

A Global Grounded Theory Exploration of Investigators' Perspectives on Male Hormonal Contraceptive Development and Acceptability

Taylor **Sheridan**¹, Piedad **Gómez-Torres**^{2*}, Germano **Vera Cruz**³, Guillermo Z. **Martínez-Pérez**²

¹ The Barcelona Institute for Global Health Foundation (ISGlobal), Barcelona, Spain

² Department of Psychiatics and Nursing, University of Saragossa, Spain

³ Department of Psychology, UR 7273 CRP-CPO, University of Picardie Jules Verne, Amiens, France

* Corresponding author: Faculty of Health Sciences – 2^a Planta, Despacho 18. Calle Domingo Miral s/n, CP 50009 Zaragoza, Spain. Tlf 34671274678.

Email: piedadgoto@gmail.com

ORCID^{2*}: 0000-0003-0045-7871

Keywords

Male hormonal contraception; Male pill; Grounded theory; Contraception development; Family planning

Words count: 5203

A Global Grounded Theory Exploration of Investigators' Perspectives on Male Hormonal Contraceptive Development and Acceptability

Abstract

Context: While best practices have been proposed on how to engage men in family planning (FP), the limited options of male hormonal contraceptives (MHC) are a barrier to reaching men as clients of FP programs. The lack of alternative MHC is preventing the global health community from providing holistic reproductive healthcare.

Methods: A qualitative grounded theory study was conducted in 2020 to explore MHC experts' perceptions around the development and theoretical acceptability of MHCs. Individual in-depth interviews were conducted with 15 key informants.

Results: The informants cited evidence that there is a demand for MHC. The inability to access this data by the pharmaceutical industry was acknowledged. Many informants expressed concern of the possibility for MHC to increase male power in a predominantly patriarchal world. To most informants, at least for the initial introduction of MHC, fertility sharing is something that will largely happen among couples alone rather than individually.

Conclusions: There is proven demand among women and men for MHC, however industries may still be reluctant to invest. Effort is needed by the sexual and reproductive health and rights community to include male engagement in FP and to advocate for the development and use of MHC as a tool for women's empowerment.

Keywords

Male hormonal contraception; Male pill; Grounded theory; Contraception development; Family planning

Introduction

As defined by the United Nations Population Fund (UNFPA), “to maintain one’s sexual and reproductive health, people need access to accurate information and the safe, effective, affordable and acceptable contraception method of their choice” ¹. The number of female contraceptive options, however, currently outweighs male alternatives. In the classification system used by Festin et.al, 2016 (p.291) there are 10 female-controlled methods compared to the three male-controlled methods (i.e., male condom, vasectomy, and withdrawal) ². This inequality often positions women alone with the primary responsibility of family planning (FP) ³⁻⁵. The availability of contraceptive methods can be seen as a direct reflection of the social, familial, and reproductive norms imposed on women to be the bearer of pregnancy prevention. In the 2019 United Nations report of Contraceptive Use by Method the estimated percentages are described to only be reflective of women’s contraceptive use with graphs titled as “*Estimated numbers of women of reproductive age (15-49 years) using various contraceptive methods*” ⁶. While the European Institute of Gender Equality recommends reporting sex-disaggregated data, many institutions, including the United Nations, remain gender blind ^{7,8}. This assumption of solely women as contraceptive users leads both health institutions’ users and staff to omit men from the narrative.

Vasectomy is more cost effective, efficacious, and safer than tubal ligation ⁹. However, rates of tubal ligation exceed vasectomy in almost all parts of the world ⁶. Although condoms are reported to be the second most commonly used method (9), there is evidence to support the populations’ dissatisfaction with this product ^{5,10}. In addition, while the efficacy of condoms is 98% with consistent and correct use, studies have shown the average effectiveness is a mere 87% with actual

use ¹¹. In turn, the lack of male hormonal contraceptive methods (MHC) removes men from the conversation around the choice to assume contraceptive responsibility ¹². The lack of alternative MHC is preventing the global health community from providing holistic reproductive healthcare. Without an effort to close this gap the sexual and reproductive health and rights (SRHR) needs of women and men cannot be fully met.

FP programs define male engagement into three categories: men as clients; men as supportive partners; and men as agents of change ¹³. While engaging men as agents of change does include shifting social norms harmful to men, most male engagement programming is focused on men as clients and as supportive partners ¹⁴. Studies have shown that any engagement of men in FP leads to better health outcomes ^{15,16}. Less is known, however, on reaching men as FP clients—a key to MHC uptake ^{12,14}. In a cross-sectional survey of 384 Ghanaian men it was shown that while there is a high level of contraceptive knowledge (90%) only 55 men (14%) were willing to assume sole responsibility for FP ¹⁷. In a study with 72 married Togolese men, it was found that limited contraceptive options along with insufficient health clinics to receive services was seen as a barrier to men engaging in FP ¹⁸. In another survey performed in 2002 (*n*=9000 men) in nine countries (France, Sweden, Germany, Spain, Brazil, Mexico, Argentina, Indonesia and the United States) the average acceptance of MHC was 55%, ranging from 28.5% in Indonesia to 71.5% in Spain ¹⁹. As to whether women would be prepared to delegate such contraceptive responsibility to men, a study conducted with women attending FP clinics in Scotland, China and South Africa (*n*=1,894), showed only 13% did not believe that MHC was a good idea and only 2% said they would not trust their partner to use a male contraceptive pill ⁴.

While best practices have been published on how to engage men in FP ^{18,20} the limited options of contraceptive choices will continue to be a barrier. Although research has been underway since the 1970s for the development of a MHC, none are available on the market ²¹. Development has proved to be difficult partly due to financing problems, which may be reflective of society's unwillingness to shift contraceptive responsibility to men ²². Since the 2000s, new MHCs have been investigated through different mechanisms to inhibit spermatogenesis or to render sperm non-functional ^{3,23}. In recent years, clinical trials have begun testing the effectiveness of new MHC methods ²². The Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center and the University of Washington have recently carried out various clinical trials on potential candidates for MHCs; a Phase 2 placebo-controlled study to investigate the spermatogenesis suppression after the oral administration of Dimethandrolone Undecanoate (DMAU) alone or with Levonorgestrel (LNG) ²⁴; a Phase 1 single-dose study evaluating DMAU administered as an injection ²⁵; a Phase 1 of a 28-day repeat-dose study of 11- β Methyl Nortestosterone Dodecylcarbonate (11 β -MNTDC) administered as an oral pill ²⁶; and recruitment has begun for a prospective Phase 2 open label, single arm, study of f Daily Application of Nestorone® (NES) and Testosterone (T) Combination Gel ²⁷.

It is important to explore socially-driven predictors of men's interest in MHC development and uptake. To palliate the dearth of information, a qualitative study was carried out in 2020 with the aim to explore the phenomena around the development and acceptability of MHCs as perceived by global MHC experts with research and publication experience in MHC development. The specific objectives of this study were: to determine the informants' perceptions regarding the acceptability of MHC and the male role in contraceptive responsibility, and to identify informants'

perceptions of possible expansion of FP with MHC interventions, and provide recommendations based on the identified gaps.

Methodology

This was a qualitative study in design conducted in the first semester of 2020 using a grounded theory approach to gather and interpret data via individual in-depth interviews (IDI) (Table 1). Grounded theory is inductive in nature and seeks constant interrogation of the data generated through the interactions of the researchers with the participants ²⁸. This study followed methodological advice provided by Kathy Charmaz ²⁸, grounded theorist who developed guidance for the conduct of constructivist grounded theory-based health research.

This research was conducted in parallel to a survey of Spanish men's acceptability of MHC, carried out in Zaragoza, in 2019-20, ²⁹ and adds to a separate quantitative component that builds on the acceptability data from a 2018 study in Mozambique exploring men's willingness to use a contraceptive pill ³⁰.

Study Population and Sampling

For the purpose of this study, key informants are defined as MHC experts with research and publication experience in the MHC development field. To be considered eligible for participation, experts had to be first, last or corresponding authors of peer-reviewed MHC articles – irrespective of whether they work as researchers, pharmacists in the contraceptive industry, or FP policy and programs-makers.

Sampling of informants was done through an internet search for email addresses of MHC articles' authors, inviting them to participate in IDI via email. Each potential informant was contacted twice by email to invite them to participate in the interviews if no response was obtained the first time.

Of the 39 potential informants reached via email, 20 never responded, four refused participation, and 15 consented to participate. Of these, six were male. Average age was 47.44 and 48.67 for female and male informants, respectively. Nine informants were from the United States, two from Spain, one from United Kingdom, one from Germany, one from Mozambique, and one from Australia. Six of them had achieved a PhD. While we initially intended to have among the study participants pharmacists in the contraceptive industry, none of the 15 KIs corresponded to this criterium. To prevent their identities from being recognized by the reader, only disaggregated socio-demographic data are presented in Table 2.

Procedures and Ethics

As part of the informed consent process, the standard IDI invitation email explained the purpose and objectives of the study; the organizations implementing this study; the potential risks of the study; measures to protect the privacy and confidentiality of participants; the time it would take to participate in the study; not receiving any reimbursement for participating; and the right to refuse to answer any questions they did not want and to withdraw from the study at any time without penalty. A date for an IDI was proposed to reached informants who answered the invitation emails and manifested interest in participation. Before the agreed date for the IDI, each informant sent their signed informed consent in writing by email and, in addition, oral consent was requested again from each participant by videoconference in the non-face-to-face interviews or in person before the start of each IDI.

This research received approval from the Ethics Committee of Aragon (CEICA, Spain) (Ref.: PI19/192).

Data Generation

Data was generated through IDI using a semi-structured guide (Table 1), with each IDI lasting 60 minutes in average. No repeat interviews were carried out. The interviews were conducted by a female Master Global Health candidate and a female PhD Health Sciences candidate (TS and PGT).

As per Kathy Charmaz's considerations, key informants are "co-generators of theory", implying that grounded theorists should approach key informants with the aim to make them co-responsible for the generation of knowledge and active participation in the research ²⁸. Based on their interactions with the interviewers, and based on their motivations additional themes were incorporated into the interview guide as they were generated anew in the course of the IDI as part of the grounded theory approach.

Strict measures were applied to ensure privacy and confidentiality. All informants gave their written consent (via email) to participate and were assigned a unique identification number (UIN). Personal identifiers were collected only for the sole purpose of re-contacting the informants to share the study findings if they indicated they would like to receive them. The UIN was used to label the interview guide, consent forms, and transcription of the IDI.

No informant requested transcriptions be returned to them for comment or correction. The IDI recordings were permanently deleted once the analysis process was completed.

Data Coding and Analysis

First, the interviews were transcribed, coded, and analyzed in parallel by (TS and PGT). Personal identifiers were not transcribed in any document or digitized into any database.

Then, the themes were inductively derived from the data and organized into a theoretical coding tree with categories and sub-categories that was used to code all IDI transcripts. Coding was done line-by-line in a printed set of the first five IDI transcripts. When the coding tree was considered final, open coding was finalized in a digital copy of the transcripts. The patterns, themes, and relationships identified in the analysis of the coded data are summarized in the Results section of this paper, which has been prepared using the COnsolidated criteria for REporting Qualitative research (COREQ)³¹.

Result

MHC Development

Despite the evidence showing the general population finds MHC acceptable there is a perception that this is not the case. KIs were in agreement that *attitudes and behaviors can be very different*. All KIs cited anecdotal or published evidence that, at least theoretically, there is demand for MHC. The lack of *ability* or *willingness* to access this data by the pharmaceutical industry was acknowledged by most KIs referencing the industry view was one of a *questionable market*. KIs largely assumed this was the reasoning behind the *lack of interest* or *hesitancy* of the pharmaceutical industry in the development of MHC.

A sense that pharmaceutical companies base their development interest on profitability prevailed across the interviews. If it is perceived that MHC are not acceptable, and people will not purchase them, then it is assumed there is no revenue to be made in this field and development is halted.

The pharmaceutical industry is an industry. Industries sell contraceptive methods, after all. They are a business in a certain way. [Hence] we have methods that are affordable to the majority of the population, and others [methods] that are unattainable.

(Female, 30-39, Spain)

Eleven of the 15 KIs cited the peaking interest of the pharmaceutical companies in the early 1990s to develop MHCs. While there is uncertainty around monetary gain, the risky task of the initial product research has been left to non-government organizations (NGOs), small-startups, and academia. As one male informant explained:

The field has been very much academically, and NGO-driven rather than commercial. So, it's been run by academics who pursue things that they find worthwhile but also intrinsically interesting to themselves. They don't necessarily have the same end product focus [in mind] as a commercial organization that really needs to get a product out there and make money from it.

(Male, 50-59, United Kingdom)

Twelve of the 15 KIs described the unfruitful cycle of NGOs, small-startups, and academia undertaking the initial, and financially risky, work to develop MHC and then pharmaceutical companies stepping in to move the process forward and through production, due to their surplus

of resources. While the general consensus for this failed process was often cited back to the *questionable market*.

Seven of 15 KIs noted a lack of definition around what an acceptable MHC method would look like. As this is a novel drug, and men are not themselves directly experiencing the physical health risks associated with pregnancy, the regulatory standards would differ from the majority of the current market. These same KIs perceived that the regulation of an MHC is and would be more rigorous given the *lack of risk of pregnancy* in men. However, it was clear among this group that there is hesitancy within the MHC and FP community to be the first to propose *hypothetical standards* around what would be considered safe. One female informant felt that the way risk is currently perceived will need to be reframed from *individualistic to dyadic*, where the health risk between two people is lower overall. Another female informant from Mozambique explained:

Women have a lot of resources to postpone pregnancy, even to avoid it. For me [that] means a gap. For me at first instance, I don't buy the idea that we have a male contraception right now.

We must go forward because we only use here condoms and vasectomy, but mostly condom.

(Female, 30-39, Mozambique)

One male informant believed the largest barrier to MHC development has been a more complicated biology of men when it comes to suppressing reproductive function. Opposite this point of view, one female working in Academia raised the concern that gender-bias may play a role in the MHC development agenda citing that *gender norms still perpetuate* among those making financial decisions within the pharmaceutical industry.

Drivers of Acceptability

KIs debated about what factors could increase or decrease potential consumers' acceptability of MHC. They raised a variety of influencing factors on MHC acceptability including side effects, effectiveness, cost, route of administration, disease transmission risk, and the scenario in which the female partner is medically unable to take a hormonal contraceptive. All but two male informants anticipated that some men might not be as tolerant of side effects as women. In their opinion, because the risk was not to the same degree, the tolerance would be lower.

Four of the 15 KIs suggested that side effect tolerance in male potential consumers of MHC could be raised by effective FP counseling to demonstrate understanding that *there is no method that is side effect free*, and that men are *capable of accepting the same side effects* as women. Opposite to this view, one male informant suggested that comparing the side effect tolerance levels of women and men was not a productive contribution to increasing MHC acceptability in men. One of the female informants working in FP, profiled the potential male consumers who could assume side effects of an MHC similar to the side effects of female hormonal methods and for whom these side effects would not be a limitation of the acceptability of an MHC:

The side effects of an MHC would be bearable for a man with a 'new masculinity' [lit. 'nuevas masculinidades' in Spanish] who not only talks about equality, but who practices it.

(Female, 30-39, Spain).

Thirteen of the 15 KIs associated the identity with either *new* or *traditional* masculinities to an increased or decreased likelihood of MHC acceptability. Describing *new* masculinity as *getting away from the hyper-masculine, less rigid gender norms and gender roles, and supportive of male contraception*. With *traditional* masculinity described as *subscribing to a certain set of notions, a lack of ability to talk about issues related to sex, and men must have all the power*. Eleven KIs described the societal shift of gender norms and roles that *new* masculinity has brought, allowing space for conversations around and the introduction of MHC and male responsibility of fertility control. The progression from *traditional* to *new* masculinity was described as a *generational transition* and a potential indicator for how successful the MHC could be in the way that the *demonstration of masculinity be influential for men's pursuit of male contraception*.

In regard to relationship status, most informants described the role this played for potential female and male users of MHC in regards to how it could influence other factors such as side effect tolerance. In this scenario, the potential MHC user would be *motivated to do the right thing for his partner* because of the relationship he was in. Majority of KIs also associated relationship status with an increased likelihood of women trusting their partners to assume contraceptive responsibility via the use of MHC. Citing that the commitment of a relationship *provides proof* of trustworthiness and increases a woman's *willingness to put the risk in somebody else's hands*.

One informant explained that, within the dynamics of a stable traditional monogamous relationship, some women might *have added control and safety* because there is an assumption that the male partner will also bear the consequences of an unwanted pregnancy. Nevertheless, while most KIs were concerned with the risk women faced with the dynamic of MHC within a

stable relationship, it must be emphasized that only one male informant considered MHC as a method to protect the male partner from an unwanted pregnancy by potential MHC users:

...the sad fact is that entrapment does occur and guys are alert to the fact that, not so much casual partners, but the sort of serial monogamy that people get up to these days you know a lot [...] I've heard of cases, you know, women who have stopped it and said "I'm telling you, we're pregnant".

(Male, 60-69, Australia)

Eight of the 15 KIs noted the limitations of theoretical acceptability data, recognizing there may be a difference between potential MHC consumers' attitudes and opinions and their actions. Eleven KIs perceive assessing theoretical acceptability as an important factor for MHC development. One male informant acknowledged the importance of framing the context and expectation when collecting this type of data. Another female informant suggested that the most important aspect of acceptability data collection is to be able to learn what MHC features are not acceptable by different types of male potential consumers, such as *to have to get an injection every three days*. Only one female informant questioned the value of continuing to discuss acceptability of MHC methods. In her opinion, there were other key informants who, in agreement with this female, also suggested a general principle had already been proven, that *there is a population of men and women out there who will be keen to see new male methods*.

The Effect of Power in Decisions around Contracepting

Nine of 15 KIs repeatedly cited the role of FP and SRHR programs as a tool for women's empowerment. In regard to the agenda of prominent FP organizations, participants described it as *all about women's empowerment* recognizing today prioritizing male inclusion in FP is not within the current agenda. With the development of a commercially available MHC on the horizon there is concern for what its introduction could take away from women. However, one male informant pointed out that if the goal is to empower women then the agenda *has to include men and boys*.

Seven KIs elicited concern of the possibility for MHC to increase male power in a predominantly patriarchal world. One male informant posed the dangerous scenario of a sexual exchange where the male says *I'm using contraception [MHC] so we don't need to use barrier protection, we don't need to use a condom*, putting the female in a position of needing to defend her reasoning for the use of barrier protection. One female informant included, in her reflection on the cases in which men would accept MHC, that some would take MHC to dominate their female partners:

Control, as we already know, is one of the many elements of a couple. Mastery, power, all that, gender goes there too, submission and mastery are a key element also in contraception.
(Female, 60-69, Spain).

Nine of 15 KIs emphasized the need to further examine these power dynamics during the development and introduction of MHC, while recognizing that the motives of health product development are often to serve, as one female from the United States put it, *the hegemonic gender* [i.e., the male] *that typically has control and power*.

For the initial introduction of MHC, fertility sharing is something that will largely happen *within a frame of communication between or within couples*. One female informant, referenced the definition of FP as *both sides are working together to make [plans]* to decide how fertility control will be shared and what the goals among the couple are for a family or lack of one.

When considering if MHC could be used in an unstable relationship, or for one-off sexual encounters, it was suggested that proof may be requested by the female partner. One female informant imagined a *certificate for those using MHC* with the understanding that there would not be enough trust built between un-coupled heterosexual partners to rely on MHC use without actual evidence of its administration.

Discussion

This qualitative research was conducted building off the acceptability data from a 2018 study of men's willingness to accept MHC in Mozambique ³⁰ and from a 2019-20 survey of men's theoretical acceptability of MHC in Spain ²⁹. This research describes MHC experts' perspectives through a constructivist grounded theory approach that allows the identification of the "why" behind the trends of MHC development and the inclusion of male-controlled contraceptive methods within the FP space. In this research, KIs described the barriers holding back the progress of MHC development as being associated with social and patriarchal values. In their opinion, the pharmaceutical industry's lack of participation in MHC development, can be related to the industry's value of profitability over gender equality progress. Financial return and regulatory barriers were frequently mentioned when the pharmaceuticals companies' withdrawal from MHC development was addressed ³²⁻³⁴.

As per the KIs' insights, factors influencing acceptability include side effects, effectiveness, cost, route of administration, relationship status, disease transmission risk, and the medical context in which the female partner is unable to take a hormonal contraceptive. MHCs are proven to be acceptable for both women and men, as many previous studies have shown ^{21,35-37}. Using data from the National Survey for Family Growth, demand estimation of the potential market size for a novel MHC method, at 50% reduced projection, suggests a pool of customers at least as large as several current female methods ³⁸. The phenomenon behind why pharmaceutical companies do not consider this proof is not understood, however, this study sheds light onto how risk perception and gendered biases may play a role.

Pharmaceutical concern with regulatory challenges can be attributed to the lack of clear definition around what society will be willing to accept in regard to key characteristics of MHC such as effectiveness and side effects. In this scenario, risk of an unwanted pregnancy is being understood in an individualistic sense. To successfully shape regulatory guidelines for MHC, risk needs to be seen as *dyadic* ³⁹, something that is shared between a pair of individuals. The use of MHC by men will reduce physical or psychosocial health risks related to unwanted pregnancy in women, and therefore the side effects experienced by men can be justified. In low-income countries this may help reduce incidence of maternal and newborn mortality by means of pregnancy prevention ^{40,41}. Previous literature has identified that for regulatory approval the benefits must outweigh the risk but clear delineation of where the boundaries can be set as a starting point would prove as useful regulatory and product design benchmarks for those working to develop MHC for commercial use

The KIs in our study affirmed that relationship status may be one of the most influential factors of MHC acceptability. A stable relationship status is expected to increase the female partner's likelihood to trust and the male partner's willingness to see pregnancy as a shared risk or health issue. In a 2009 study on attitudes towards the MHC 'pill' in casual and stable sexual relationships, gender, relationship type and trust to effectively use a MHC pill were shown to predict that women are unlikely to trust the use of MHC outside of a stable relationship, and men are likely unwilling to assume contraceptive responsibility, by means of MHC, outside of a stable relationship³⁷. This is something that warrants caution. As studies have demonstrated^{45,46}, in some contexts, providers offer FP methods based on their prejudices or stereotypes on who are to accept or to use them. As with any other method, once MHC are in the market, these need to be offered together with other methods to every user of FP service, regardless of their relationship status. More efforts are needed to empower and to increase education on contraception and achieve the elimination of prejudices and stereotypes regarding the use of any contraceptive method.

Another interesting finding of our study regarding relationship status' effect on MHC acceptability was the relationships' influence on men's side effect tolerance. As our KIs anticipated, a relationship may increase the male tolerance of unwanted side effects. Also, it needs be considered that other non-hormonal methods for male consumers are under development including gel-based vas deferens obstruction, contraceptive vaccines, sperm-specific calcium ion channel blockers, antispermatogenic indenopyridines⁴⁷ or the triptonide⁴⁸. Some of these methods might end up being safer and with less side effects for males and can replace the need for MHC. But the future

will tell if there are more widely accepted by potential male method users, as they are in less advanced stages of commercialization than MHCs.

Most MHC studies investigate acceptability related to context of use (e.g., route of administration, side effects, cost). To our knowledge, only one other study examines men's behavior in relation to "men's social identity"⁴⁹. Peterson and colleagues demonstrated the importance of considering socially-driven perceptions motivating men's interest in MHC⁴⁹. Our findings echoed this, with KI descriptions of an individual's view of masculinity as it relates to their willingness to use MHC. A male's mindset of either *traditional* or *new* masculinities—as defined by our KIs—will play a large role in MHC acceptability. Although, *new* masculinities may be likely to favor MHC more positively, both *new* and *traditional* have key characteristics that can be capitalized on when the time to market these products arises. The rise of 'new' masculinities allows for less rigid gender norms creating space for men to assume contraceptive responsibility. A two-way dialogue can be created in which 'new' masculinity helps reframe FP services and FP services work to empower male inclusivity. In this way, men will recognize the importance of FP and MHC use and visit health clinics in support of their partners but also for their own services and care.

From KIs' perspectives, there is an enduring myth that men are unwilling to use MHC, due to rigid gender norms and unwillingness to accept side effects, that needs to be dispelled. Nevertheless, academic institutions and MHC researchers cannot regard social myths alone. FP clinics that provide condoms and sexually transmitted disease (STD) testing could expand their services to counseling their male patients and having discussion around the contraceptive options available to them. This inclusion could also be expressed in the promotion of gender-transformative sexual

education. By engaging men and boys as clients of FP/STD services, a foundation will be laid for when MHC becomes available.

Finally, the KIs reiterated concerns of MHC introduction and gender power dynamics. Several organizations, including the World Health Organization, have published advocacy tools on male engagement and inclusion in FP programs^{50–52}. Each of these materials includes discussion around gender power dynamics. However, this is seldom mentioned in published academic literature on MHC. A 2019 analysis concluded that it is not until gender-sensitive measures are implemented in FP services that these types of nuances will be seen (i.e., household power-dynamics driving couples' contraceptive decisions)¹³. Empowerment of women is impeded without the inclusion of men and boys as equally responsible parties for pregnancy prevention.

Limitations

A strength of this study is the inclusion of multiple expert perspectives of both women and men, across fields, age ranges, and locations. This allows for the data to reflect a consensus on trends around MHCs.

A number of limitations must also be mentioned. Due to the nature of the study, memory bias needs be considered, as a number of KIs engaged in MHC research more than a year before this study. Another limitation was the small sample size of 15 KIs – albeit the pre-identified ‘community’ of authors in the field of MHC was as large as 39. In addition, more equitable distribution of perspectives from the global south and inclusion of informants from the pharmaceutical industry could have enriched the study’s narratives. For future studies, it would be

recommended to include not only researchers – as we did – but also informants who commission MHC studies or who pool funds for MHC studies, irrespective of whether they are engaged in publication processes or not. Finally, because of the participants limited availability, the transcripts were not return to the KIs for further consideration as it is recommended by the ground theory guidelines. However, this deficiency was compensated by the fact that, at the end of each interview, the interviewers and the interviewees reviewed together what has been said for corrections and re-elaborations.

Conclusion

A study with MHC experts was carried out in 2020 suggesting that, while MHC development has been halted by the lack of pharmaceutical interest, academic institutions continue to carry the torch and promising MHC developments are on the horizon. While there is evidence of demand among both women and men for an MHC, there is progress to be made in regard to paving the way for the imminent introduction of commercially available MHCs. Effort is needed to improve inclusion of males in FP and to advocate for the development of MHC as a tool for women’s empowerment. Use or availability of new male methods of contraception need not be in lieu of a female partner using her own method. Further research should continue to explore the challenges facing MHC and to better understand the underlying social drivers and barriers to both women and men’s willingness to accept and use MHC. Finally, there is a need for more data on women’s perspectives of MHC, as women are positioned as the gatekeepers of contraception and their voice will be critical in the success of MHC.

Acknowledgements. We would like to thank the participants in the interviews conducted for this study for their time and contribution to scientific progress.

Funding statement. This investigation did not receive any specific subsidy from any funding agency in the public, commercial or non - profit sectors.

Declaration of conflict of interest. The authors declare that there is no conflict of interest in the preparation of this article.

References

1. United Nations Population Fund. Sexual & reproductive health | UNFPA - United Nations Population Fund. Sexual and Reproductive Healthcare. 2015. <https://www.unfpa.org/sexual-reproductive-health>
2. Festin RMP, Kiarie J, Solo J, Spieler J, Malarcher S, Van Look FAP, Temmerman M. Moving towards the goals of FP2020—classifying contraceptives. *Contraception*. 2016;94(4):289–294. doi:<https://doi.org/10.1016/j.contraception.2016.05.015>
3. Murdoch FE, Goldberg E. Male contraception: Another holy grail. *Bioorganic and Medicinal Chemistry Letters*. 2014;24(2):419–424. <http://dx.doi.org/10.1016/j.bmcl.2013.12.004>. doi:10.1016/j.bmcl.2013.12.004
4. Glasier AF, Anakwe R, Everington D, Martin CW, Van der Spuy Z, Cheng L, Ho PC, Anderson RA. Would women trust their partners to use a male pill? claim to believe that they should take more responsibility for. *Human Reproduction*. 2000;15(3):646–649.

doi:10.1093/humrep/15.3.646

5. Higgins JA, Hoffman S, Graham CA, Sanders SA. Relationships between condoms, hormonal methods, and sexual pleasure and satisfaction: an exploratory analysis from the women's well-being and sexuality study. *Sexual Health*. 2008;5(4):321–330. doi:10.1071/SH08021

6. United Nations: Department for Economic and Social Affairs. Contraceptive use by method 2019 - Data Booklet. New York, NY: United Nations; 2020.

https://www.un.org/development/desa/pd/sites/www.un.org.development.desa.pd/files/files/documents/2020/Jan/un_2019_contraceptiveusebymethod_databooklet.pdf

7. About the Gender Statistics Database | Gender Statistics Database | European Institute for Gender Equality. <https://eige.europa.eu/gender-statistics/dgs/about>

8. Key considerations for the appropriate integration of sex as a biological variable. Canadian institutes of Health Research. https://cihr-irsc.gc.ca/e/documents/sgba_criteria_sex-en.pdf

9. Shih G, Turok DK, Parker WJ. Vasectomy: The other (better) form of sterilization. *Contraception*. 2011;83(4):310–315. doi:10.1016/j.contraception.2010.08.019

10. Higgins JA, Hirsch JS. Pleasure, power, and inequality: Incorporating sexuality into research on contraceptive use. *American Journal of Public Health*. 2008;98(10):1803–1813. doi:10.2105/AJPH.2007.115790

11. Beksinska M, Wong R, Smit J. Male and female condoms: Their key role in pregnancy and STI/HIV prevention. *Best Practice and Research: Clinical Obstetrics and Gynaecology*. 2020;66:55–67. doi:10.1016/j.bpobgyn.2019.12.001

12. Hardee K, Croce-Galis M, Gay J. Are men well served by family planning programs? *Reproductive Health*. 2017;14(1):1–12. doi:10.1186/s12978-017-0278-5

13. Adamou BM, Iskarpatyoti BS, Agala CB, Mejia C. Exploring gaps in monitoring and

evaluation of male engagement in family planning. *Gates Open Research*. 2019;3:1114.

doi:10.12688/gatesopenres.12927.1

14. Hardee K, Croce-Galis M, Gay J. “Men as Contraceptive Users: Programs, Outcomes and Recommendations.” Washington DC; 2016. https://evidenceproject.popcouncil.org/wp-content/uploads/2016/09/Men-as-FP-Users_September-2016.pdf

15. Boender C, Santana D, Santillán D, Hardee K, Greene ME., Schuler S. The ‘So What’ Report: A Look at Whether Integrating a Gender Focus Into Programmes Makes a Difference to Outcomes. 2004. <https://www.igwg.org/wp-content/uploads/2017/07/TheSoWhatReport.pdf>

16. Kraft JM, Wilkins KG, Morales GJ, Widyono M, Middlestadt SE. An evidence review of gender-integrated interventions in reproductive and maternal-child health. *Journal of Health Communication*. 2014;19(sup1):122–141. doi:10.1080/10810730.2014.918216

17. Appiah SCY, Osei FA, Mensah NK, Adonoo PL, Tanko AG, Sarpong PO. Males as Partners in Family Planning Service Uptake in Ghana: A Descriptive Cross-Sectional Survey. *Health*. 2019;11(08):1043–1054. doi:10.4236/health.2019.118082

18. Koffi TB, Weidert K, Bitasse EO, Mensah MAE, Emina J, Mensah S, Bongiovanni A, Prata N. Engaging men in family planning: Perspectives from married men in Lomé, Togo. *Global Health Science and Practice*. 2018;6(2):316–327. doi:10.9745/GHSP-D-17-00471

19. Heinemann K, Saad F, Wiesemes M, White S, Heinemann L. Attitudes toward male fertility control: Results of a multinational survey on four continents. *Human Reproduction*. 2005;20(2):549–556. doi:10.1093/humrep/deh574

20. Msovela J, Tengia-Kessy A. Implementation and acceptability of strategies instituted for engaging men in family planning services in Kibaha district, Tanzania. *Reproductive Health*. 2016;13(1):1–9. doi:10.1186/s12978-016-0253-6

21. Plana O. Male Contraception: Research, New Methods, and Implications for Marginalized Populations. *American Journal of Men's Health*. 2017;11(4):1182–1189.
doi:10.1177/1557988315596361
22. Glasier A. Acceptability of contraception for men: a review. *Contraception*. 2010 [accessed 2019 Aug 31];82(5):453–456. <https://linkinghub.elsevier.com/retrieve/pii/S0010782410001332>.
doi:10.1016/j.contraception.2010.03.016
23. Zdrojewicz Z, Konieczny R, Papier P, Szten F. Brdt Bromodomains Inhibitors and Other Modern Means of Male Contraception. *Advances in Clinical and Experimental Medicine*. 2015 [accessed 2019 May 17];24(4):705–714.
<http://www.advances.umed.wroc.pl/en/article/2015/24/4/705/>. doi:10.17219/acem/33827
24. Study of Spermatogenesis Suppression With DMAU Alone or With LNG Versus Placebo Alone in Normal Men - Full Text View - *ClinicalTrials.gov*. [accessed 2019 May 17].
<https://clinicaltrials.gov/ct2/show/study/NCT03455075>
25. Injectable DMAU for Male Contraception in Healthy Male Volunteers (CCN015) - Full Text View - *ClinicalTrials.gov*.
26. 28-Day Repeat-Dose, Dose Escalation Study of 11- β Methyl Nortestosterone Dodecylcarbonate (11 β -MNTDC) in Healthy Men - Tabular View - *ClinicalTrials.gov*.
27. Study of Daily Application of Nestorone® (NES) and Testosterone (T) Combination Gel for Male Contraception - Full Text View - *ClinicalTrials.gov*. U.S. National Institute of Health.
28. Charmaz K. *Constructing Grounded Theory*. SAGE; 2014.
29. Gómez-Torres P, Martínez-Pérez GZ, Gómez-Barrera M, Mullet E, Vera Cruz G. Assessing Spaniard men's willingness and determinants to use a male contraceptive pill. *European Journal of Contraception & Reproductive Health Care*. 2022:1–8. doi:10.1080/13625187.2022.2026326

30. Vera Cruz G, Humeau A, Moore PJ, Mullet E. Identifying determinants of Mozambican men's willingness to use a male contraceptive pill. *European Journal of Contraception and Reproductive Health Care*. 2019;24(4):266–273.
<https://doi.org/10.1080/13625187.2019.1630816>. doi:10.1080/13625187.2019.1630816
31. COREQ (COnsolidated criteria for REporting Qualitative research) Checklist.
32. Chao JH, Page ST. The current state of male hormonal contraception. *Pharmacology and Therapeutics*. 2016;163:109–117. doi:10.1016/j.pharmthera.2016.03.012
33. Wang C, Festin MPR, Swerdloff RS. Male Hormonal Contraception: Where Are We Now? *Current Obstetrics and Gynecology Reports*. 2016;5(1):38–47. doi:10.1007/s13669-016-0140-8
34. Roth MY, Page ST, Bremner WJ. Male hormonal contraception: looking back and moving forward. *Andrology*. 2016 [accessed 2019 Sep 15];4(1):4–12.
<http://doi.wiley.com/10.1111/andr.12110>. doi:10.1111/andr.12110
35. Martin CW, Anderson RA, Cheng L, Ho PC, Van Der Spuy Z, Smith KB, Glasier AF, Everington D, Baird DT. Potential impact of hormonal male contraception: Cross-cultural implications for development of novel preparations. *Human Reproduction*. 2000;15(3):637–645.
doi:10.1093/humrep/15.3.637
36. Weston GC, Schlipalius ML, Bhuinneain MN, Vollenhoven BJ. Will Australian men use male hormonal contraception? A survey of a postpartum population. *Medical Journal of Australia*. 2002;176(5):208–210. doi:10.5694/j.1326-5377.2002.tb04374.x
37. Eberhardt J, Van Wersch A, Meikle N. Attitudes towards the male contraceptive pill in men and women in casual and stable sexual relationships. *Journal of Family Planning and Reproductive Health Care*. 2009;35(3):161–165. doi:10.1783/147118909788707986
38. Dorman E, Bishai D. Demand for male contraception. *Expert Review of Pharmacoeconomics*

- & Outcomes Research. 2012 [accessed 2019 May 17];12(5):605–613.
<http://www.tandfonline.com/doi/full/10.1586/erp.12.52>. doi:10.1586/erp.12.52
39. Campelia GD, Abbe C, Nickels LM, McElmeel E, Amory JK. “Shared risk”: Reframing risk analysis in the ethics of novel male contraceptives. *Contraception*. 2020;102(2):67–69.
doi:10.1016/j.contraception.2020.05.014
40. Stover J, Ross J. How increased contraceptive use has reduced maternal mortality. *Maternal and Child Health Journal*. 2010;14(5):687–695. doi:10.1007/s10995-009-0505-y
41. Chola L, McGee S, Tugendhaft A, Buchmann E, Hofman K. Scaling up family planning to reduce maternal and child mortality: The potential costs and benefits of modern contraceptive use in South Africa. *PLoS ONE*. 2015;10(6). doi:10.1371/journal.pone.0130077
42. Zitzmann M. Would male hormonal contraceptives affect cardiovascular risk? *Asian Journal of Andrology*. 2018;20(2):145. doi:10.4103/aja.aja_2_18
43. Roth MY, Amory JK. Beyond the Condom: Frontiers in Male Contraception. *Seminars in Reproductive Medicine*. 2016;34(3):183–190. doi:10.1055/s-0036-1571435
44. Thirumalai A, Page ST. Recent Developments in Male Contraception. *Drugs*. 2019;79(1):11–20. doi:10.1007/s40265-018-1038-8
45. Carvajal DN, Zambrana RE. Challenging Stereotypes: A Counter-Narrative of the Contraceptive Experiences of Low-Income Latinas. doi:10.1089/heq.2019.0107
46. Dismore L, Van Wersch A, Swainston K. Social constructions of the male contraception pill: When are we going to break the vicious circle? *Journal of Health Psychology*. 2014;21(5):788–797. doi:10.1177/1359105314539528
47. Kent K, Johnston M, Strump N, Garcia TX. Toward Development of the Male Pill: A Decade of Potential Non-hormonal Contraceptive Targets. *Frontiers in Cell and Developmental*

Biology. 2020;8. doi:10.3389/FCELL.2020.00061/FULL

48. Chang Z, Qin W, Zheng H, Schegg K, Han L, Liu X, Wang Y, Wang Z, McSwiggin H, Peng H, et al. Triptonide is a reversible non-hormonal male contraceptive agent in mice and non-human primates. *Nature Communications*. 2021;12(1):1–14. doi:10.1038/s41467-021-21517-5
49. Peterson LM, Campbell MAT, Laky ZE. The next frontier for men’s contraceptive choice: College men’s willingness to pursue male hormonal contraception. *Psychology of Men and Masculinity*. 2019;20(2):226–237. doi:10.1037/men0000174
50. High-Impact Practices in Family Planning (HIPs). *Engaging Men and Boys in Family Planning: A Strategic Planning Guide*. Washington DC; 2018.
51. Barker G, Ricardo C, Nascimento M. *Engaging men and boys in changing gender-based inequity in health: Evidence from programme interventions*.
52. *Advancing Male Engagement in Family Planning + Reproductive Health*. Baltimore: Johns Hopkins Center for Communication Programs; 2018.

Table 1. Semi-Structures Data Collection Instrument: Core Themes and Sub-Themes

THEME	Sub-Themes (Areas of interest considered by interviewers to probe the Key Informants)
1) Research / Knowledge	Probes: Studies conducted; Health policy decisions
2) Demand population	Probes: New methods used; Unsatisfied with current methods (e. G. vasectomy, condom)
3) Development of male hormone methods	Probes: Pharmaceutical industry; Effectiveness of the method; Acceptability of the method
4) Pharmaceutical industry	Probes: Financing; Perspective of research
5) Contraceptive responsibility	Probes: Sexual and reproductive health programs; Integral sex education
6) Women's trust	Probes: Define confidence; Gender roles
7) Acceptability of a male hormonal contraceptive methods	Probes: Acceptability for both; Context; Side effects; Effectiveness; Cost; Route of administration; Disease transmission risk; Dependent on the intercourse; Type of relationship; Religion; Masculinity
8) Male family planning programs	Probes: Training of health agents; Development of equal programs between men and women for family planning; Influence of governments or political ideologies
9) Emerging themes in previous interviews	“New Masculinities”; “Patriarchy”

Table 2. Sociodemographic data of key informants

KI	Sex	Age	Education	Profession	Occupation	Country of residence
1	Female	34	University	Midwife	Midwife	Spain
2	Female	64	Gynecology	Gynecologist	Retired	Spain
3	Female	57	PhD	Researcher, Demographer	Researcher	USA
4	Male	31	Masters	-	-	USA
5	Male	58	Postgraduate	Doctor, University Employee	Academic in Reproductive Medicine	UK
6	Female	35	PhD	Assistant Professor	Assistant Professor	USA
7	Female	28	PhD	Medical Doctor	Medical Doctor	Germany
8	Female	67	Master's degree	Independent consultant	No occupation	USA
9	Female	60	PhD	Global Reproductive Health	Consultant	USA
10	Male	71	PhD	Psychologist	Social scientist	USA
11	Male	36	Medical degree	Physician	Physician	USA
12	Female	36	Master of Public Health	Anthropologist	Deputy Dean of Research	Mozambique
13	Female	46	Master of Public Health	Public Health Researcher	Male Contraceptive	USA

					Initiative, Executive Director	
14	Male	31	PhD	Director of operations and programs	Brand Manager	USA
15	Male	65	Medical degree, PhD	Endocrinologist	Clinical practice and Public Health promotion as consultant	Australia