rather than restrict, reproductive autonomy for all.

A level of skepticism on whether men's use of contraception can be relied on in practice is to be expected, particularly as men do not bear the full consequence of unintended pregnancies. While ultimately the issue of trust comes down to the intimate, personal relationships between partners, **studies have shown that overall, a majority of women would trust their partners to use contraception**[30]. At the same time, at least half reported that they would want to continue their own contraceptive methods[31].

The introduction of any new contraceptive method should be paired with comprehensive sexuality education (CSE) and lifelong access to contraceptive counselling to inform users about choice and best practices linked to contraceptive use.

30 https://onlinelibrary.wiley.com/doi/10.1111/andr.13726
31 https://onlinelibrary.wiley.com/doi/10.1111/andr.13726
32 https://commission.europa.eu/document/download/0c3fe55d-9e4f-4377-9d14-93d03398b434_en?filename=Gender%20Equality%20Report%20Chapeau%20Communication.pdf
33 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:42017Y0630(01)
34 https://health.ec.europa.eu/document/download/25f21cf5-5776-477f-b08e-d290392fb48a_en?filename=international_ghs-report-2022_en.pdf
35 https://commission.europa.eu/document/download/7d965089-e332-473a-88a9-e246f214e3bf_en?filename=Gender%20Equality%20Roadmap%20-%20Annex.pdf

Improving health and advancing equality in the EU and globally

Equality between women and men is a fundamental value enshrined in EU law[32]. The institutions have long committed to the promotion of sexual and reproductive health and rights (SRHR), which includes access to contraception, both in the EU's internal and external action.[33,34,35]

Investing in the development of expanded contraceptive technologies would deliver significant public health gains in Europe and beyond.

While philanthropic and public funders, especially those focused on low- and middle-income countries (LMICs), have historically shouldered a substantial proportion of investment in contraceptive development, many barriers persist in accessing existing and novel contraceptives in LMICs, including challenges around affordability, availability, and acceptance.

A human centred design approach should be adopted in the development of new contraceptives, including end users in LMICs, to ensure novel options meet the needs of diverse populations globally.

Tackling shared public health challenges

European and African leaders have committed to collectively '*advancing key health priorities critical to the shared prosperity and well-being of our peoples*'[36]. **Sub-Saharan Africa bears the highest proportion of women with unmet need for contraception worldwide, and African countries surveyed demonstrated the highest interest in, and desire to use novel male contraceptives**[37].

Through joint initiatives such as the AU-EU Innovation Agenda, supported by the EU's research framework programme, investing in the development of novel contraceptives offers an opportunity to advance on shared public health priorities while building on, and driving sustainability in the EU's long-term investments in Africa. These include those made as part of the Global Health EDCTP3 Joint Undertaking and the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV+).

The EU should leverage the many tools at its disposal to advance contraceptive technology development, and use its convening power to align Member States' national initiatives with those of diverse European and global actors, and lead the urgent reform that is needed in contraceptive R&I investment and regulation with the potential for truly life-changing impact.

36 https://www.consilium.europa.eu/media/q50bjauc/joint-communiqu%C3%A9-21052025.pdf
37 https://www.malecontraceptive.org/market-research.html

Year of publication: 2025