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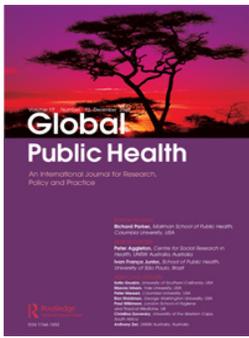
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RESEARCH ARTICLE



A global grounded theory exploration of investigators' perspectives on male hormonal contraceptive development and acceptability

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ABSTRACT

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. 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. 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. 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.

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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' (UNFPA, 2015). 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). This inequality often positions women alone with the primary responsibility of family planning (FP) (Glasier et al., 2000; Higgins et al., 2008; Murdoch & Goldberg, 2014). 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 on Contraceptive Use by Method the estimated percentages are described to only be reflective of women's contraceptive use with graphs

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titled as 'Estimated numbers of women of reproductive age (15–49 years) using various contraceptive methods' (United Nations, Department of Economic and Social Affairs, 2019). While the European Institute of Gender Equality recommends reporting sex-disaggregated data, many institutions, including the United Nations, remain gender blind (Canadian Institutes of Health Research (CIHR), n.d.; European Institute for Gender Equality, n.d.). 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 (Shih et al., 2011). However, rates of tubal ligation exceed vasectomy in almost all parts of the world (United Nations, Department of Economic and Social Affairs, 2019). Although condoms are reported to be the second most commonly used method (Shih et al., 2011), there is evidence to support the populations' dissatisfaction with this product (Higgins et al., 2008; Higgins & Hirsch, 2008). 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 (Beksinska et al., 2020). In turn, the lack of male hormonal contraceptive methods (MHC) removes men from the conversation around the choice to assume contraceptive responsibility (Hardee et al., 2017). 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 programmes define male engagement into three categories: men as clients; men as supportive partners; and men as agents of change (Adamou et al., 2019). 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 (Hardee et al., 2016). Studies have shown that any engagement of men in FP leads to better health outcomes (Boender et al., 2004; Kraft et al., 2014). Less is known, however, on reaching men as FP clients—a key to MHC uptake (Hardee et al., 2016, 2017). 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 (Appiah et al., 2019). In a study with 72 married Togolese men, it was found that limited contraceptive options along with insufficient health clinics to receive services were seen as a barrier to men engaging in FP (Koffi et al., 2018). 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 (Heinemann et al., 2005). 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 ($n = 1894$), 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 (Glasier et al., 2000).

While best practices have been published on how to engage men in FP (Koffi et al., 2018; Msovela & Tengia-Kessy, 2016) the limited options of contraceptive choices will continue to be a barrier. Although research has been underway since the 1970s for the development of an MHC, none are available on the market (Plana, 2015). 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 (Glasier, 2010). Since the 2000s, new MHCs have been investigated through different mechanisms to inhibit spermatogenesis or to render sperm non-functional (Murdoch & Goldberg, 2014; Zdrojewicz et al., 2015). In recent years, clinical trials have begun testing the effectiveness of new MHC methods (Glasier, 2010). 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) (NICHD, 2018a); a Phase 1 single-dose study evaluating DMAU administered as an injection (NICHD, 2016); a Phase 1 of a 28-day repeat-dose study of 11- β Methyl Nortestosterone Dodecylcarbonate (11 β -MNTDC) administered as an oral pill

(NICHD, 2017); 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 (NICHD, 2018b).

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 (Charmaz, 2014). This study followed methodological advice provided by Charmaz (2014), 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 2019–2020, (Gómez-Torres et al., 2022) 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 (Vera Cruz et al., 2019).

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 programmes; 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 programmes	Probes: Training of health agents; Development of equal programmes between men and women for family planning; Influence of governments or political ideologies
(9) Emerging themes in previous interviews	'New Masculinities'; 'Patriarchy'

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 programmes-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 Ph.D. 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 recognised 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 organisations 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 reach 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

Table 2. Socio-demographic 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	Ph.D.	Researcher, Demographer	Researcher	U.S.A.
4	Male	31	Masters	–	–	U.S.A.
5	Male	58	Postgraduate	Doctor, University Employee	Academic in Reproductive Medicine	UK
6	Female	35	Ph.D.	Assistant Professor	Assistant Professor	U.S.A.
7	Female	28	Ph.D.	Medical Doctor	Medical Doctor	Germany
8	Female	67	Master's degree	Independent consultant	No occupation	U.S.A.
9	Female	60	Ph.D.	Global Reproductive Health	Consultant	U.S.A.
10	Male	71	Ph.D.	Psychologist	Social scientist	U.S.A.
11	Male	36	Medical degree	Physician	Physician	U.S.A.
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 Initiative, Executive Director	U.S.A.
14	Male	31	Ph.D.	Director of operations and programmes	Brand Manager	U.S.A.
15	Male	65	Medical degree, Ph.D.	Endocrinologist	Clinical practice and Public Health promotion as consultant	Australia

again from each participant by videoconference during 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 were generated through IDI using a semi-structured guide (Table 1), with each IDI lasting 60 min in average. No repeat interviews were carried out. The interviews were conducted by a female Master Global Health candidate and a female Ph.D. Health Sciences candidate (TS and PGT).

As per Charmaz's (2014) 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. 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 digitised into any database.

Then, the themes were inductively derived from the data and organised into a theoretical coding tree with categories and sub-categories that were 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 finalised in a digital copy of the transcripts. The patterns, themes and relationships identified in the analysis of the coded data are summarised in the Results section of this paper, which has been prepared using the *COnsolidated Criteria for REporting Qualitative Research Checklist* (COREQ, 2007).

Results

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 behaviours 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 the 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 counselling 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 of 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 emphasised 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, recognising 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 the 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 the 15 KIs repeatedly cited the role of FP and SRHR programmes as a tool for women's empowerment. In regard to the agenda of prominent FP organisations, participants described it as *all about women's empowerment* recognising today prioritising 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 the 15 KIs emphasised the need to further examine these power dynamics during the development and introduction of MHC, while recognising 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 (Vera Cruz et al., 2019) and from a 2019–2020 survey of men's theoretical acceptability of MHC in Spain (Gómez-Torres et al., 2022). This research describes experts' MHC 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 (Chao & Page, 2016; Roth et al., 2016; Wang et al., 2016).

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 (Eberhardt et al., 2009; Martin et al., 2000; Plana, 2015; Weston et al., 2002). 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 (Dorman & Bishai, 2012). 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* (Campelia et al., 2020), 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 (Chola et al., 2015; Stover & Ross, 2010). 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 (Roth & Amory, 2016; Thirumalai & Page, 2019; Zitzmann, 2018).

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 relationship (Eberhardt et al., 2009). This is something that warrants caution. As studies have demonstrated (Carvajal & Zambrana, 2020; Dismore et al., 2014), in some contexts, providers offer FP methods based on their prejudices or stereotypes on who is 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 to 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, anti-spermatogenic indenopyridines (Kent et al., 2020) or the triptonide (Chang et al., 2021). 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 commercialisation 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 behaviour in relation to 'men's social identity' (Peterson et al., 2019). Peterson and colleagues demonstrated the importance of considering socially-driven perceptions motivating men's interest in MHC (Peterson et al., 2019). 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 favour MHC more positively, both *new* and *traditional* have key characteristics that can be capitalised 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 recognise 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 need 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 counselling 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 organisations, including the World Health Organization, have published advocacy tools on male engagement and inclusion in FP programmes (Barker et al., 2007; Breakthrough ACTION., 2018; United States Agency for International Development, 2018). 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) (Adamou et al., 2019). 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 to 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, a 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 returned 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 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.

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