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Will men use novel male contraceptive methods, and will women trust them? A systematic review

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Manuscripts

Will men use novel male contraceptive methods, and will women trust them? A systematic review

Novel male contraceptives have been in development for almost as long as female methods, yet there are no products available on the market. Hormonal approaches tested clinically to date include the use of oral, injectable, implant and transdermal methods. The study of attitudes towards male contraception has been inconsistent and there have been no systematic reviews drawing these data together. We conducted a systematic review of the available evidence for male and female acceptability of novel male contraception. We identified 32 studies and present a narrative synthesis of quantitative data and a thematic synthesis of qualitative data. In novel drug trials, the proportion of male participants willing to use a male contraceptive ranged from 34.0% to as high as 82.3%. In studies regarding hypothetical drugs, male willingness to use ranged from 13.6% to 83.0%. High proportions of women (42.8-94.0%) reported willingness to use a novel male method in both hypothetical studies and actual drug trials. In qualitative studies, both men and women expressed the desire to share responsibility for contraception. There is consistent interest among both men and women in novel male contraceptive methods and willingness to use them. The systematic review was registered with PROSPERO: [removed for blind review]

Keywords: Contraception, Reproductive Health, Hormonal Methods, sexuality-related attitudes, feelings and beliefs.

Introduction

There are currently far fewer contraceptive options for men than for women, and none could be described as modern. Currently, male contraceptive methods consist of condoms, vasectomy and withdrawal. However, the limitations of these methods mean that they are not suitable for many men and women of reproductive age. Vasectomy is designed to be permanent and reversal of vasectomy has a low success rate. So although it is a highly effective method, it is an unsuitable option for many men who are younger or who wish to have children in the future.

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3 Condoms are very widely used and promoted as they are the only method that also
4 provides protection against sexually transmitted infections but are often avoided
5 by people in longer-term relationships as they are perceived to decrease sexual
6 pleasure, and as such are associated with low levels of satisfaction (Buck et al.,
7 2005). Condoms and withdrawal have relatively low success rates among typical
8 users (Trussel, 2011). The clear drawbacks of currently available male
9 contraceptive options mean that the majority of contraceptive responsibility
10 (including the resulting risk of side-effects) must be shouldered by women who
11 are already disproportionately affected by the consequences of unintended
12 pregnancy and whose acceptance of female contraception is taken for granted
13 (Kimport, 2018; Littlejohn & Kimport, 2017). More male contraceptive options
14 would give the opportunity to ease this burden while also allowing men to have
15 greater control over their own fertility.
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33 Development of novel male contraceptive methods has been ongoing for over
34 fifty years, and during this time many promising methods in several modalities – oral
35 pills, injections, implants and topical gels – have been developed yet not reached the
36 market (Handelsman, 2003; Plana, 2017). The World Health Organisation was heavily
37 involved in the development of novel male hormonal contraceptives, with conceptual
38 proof demonstrated by studies with testosterone enanthate (World Health Organisation
39 Task Force on Methods for the Regulation of Male Fertility, 1990, 1996) and most
40 recently with the combination of long-acting testosterone undecanoate with
41 norethisterone enanthate (Behre et al., 2016). This particular study was stopped early by
42 a secondary safety monitoring panel that had concerns regarding the frequency of
43 adverse events in the trial (particularly mood disturbance, increased libido and injection
44 site discomfort) and their judgement was that this outweighed the benefits of continuing
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3 at that late stage in the trial. There is a common misconception that the trial was stopped
4 because the male participants could not accept the side effects of the drug, but that is
5 inaccurate: only 19 men (of 301 recruited) withdrew because of side effects (Behre et
6 al., 2016).
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12 New forms of male hormonal contraception which are currently in development
13 include synthetic androgen-progestogen compounds such as 7 α -methyl-19-
14 nortestosterone (MENT) and dimethandrolone undecanoate (DMAU), both of which
15 can be administered orally once per day. Additionally, a nestorone[®]-testosterone
16 contraceptive gel has been developed by the Population Council and the Male
17 Contraceptive Clinical Trials Network and is now in phase II clinical testing. Non-
18 hormonal methods are also being developed, such as the RISUG technique, an
19 intravasal contraceptive agent which is currently undergoing phase III clinical trials. A
20 brief history and current review of the development of novel male contraception has
21 been described elsewhere (Reynolds-Wright & Anderson, 2019).
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35 Despite the significant progress in the development of novel male
36 contraceptives, there continues to be a portrayal of novel male contraceptives in the
37 mainstream media that a new method would not be widely used, with the additional
38 concern that their female partners may not support their use (Prasad, 2019; Sanghani,
39 2019). Therefore, studies of attitudes towards male contraception, including
40 acceptability, are important to understand how likely men and their partners would be to
41 use new contraceptives. These studies help to illustrate the factors which would limit or
42 dissuade men from using them, and how these barriers can be overcome to maximise
43 uptake.
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56 Many acceptability studies have been carried out amongst men involved in clinical
57 trials of potential contraceptives. These are important for understanding which aspects
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3 of male contraception men like and dislike, and allow comparisons to be made between
4 new methods and those which participants have used previously. However, the views of
5 men who participate in clinical trials may not be representative of the wider population
6 of potential users and they may respond only with the specific trialled method in mind.
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8 Studies of hypothetical male contraceptives are therefore important for assessing the
9 general acceptability of male contraception, including a variety of modalities, building a
10 profile of the type of people who would use it, their preferences, and for estimating
11 market size.
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21 Studies of acceptability and more broadly attitudes towards male contraception have
22 been conducted in various settings and over the last 60 years, however there is no
23 systematic review published to date that has identified and collated this information.
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30 **Methods**

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32 We conducted a systematic review of studies reporting attitudes towards male
33 contraception, and the protocol was registered with PROSPERO (number: removed for
34 blind review). Our intention was not to conduct a review with a focused question as the
35 field is broad. Rather we wanted to detect and map the existing literature as entirely as
36 possible and describe the existing knowledge.
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45 ***Eligibility Criteria***

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48 • Population: all human participants, including male and female, in trials that have
49 reported on attitudes towards male contraception.
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53 • Intervention: any real or hypothetical novel male contraceptive method,
54 excluding vasectomy, condoms and withdrawal.
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- 57
58 • Comparators: no comparators were included
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- Outcomes: The primary outcome measures sought were proportion of men reporting willingness to use a novel male contraceptive method and proportion of female partner's willingness to rely on their male partner for male contraception. Other outcomes of interest included sociodemographic correlates with acceptability and type of male contraceptive impact on acceptability, if reported. From qualitative studies, themes of interest included any exploration of responsibility for family planning, particularly with regard to gender and family-building status; properties of male contraceptives that make them more or less attractive to men and women; and any barriers or facilitators to their use and acceptability.
- Studies: a combination of cross-sectional and cohort quantitative surveys and qualitative interviews and focus groups. Review articles were excluded.

Information Sources

The following databases were searched on 25th May 2020: Pubmed, Medline, Cochrane Library, Embase, PsycInfo and Web of Science. There was no date limit to the search, but language was restricted to papers with title and/or abstract in English.

Search Strategy

An initial limited search of Medline and EMBASE was performed to identify relevant keywords contained in the title, abstract and subject descriptors. The initial search terms were 'male', 'contraception' and 'attitude' combined using Boolean operator 'AND'. In databases with MeSH headings, these were utilised. Please see Supplementary File 1 for full search strategies for each database.

Study Selection

Initial screening of titles and abstracts was performed independently by two authors (JJRW and NJC) against the inclusion criteria using Rayyan systematic review software (Ouzzani, M et al., 2016). Discrepancies in reviewer selections were resolved at a meeting between authors prior to selected articles being retrieved.

For those that met the inclusion criteria, full text copies were obtained and reviewed. If full text copies were not available, attempts were made to obtain it, by contacting relevant archives. Articles identified through reference lists and bibliographic searches were also considered for data collection, based on their title.

Data extraction

If the full text met the inclusion criteria, data were extracted independently by two authors (JJRW and NJC) using a pre-constructed data capture form and discrepancies resolved at a meeting with a third author (RAA). For qualitative studies, the results sections of these studies were extracted in their entirety by JJRW.

Variables of interest

For each study, we attempted to extract year of data collection, location of study, number of participants, gender of participants, whether the study concerned real (experimental) methods of male contraception or hypothetical, acceptability measures, willingness to use method and women's willingness for partner to use, if the participant thought male contraception was a good idea in principle, and finally a category for other outcomes of interest such as any correlation with demographics.

Risk of bias and Quality assessment

Risk of bias was not assessed within or between studies using a formal tool. Included studies were divided into qualitative and quantitative studies (i.e. questionnaires/surveys). Quality assessment was performed by two authors (JJRW and NJC) independently using the appropriate CASP checklists. Disagreements were resolved by consensus and input from the third author (RAA). Supplemental File 2 contains the CASP checklist quality assessment ratings for each study.

Synthesis of results

Given the variation in the nature and design of the studies, we elected not to attempt meta-analysis nor meta-synthesis. Rather, we presented a narrative synthesis of the studies identified. Data are presented according to gender and then subdivided in quantitative and qualitative.

For quantitative studies, this was done in accordance with the SWiM guideline (Campbell et al., 2020). For qualitative studies, this was done separately in accordance with the ENTREQ Statement (Tong et al., 2012).

Results

Our initial search yielded 13659 results, of which 4769 were duplicates. This left 8890 results to be screened for title and abstract. 8851 were excluded for not meeting inclusion criteria, leaving 39 identified for full text review. Four entries were excluded: 2 were duplicates of other studies detected in the search (trial registry and conference abstract), 2 were out of print and in foreign languages (Polish and Korean). Thirty-five papers (representing 32 individual studies) were assessed for quality using CASP checklists and included in the review. Study flow is shown in figure 1. The included studies were narratively synthesised and presented.

Will men use novel male contraception?

Of the 35 papers included, 34 presented data on men's interest in novel male contraception. Six of these papers were qualitative, one paper used mixed methods and 27 papers presented quantitative data.

Quantitative Data

The majority of quantitative studies asked men about their willingness to use novel male contraceptives, either questioning if a specific product were on the market, would they use it; or how likely they would be to use a novel male contraceptive in general; or how acceptable male contraception was to them in general. Some studies asked about novel male contraception in general, many specified a male pill, and others injections, implants or gels/patches. The majority of results were presented as percentages of respondents; however, a small number presented a mean score for the ratings. While the reported willingness to use a novel male contraceptive varied considerably between studies, many reported at least a third of men questioned would use them. Willingness to use a novel male method did not cluster when accounting for type of male contraceptive (real or hypothetical) and no single novel male contraceptive method had consistently high ratings for willingness to use (Table 1). There did not appear to be an overall change in acceptability over time.

Men who have used a novel male contraceptive

The proportion reporting willingness to use novel methods ranged between 34% (Roth et al., 2014) and 82.3% (Behre et al., 2016) in men who were involved in trials of novel drugs. In the Roth trial, this used a combination of two gels that needed to be applied to the skin daily and in the Behre trial this was 2 injections given every 8 weeks. The need to apply multiple gels may contribute to the lower proportion willing to use

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3 this method and indeed this has been reformulated into a single gel under investigation
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5 presently.
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8 In some of the studies where a real drug trial was performed, men were asked
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10 about their satisfaction with this novel male contraceptive method and if they found it to
11
12 be better or worse than their current or most recently used method of contraception,
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14 which could have been a male method such as condoms or a female method (table 2).
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16 The proportion of those satisfied or very satisfied ranged between 50% (Amory et al.,
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18 2007) and 80.1% (Behre et al., 2016), and when comparing to an existing method of
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20 contraception 34% (Roth et al., 2014) to 40% (Amory et al., 2007) of men rated the
21
22 novel male contraceptive better in some way. Several of these studies also reported on
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24 whether or not the men would recommend this method of contraception to others and
25
26 the results were similarly positive. In these studies, men were questioned at multiple
27
28 time points during and after drug cessation. None of the studies had high levels of
29
30 discontinuation and acceptability ratings between time points in the studies were not
31
32 significantly different. Some studies only presented a single timepoint and others
33
34 multiple. In Table 1, acceptability is presented at the latest time point in the study.
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41 Men considering hypothetical novel male contraceptives

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43 The proportion reporting willingness to use novel methods ranged between
44
45 13.6% (Weston, Schlipalius, & Vollenhoven, 2002) and 83% (Martin et al., 2000) in
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47 men who were asked about hypothetical male contraceptives.
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51 A small number of studies reported interest in different modalities of
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53 hypothetical novel male contraception, i.e. pill, gel, injection, and the frequency of
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55 administration, e.g. daily, weekly, monthly, yearly (table 3). No single modality or
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57 timing was clearly favoured by respondents: preference for a daily oral pill ranged
58
59 between 25.5% (Weston, Schlipalius, & Vollenhoven, 2002) and 83% (Martin et al.,
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3 2000), while that of an injectable method ranged from 0% (Skrzypulec et al., 2006) (if
4 weekly) to 62% (Martin et al., 2000) (no frequency specified). These studies included
5 men from a range of geographical locations (south Asia, south east Asia, Europe, North
6 America, Australia and South Africa).
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12 Two studies (Heinemann et al. 2005; Vera Cruz, et al., 2019) used cluster
13 analyses and regression models to describe types of men who may be interested in a
14 contraceptive and factors that influence these decisions (table 4). These studies indicate
15 that prevalence and severity of side effects, cost of the drug, religion and religiosity and
16 their partner's health all affected willingness to use a novel male contraceptive method.
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23 24 25 *Qualitative Data*

26
27 Qualitative studies recruited men from both studies of real drugs and members of the
28 public to discuss hypothetical drugs (Table 5). Two broad themes emerged from
29 qualitative studies regarding the acceptability of male contraception – *User factors* and
30 *Drug factors*.
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37 *User factors* refer to dimensions of acceptability that relate to potential users of
38 novel male contraception and five subthemes were identified: *Equality*, *Male*
39 *trustworthiness*, *Relationship type*, *Masculine identity* and *Freedom*.
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44 Men talked of *equality* by wanting to share the responsibility for contraception
45 with the women in their lives. Across all studies, men spoke of how women had been
46 “burdened” by contraception and that they felt it only right to take on the responsibility
47 if possible. Men described a conflict between traditional and modern gender roles and
48 contraception being another avenue through which they could lead more equal lives
49 with their partners (Dismore et al., 2016; Marcell et al., 2005; Ringheim, 1995).
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51 Interestingly, within this narrative, there were expressions of more traditional
52 stereotypes, using terminology of strength and leadership – men needing to “take
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3 charge” and “step up” for the women in their lives (Dismore et al., 2016; Lantelme,
4
5 2017).

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7 *Male trustworthiness* was questioned by the men themselves, though often
8
9 through the lens that “men in general” may not be trusted to use the method even if they
10
11 believed themselves to be trustworthy (Dismore et al., 2016). This linked to the concept
12
13 that *relationship type* would play a role in the use of a novel male contraceptive, with it
14
15 being viewed as more likely within an existing long-term relationship where there was
16
17 already a foundation of trust than as a method a less committed couple might use
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19 (Lantelme 2017; Ringheim 1995; Walker 2011).

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24 Men’s sense of *masculine identity* featured strongly in all studies although the
25
26 relationship of novel male contraception to this identity varied. Some felt that the use of
27
28 contraception was neutral, like taking any other medicine and had no connotations of
29
30 manliness (Dismore et al., 2016). Others talked of how using novel male contraception
31
32 was even more manly than not, particularly having an injection with a needle was “even
33
34 more macho” (Ringheim, 1995). However, many still had concerns at the connotations
35
36 of contraception being feminine and as such a threat to their masculinity. This did not
37
38 preclude novel male contraceptive use altogether but for many meant that if they used it
39
40 they believed they would keep it a secret (Dismore et al., 2016; Marcell et al., 2005;
41
42 Walker, 2011; Zhang et al., 2006).

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47 Men spoke of how novel male contraceptives may give them and their partners
48
49 *freedom* from worry about unplanned pregnancy that could lead to greater closeness and
50
51 intimacy (Dismore et al., 2016; Ringheim, 1995; Solomon et al., 2007). Men across
52
53 several studies mentioned that they could use this method to protect themselves from
54
55 becoming “trapped” by a woman who had stopped using a hormonal method or had
56
57 tampered with condoms to become pregnant (Lantelme, 2017; Ringheim, 1995; Walker,
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1
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3 2011). While this trope is perhaps not as common in reality as that of a woman made
4 pregnant by a man and then left to raise a child by herself, it does highlight the desire
5 and need for reproductive autonomy that should be guaranteed regardless of sex.
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10 *Drug factors* refer to dimensions of acceptability related to the novel male
11 contraceptives themselves and contains six subthemes: *Positive side effects*, *Negative*
12 *side effects*, *Long term consequences*, *Drug reliability*, *STI risk* and *Method preference*.
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16
17 Willingness to use novel male contraceptives centred strongly on the presence of
18 *negative side effects* and any potential of *long-term consequences* relating to use. Some
19 men were unwilling to entertain any type of side effect and were wary of the safety of
20 the drug, particularly with regard to long term cancer risks and reversibility (Dismore et
21 al., 2016; Lantelme, 2017). It is possible that these concerns are fuelled by negative
22 press given to female hormonal contraception and the various ‘pill scares’ that have
23 occurred over the last 30 years. Some men were accepting of the possibility of side
24 effects, usually if they were milder, such as acne, and especially if there were *positive*
25 *side effects* as a trade-off. In studies where a novel drug had been used, several men
26 described an increase in sex drive and also sexual satisfaction as a result of using the
27 drug. In an Indonesian study, weight gain was mentioned as a positive and attractive
28 feature of the drug and was felt to signal manliness (Solomon, 2007).
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44 There were concerns from some men about *drug reliability* - wanting to know
45 how likely it was to fail and the extent to which it had been researched. There was an
46 expectation that any novel male contraceptive should be totally reliable and totally safe
47 (Lantelme, 2017; Ringheim 1995; Walker, 2011).
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53 *Sexually Transmitted Infection (STI) risk* was raised as a concern for any method
54 that encouraged a move away from condoms (Dismore et al., 2016; Lantelme, 2017;
55 Walker, 2011). As with the theme in trustworthiness, this was framed not as an issue for
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3 the participants themselves but as a concern about other men, specifically those who
4
5 were younger, less educated or from a lower social class.
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7
8 Choice of novel male contraceptive *method* focused primarily on pills and
9
10 injections, with the preference for injections linking to the theme of trustworthiness and
11
12 having a method that would be difficult to forget. Pills were favoured by men who were
13
14 more concerned with the pain of injection (Dismore et al., 2016; Marcell et al., 2005;
15
16 Ringheim, 1995). There was mention of preferring an episodic method of contraception,
17
18 like condoms, as this meant that the men would not have to have long term exposure to
19
20 a drug.
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22

23 24 25 ***Will women trust men to use novel male contraception?*** 26

27
28 Of the 35 papers included in the review, 15 presented data on women's views on novel
29
30 male contraceptives. Four papers were qualitative, one paper was mixed methods and
31
32 10 papers were quantitative in nature.
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35 36 ***Quantitative Data*** 37

38
39 As with studies presenting men's views, the outcome measures used in studies of
40
41 women varied considerably between papers and in one paper (Walker, 2011) women's
42
43 responses are aggregated with men's responses (Table 6). One study (Glasier et al.,
44
45 2000) asked women in different geographical areas if they thought that male
46
47 contraception was a good idea in principle – more than 70% of women surveyed agreed
48
49 (from 71% in Hong Kong, up to 97% in Cape Town). Other studies asked if they would
50
51 be happy for their male partner to use novel male contraception, or how likely they as a
52
53 couple would be to use novel male contraception – reported willingness ranged from
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55 42.8% (Amouroux et al., 2018) to 94% (Glasier et al., 2000).
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3 Regardless of measure used, high proportions of women would be willing for
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5 their partner to use a novel male contraceptive. This is bound by caveats around side
6
7 effects and cost as for men considering novel male contraception but should reassure
8
9 those developing these drugs that women would rely upon men to use them and not
10
11 distrust men.
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14 15 16 *Qualitative Data*

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18 Analysis of female participant responses in the qualitative studies (Table 5) yielded
19
20 largely the same themes as the male data, however the emphasis on these themes is
21
22 different.
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25 *Equality* between men and women was a strong feature of female responses in
26
27 qualitative studies, with a sharing of responsibility and burden seen as a strong positive
28
29 of male contraceptive options. It was mentioned in two studies that women would like
30
31 for men to experience what they went through with female contraceptive methods and
32
33 so understand them better (Lantelme, 2017; Marcell et al., 2005).
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37 Women expressed doubt that men would be *trustworthy* to use male
38
39 contraception, due to lack of training in health behaviours and exposure to the
40
41 healthcare system that women have (Dismore et al., 2016; Lantelme, 2017; Marcell et
42
43 al., 2005). Like men, they felt that its use would largely depend on *relationship type* and
44
45 would continue to use female methods and/or condoms in addition to male
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47 contraception in a new relationship (Lantelme, 2017). Women echoed men's concerns
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49 that there will be a proportion of men and women that perceive male contraception as
50
51 *emasculating*, but once again this was portrayed as an external view, held by others
52
53 rather than themselves (Lantelme, 2017; Marcell et al., 2005; Walker, 2011). It could be
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55 that this externalised view served to present views the women didn't feel they *should*
56
57 hold. Women talked of the *freedom* from worry about pregnancy that male
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3 contraception could bring for them, quoting concerns over the efficacy of condoms and
4 using male contraception as an ‘additional’ method (Lantelme, 2017; Walker, 2011).

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6
7 Women in two studies also raised the trope of a woman “trapping” a man with a
8 pregnancy and sympathising that male contraception could protect men from this.
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12 Women considered *side effects* in the context of female contraception and
13 expressed concern that men may not be able to manage effects on weight and
14 particularly mood (Lantelme, 2017; Solomon et al., 2007). They shared men’s concerns
15 regarding *long-term consequences*, particularly the reversibility of the method, however
16 they did not raise concerns about *drug reliability*, possibly because of their familiarity
17 with hormonal contraception options. Likewise, women considered the use of condoms
18 alongside novel male contraception to reduce *STI risk*, however this did not feature as
19 prominently as among men. In one study, women expressed a *method preference* for
20 injectable male contraception to mitigate the risk of forgetting to use it, reflecting the
21 theme of male trustworthiness (Marcell et al., 2005).
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37 **Discussion**

38 The studies included in this systematic review are heterogenous in their design,
39 participant populations and outcome measures. Meta-synthesis and meta-analysis were
40 not attempted as any outcome sufficiently focused would exclude many of the studies
41 and be of limited value. However, it is clear across all of these studies that a substantial
42 proportion of men and women surveyed are willing to use a novel method of male
43 contraception. This would represent a large potential market for pharmaceutical
44 companies should they invest in the development and manufacture of novel male
45 contraceptives. Further, these levels of interest have remained consistent across the
46 entire time period that these studies span – the desire for novel male contraceptives is
47 neither new nor fleeting.
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3 This information is useful to researchers developing contraceptive methods,
4 funding bodies investing in these new medications and to sexual and reproductive
5 health clinicians. Despite the long journey taken to develop new methods, there is an
6 appetite for novel male contraceptives among both men and women – indeed it is
7 striking how similar the rates of acceptability were between genders in the quantitative
8 studies and how closely the qualitative themes aligned.
9

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11
12 It is also clear from these studies that no single formulation was a clear favourite
13 among participants. Researchers therefore should not focus their efforts on the
14 development of a single formulation and rather need to develop multiple approaches to
15 suit a broad range of men. The need to provide a diverse range of female contraceptive
16 methods has long been recognised as the basis for increasing uptake, and these data
17 suggest the same will be true for novel male methods.
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21
22 Of particular note are the qualitative data and cluster analyses, which suggest
23 that drug cost, side effect frequency and severity, their relationship status and their
24 partners' health needs all affect men's acceptability and willingness to use. It is a
25 frequently expressed belief that men will not tolerate any kind of side effects and would
26 be too selfish to use a male method. These data suggest otherwise, with mild but more
27 frequent side effects, such as skin changes, being of relatively low concern for men,
28 particularly if they are motivated to take the contraceptive burden away from their
29 partners; the validity of this finding is supported by the low drop-out rate in the most
30 recent clinical efficacy trial (Behre et al., 2016). Some participants in a qualitative study
31 (Lantelme 2017) expressed concern over safety and a wish that any novel male
32 contraceptive be totally reliable and safe – while admirable, this would hold male
33 contraceptives to a higher (and impossible) standard than female contraceptives. These
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3 expectations would need to be addressed in any promotional or educational material
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5 produced alongside a novel male contraceptive.
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8 Male contraception is sometimes conceptualised as a medication to prevent a
9
10 condition in another person (i.e. pregnancy in female partner) whereas female
11
12 contraceptives prevent a condition (pregnancy) in themselves. The earliest studies in
13
14 this review were from the 1970s and even in these it was clear that men conceptualise
15
16 pregnancy as something that happens to *them* rather than just their partner, strongly
17
18 supporting the need to appreciate that men will accept a degree of side effects in
19
20 exchange for contraception for *themselves* as well as their partner.
21
22

23
24 There are groups that have not been included or are under-represented in these
25
26 studies, such as those from Black African or Caribbean backgrounds, LGBT people
27
28 who are in couplings where they or their partner could become pregnant, that future
29
30 studies, particularly qualitative studies, should seek to include. However, in general
31
32 there does not seem to be a great need to further describe attitudes towards novel male
33
34 contraceptives while there are not any novel methods available – the extant studies
35
36 clearly demonstrate interest in the method. What is needed is for the novel male
37
38 methods to be brought to market and for further study of attitudes, willingness and
39
40 acceptability at that stage, when novel male contraceptives are a real tangible option.
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45 46 ***Strengths and Limitations*** 47

48
49 To our knowledge this is the first systematic review of attitudes towards male
50
51 contraception among men and women. We employed a broad search strategy to detect
52
53 studies and used the Cochrane-recommended approach of two reviewers independently
54
55 assessing studies and extracting data with a third to resolve conflicts. The studies
56
57 included were of varying quality, however none were deemed to be of such low quality
58
59 that they warranted exclusion. The qualitative studies sampled predominately white
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1
2
3 western and east Asian participants, which may limit transferability to other groups. The
4
5 research questions were simple and focused, allowing data to be extracted from studies
6
7 that employed a broad range of methodologies and outcome measures.
8
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10 The men who had volunteered to participate in clinical trials of novel male
11
12 contraceptives may be different to the men responding to surveys regarding a
13
14 hypothetical drug – they had self-selected to participate in a trial and were likely to be
15
16 in a long-term relationship by virtue of the study entry requirements, and so may be
17
18 more willing and inclined to use a novel male contraceptive. However, interest in male
19
20 methods was high in the studies of hypothetical drugs which may have included other
21
22 men not in relationships. Studies of hypothetical drugs have some limitations,
23
24 particularly where participants speculate on scenarios they do not envisage taking place
25
26 for themselves, such as the qualitative subtheme of *STI protection*.
27
28
29

30 Decision making, attitudes and behaviours are all distinct factors that contribute
31
32 to the use (and future use) of a drug. These factors should be evaluated with tools
33
34 grounded in behavioural theory. In this review, only three studies (Jaccard et al., 1981;
35
36 O'Connor et al., 2005; Peterson et al., 2019) mentioned the use of a theoretical
37
38 framework to guide their approach and so there may be variation in what is actually
39
40 measured between studies in terms of willingness and acceptability.
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44 Due to the heterogenous nature of the studies, meta-analysis and meta-synthesis
45
46 were not attempted. If we had employed a narrower set of inclusion criteria, we may
47
48 have been able to include a smaller number of studies that could have possibly been
49
50 meta-analysed. However, this would have been at the expense of the broad range of
51
52 studies that we have identified that consistently demonstrate support for and interest in
53
54 novel male contraception. Going forward, the field would benefit from clear reporting
55
56 guidelines and common outcome sets, ideally grounded in behavioural theory and
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1
2
3 validated across different populations, to allow for a meaningful meta-analysis to be
4
5 conducted across studies.
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7

8 9 **Summary**

10
11 Until a novel male contraceptive product is brought to market we will not truly know
12
13 the extent to which men and their partners will embrace it. However, through this
14
15 review we have identified consistent evidence that there are a substantial proportion of
16
17 men that would be willing and motivated to use a novel male contraceptive and indeed
18
19 that their partners would rely on this too.
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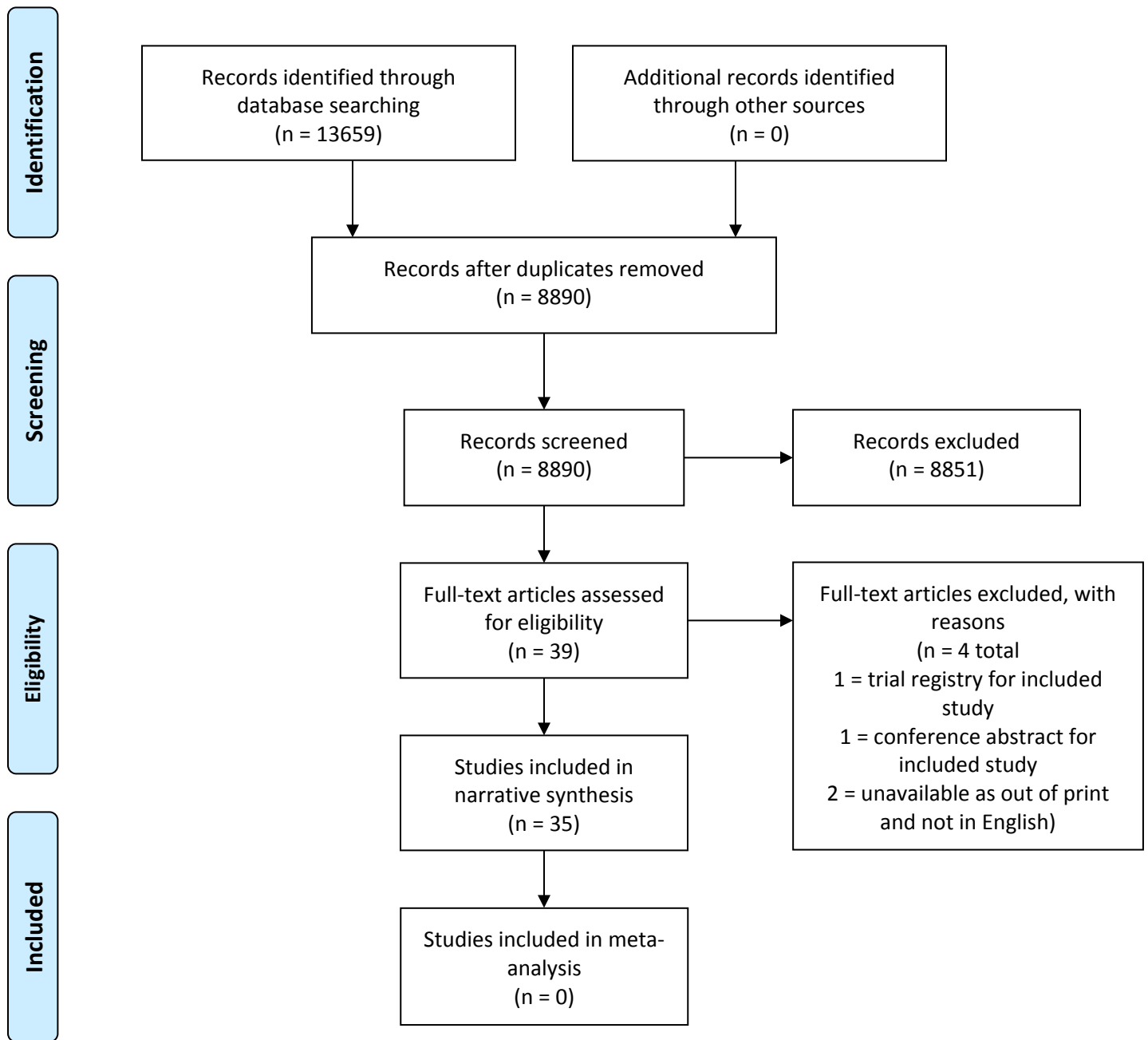
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Figure 1. Prisma Flow Diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Table 1. Men's willingness to use a novel male contraceptive.

Study Name, Year and Location	Drug Type	Number of Participants	Would you use a male contraceptive if it was available?
Amory 2007 (USA)	Real (gel + injection)	38 men	Strongly agree/Agree = 45% Undecided = 13% Strongly Disagree/Disagree = 42%
Anawalt 2019 (USA)	Real (gel)	28 men	Strongly agree/Agree = 50% Undecided = 39% Strongly Disagree/Disagree = 11%
Behre 2016 (USA, UK, Indonesia, Australia, India, Chile, Germany)	Real (injection)	271 men	Yes = 82.3% Undecided = 12.5% No = 5.2%
Merigiola 2006 (Italy)	Real (injection)	47 men	Yes = 66% Yes with changes = 26% No = 8%
Roth 2014 (USA)	Real (gel)	79 men	34% (strongly agree/agree) would use this method today
WHO Task Force 1982 (Thailand, UK, Chile, South Korea, Canada, Hong Kong)	Real (various oral and injectable)	119 men	Mean score (low = 1, high willingness = 5) = 3.87 Probable or definite intention to use in the future = 75.7%
Amouroux 2018 (France)	Hypothetical (thermal)	304 men	I would totally accept = 7.2% I would generally accept = 22% I would generally not accept = 30.3% I would not at all accept = 40.5%
Balswick 1972 (USA)	Hypothetical (pill)	93 men	<i>Do you object to the use of a male pill:</i> No 41% Undecided 2% Yes 47%
Brooks 1998 (UK)	Hypothetical (pill)	103 men	21 ranked a hypothetical male pill as first choice for contraception
Eberhardt 2009 (UK)	Hypothetical (pill)	110 men	<i>Mean score on 4 point scale, 1 = lowest, 4 = highest</i> Overall attitude = 2.86 (SD 0.599)
Gough 1979 (USA)	Hypothetical (pill)	151 men	Yes = 56.6% Probably Yes = 18.5% Probably No = 18.5% No = 7.3%
Heinemann 2004 (International – see rightmost column)	Hypothetical (various methods)	9342 men	<i>Split by location and into 'willing' 'uncertain' and 'disapproving':</i> Germany (1021) Willing = 69% Uncertain = 24.4% Disapproving = 6.6% France (725) Willing = 47% Uncertain = 34.9% Disapproving = 17.5% Spain (1049) Willing = 71.4% Uncertain = 26.2% Disapproving = 2.4% Sweden (1023) Willing = 58.1% Uncertain = 17.4% Disapproving = 24.4% USA (1500) Willing = 49.3% Uncertain = 38.4% Disapproving = 12.4% Argentina (1000) Willing = 44.5% Uncertain = 13.2% Disapproving = 42.3% Brazil (1000) Willing = 62.7% Uncertain = 12.8% Disapproving = 24.5% Mexico (1024) Willing = 65.4% Uncertain = 8.9% Disapproving = 25.7%

			Indonesia (1000) Willing = 28.5% Uncertain = 37.3% Disapproving = 34.2%
Jaccard 1981 (USA)	Hypothetical (pill)	240 men	<i>Intention to use = mean score (0 = no, 1 = yes)</i> If small risk of major side effects = 0.21 If moderate risk of minor side effects = 0.52
Laird 1994 (USA)	Hypothetical (pill)	83 men	Very Likely = 1.2% Likely = 19.2% Neutral = 22.9% Unlikely = 31.2% Very Unlikely = 25.3%
Marsiglio 1985 (USA)	Hypothetical (pill)	49 men	Very Likely = 31% Somewhat likely = 39% Somewhat unlikely = 12% Very unlikely = 18%
Martin 2000 (International – see rightmost column)	Hypothetical (various methods)	1829 men	<i>Proportion answering 'Definitely' or 'Probably'</i> <i>Split by method and centre:</i> Edinburgh pill 66% (of 436) Edinburgh inj. 32% (of 436) Hong Kong pill 44% (of 450) Hong Kong inj. 32% (of 450) Shanghai pill 50% (of 450) Shanghai inj. 35% (of 450) Cape Town (<i>further split by racial group</i>) Black pill 55% (of 153) Black inj 48% (of 153) Coloured pill 66% (of 169) Coloured inj. 55% (of 169) White pill 83% (of 171) White inj 62% (of 171)
Mbizvo 1992 (Zimbabwe)	Hypothetical (pill or injection)	711 men	Yes = 37.7% Uncertain = 7.2% No = 61.1%
O'Connor 2005 (UK)	Hypothetical (pill or injection)	152 men	Intention to use measured on a scale -3 to +3 Mean (loss frame) = -0.49 SD 2.00 Mean (gain frame) = -0.47 SD 1.93
Peterson 2018 (USA)	Hypothetical (not specified)	160 men	High willingness = 35% Low willingness = 42.5% Not willing = 22.5%
Skrzypulec 2006 (Poland)	Hypothetical (various)	59 men	70% would accept
Thompson 2007 (USA)	Hypothetical (various)	205 men	Score averaged from several measures about willingness to use (1 = totally unwilling, 5 = totally willing) = 3.86 SD 0.99
Walker 2011* (UK)	Hypothetical (pill)	54 men	Would use= 49.5% Unsure = 31.3% Would not use = 19.2%
Weston 2002a (Australia)	Hypothetical (various)	118 men	Definitely would use = 19.5% Probably would use = 28% Maybe = 28% Probably would not use = 11.9% Definitely would not use = 12.7%
Weston 2002b (Australia)	Hypothetical (various)	76 men	Definitely would use = 4.1% Probably would use = 9.5% Maybe = 52.7% Probably would not use = 14.9% Definitely would not use = 18.9%

Footnote: *NB: The data in this paper combined male and female responses and could not be disaggregated.

Table 2. Satisfaction with novel male contraceptive and comparison to previous method.

Study Name, Year and Location	Drug Type	Number of Participants	Satisfaction	Comparison to current method
Amory 2007 (USA)	Real (gel + injection)	38 men	Very satisfied/Satisfied = 50% Undecided = 18% Very dissatisfied/Dissatisfied = 32%	A lot better/ Better = 40% Undecided = 18% A lot worse/Worse = 42%
Anawalt 2019 (USA)	Real (gel)	28 men	Very satisfied/Satisfied = 79% Undecided = 14% Very dissatisfied/Dissatisfied = 7%	Not reported.
Behre 2016 (USA, UK, Indonesia, Australia, India, Chile, Germany)	Real (injection)	271 men	Very satisfied/Satisfied = 80.1% Neither = 14.8% Very dissatisfied/Dissatisfied = 5.2%	Not reported.
Roth 2014 (USA)	Real (gel)	79 men	Overall 'satisfied' (strongly agree and agree) = 58%	A lot better/better = 34% A lot worse/worse = 35%
Sjogren 2001 (Sweden)	Real (injection)	20 men	Not reported.	<i>Freedom compared to other methods tried</i> Yes, a lot = 13/20 Yes, some = 2/20 No = 5/20

Table 3. Preference for a novel male contraceptive formulation

Study Name, Year and Location	Number of Participants	Preferred formulation:
Brooks 1998 (UK)	103 men	Daily pill = 46% 3-monthly injection = 19% 6-monthly injection = 36%
Martin 2000 (International – see rightmost column)	1829 men	Proportion answering 'Definitely' or 'Probably' Split by method and centre: Edinburgh pill 66% (of 436) Edinburgh injection 32% (of 436) Hong Kong pill 44% (of 450) Hong Kong injection 32% (of 450) Shanghai pill 50% (of 450) Shanghai injection 35% (of 450) Cape Town (further split by racial group) Black pill 55% (of 153) Black injection 48% (of 153) Coloured pill 66% (of 169) Coloured injection 55% (of 169) White pill 83% (of 171) White injection 62% (of 171)
Skrzypulec 2006 (Poland)	59 men	Daily pill = 36% 3-weekly Injection = 11% Weekly Injection = 0%
Thompson 2007 (USA)	205 men	Score averaged from several measures about willingness to use (1 = totally unwilling, 5 = totally willing) Monthly injection = 2.95 SD 1.45 Daily pill = 3.63 SD 1.3 Patch = 3.04 SD 1.34
Weston 2002a (Australia)	118 men	Of white Australians who answered Definitely/Probably/Maybe (n=89): Daily pill = 33.3% 3-monthly injection = 27.4% 2-yearly injection = 21.4% Monthly injection = 13.1% Patch = 3.6% Weekly injection = 1.2%
Weston 2002b (Australia)	76 men	Of foreign-born participants who answered Definitely/Probably/Maybe (n=47): Daily Pill = 25.5% 3-monthly injection = 21.3% 2-yearly injection = 38.3% Monthly injection = 2.1% Patch = 10.6% Weekly injection = 2.1%

Table 4. Cluster analyses

Study Name, Year and Location	Number of Participants	Cluster Analysis
Heinemann 2005 (Argentina, Brazil, Germany, Indonesia, Mexico, Spain, Sweden, USA, France)	9342 men	<p>Cluster 1 – ‘The Sex-oriented narcissist’ (n=3534) interested in potential benefit of male contraception on sex life and body image, but equally concerned by any potential detriment to these. May reject a drug if <i>solely</i> for contraception but may consider for any additional benefits.</p> <p>Cluster 2 – ‘The religious refuser’ (n=1906) negative attitude toward any male contraceptive method on a religious ground. Safety and efficacy of a drug have little effect on attitude.</p> <p>Cluster 3 – ‘The informed’ (n=2651) attitude influenced by safety and efficacy of the drug as well as ease of use. This group is less worried about sexual side effects and religious objections.</p>
Vera Cruz 2019 (Mozambique)	412 men	<p>Cluster 1 – ‘Never’ (n=44) always unwilling even if low cost and no side effects. More likely to be Muslim and/or highly religious</p> <p>Cluster 2 – ‘Cost and side effects’ (n=45) more accepting as less severe side effects and as cost decreases.</p> <p>Cluster 3 – ‘Side effects’ (n=104) more accepting as less severe side effects, regardless of cost of drug</p> <p>Cluster 4 – ‘Context and side effects’ (n=190) more accepting as side effects less severe and also if their female partner cannot take contraception for medical reasons</p> <p>Cluster 5 – ‘Undetermined’ (n=29) cost, side effects and medical/social context have no influence on acceptability</p>

Table 5. Qualitative Studies

Study Name, Year and Location	Participants (number, gender and relationship status)	Type of Drug	Themes Expressed
Dismore 2016 (UK)	22 men	Hypothetical (pill)	<u>User Factors:</u> Equality, Male trustworthiness, Masculine identity, Freedom <u>Drug Factors:</u> Negative side effects, Long term consequences, STI risk, Method type
Lantelme 2017 (USA)	8 men, 8 women (8 couples)	Hypothetical (various)	<u>User Factors:</u> Equality, Relationship type, Freedom, Male trustworthiness, Masculine identity <u>Drug Factors:</u> Negative side effects, Long term consequences, Drug reliability, STI risk
Marcell 2005 (USA)	15 men, 15 women (not couples)	Hypothetical (various)	<u>User Factors:</u> Equality, Masculine identity, Male trustworthiness <u>Drug Factors:</u> Method type
Ringheim 1995 (Australia, Thailand, Singapore, UK)	23 men	Actual drug (injection)	<u>User Factors:</u> Equality, Relationship type, Masculine identity, Freedom <u>Drug Factors:</u> Drug reliability, Method type
Solomon 2007 (Indonesia)	24 men, 24 women (24 couples)	Actual drug (injection)	<u>User Factors:</u> Freedom <u>Drug Factors:</u> Positive side effects
Walker 2011 (UK)	18 men, 16 women (not couples)	Hypothetical (pill)	<u>User Factors:</u> Relationship type, Masculine identity, Freedom <u>Drug Factors:</u> Drug reliability, STI risk
Zhang 2005 (China)	67 men, 45 women (couples, but separate focus groups, not attended by all female partners)	Actual drug (injection)	<u>User Factors:</u> Masculine identity <u>Drug Factors:</u> Method

Table 6. Women's willingness to rely on male contraception

Study Name, Year and Location	Drug Type	Number of Participants	Would you use a male contraceptive if it was available?
Amouroux 2018 (France)	Hypothetical (thermal)	203 women	I would totally agree to try = 9.3% I would rather agree to try = 33.5% I would rather not agree to try = 40.9% I would not at all agree to try = 14.3%
Behre 2016 (USA, UK, Indonesia, Australia, India, Chile, Germany)	Real (injection)	250 women	Yes = 76% No = 6.4% Undecided = 17.2%
Eberhardt 2009 (UK)	Hypothetical (pill)	110 women	<i>Mean score on 4 point scale, 1 = lowest, 4 = highest</i> Overall attitude = 2.86 (SD 0.599)
Glasier 2000 (International – see rightmost column)	Hypothetical (not specified)	1894 women	Split by centre: Edinburgh 94% (of 450) Hong Kong 71% (of 450) Shanghai 87% (of 450) Cape Town (further split by racial group) Black 93% (of 286) Coloured 91% (of 151) White 97% (of 107)
Jaccard 1981 (USA)	Hypothetical (pill)	240 women	Mean intention to use score (0= no, 1= yes) If small risk of major side effects = 0.17 If moderate risk of minor side effects = 0.68
Laird 1994 (USA)	Hypothetical (pill)	120 women	Hesitant (about male contraception) = 20% Unsure = 29.2% Not hesitant = 50.8%
Marsiglio 1987 (USA)	Hypothetical (pill)	47 women	Very Likely = 23.4% Somewhat likely = 36.2% Somewhat unlikely = 12.8% Very unlikely = 27.7%
O'Connor 2005 (UK)	Hypothetical (pill and injection)	152 women	Intention to use measured on a scale -3 to +3 Mean (loss frame) = -0.55 SD 1.61 Mean (gain frame) = -0.89 SD 1.67
Skryzpulec 2006 (Poland)	Hypothetical (various methods)	78 women	77% would accept
Walker 2011* (UK)	Hypothetical (pill)	134 women	Would use= 49.5% Unsure = 31.3% Would not use = 19.2%

Footnote: *NB: The data in this paper combined male and female responses and could not be disaggregated.

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3 S1. Search Strategies
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6 **Cochrane Clinical Trials Register**
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- 8 1. Male – title, abstract and keyword
9 2. Contraception – title, abstract and keyword
10 3. Attitude – title, abstract and keyword
11 4. 1 AND 2 AND 3
12
13

14 **APA PsycInfo**
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- 16 1. Male contraception.mp.
17 2. Male.mp.
18 3. Contraception.mp. or exp Birth Control/
19 4. Contracept*.mp.
20 5. 3 OR 4
21 6. Attitude.mp. or exp Attitudes/
22 7. 2 AND 5
23 8. 1 OR 7
24 9. 6 AND 8
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29 **Web of Science**
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- 31 1. Male
32 2. Male AND contracept* AND attitude*
33 3. "male contraception"
34 4. 1 OR 2
35
36
37

38 **Medline**
39

- 40 1. Male/
41 2. male.mp. [mp=title, abstract, original title, name of substance word, subject heading
42 word, floating sub-heading word, keyword heading word, organism supplementary
43 concept word, protocol supplementary concept word, rare disease supplementary
44 concept word, unique identifier, synonyms]
45 3. 1 OR 2
46 4. Long-Acting Reversible Contraception/ or Contraception/ or Contraception,
47 Immunologic/ or contraception.mp. or Hormonal Contraception/
48 5. Contraceptives, Oral/ or contracept*.mp.
49 6. male contracept*.mp.
50 7. "male contraception".mp.
51 8. 4 OR 5 OR 6 OR 7
52 9. 3 AND 8
53 10. Attitude/ or attitude.mp.
54 11. 9 AND 10
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1. Male/
2. male.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
3. 1 OR 2
4. Long-Acting Reversible Contraception/ or Contraception/ or Contraception, Immunologic/ or contraception.mp. or Hormonal Contraception/
5. Contraceptives, Oral/ or contracept*.mp.
6. male contracept*.mp.
7. "male contraception".mp.
8. 4 OR 5 OR 6 OR 7
9. 3 AND 8
10. Attitude/ or attitude.mp.
11. 9 AND 10

Pubmed

((Male/) OR (male)) AND ((Long-Acting Reversible Contraception/) OR (Contraception/) OR (Contraception, Immunologic/) OR (contraception) OR (Hormonal Contraception/) OR (Contraceptives, Oral/) OR (contracept*) OR (male contracept*) OR ("male contraception")) AND ((Attitude/) OR (attitude))

Qualitative Studies – CASP Checklists

Element of CASP Tool	Dismore 2016	Lantelme 2017	Marcell 2005	Ringheim 1995	Solomon 2007	Walker 2011^	Zhang 2005
Was there a clear statement of the aims of the research?	No	Yes	Yes	Yes	Yes	Yes	Yes
Is a qualitative methodology appropriate?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was the research design appropriate to address the aims of the research?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was the recruitment strategy appropriate to the aims of the research?	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes
Were the data collected in a way that addressed the research issue?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Has the relationship between researcher and participants been adequately considered?	No	Yes	Unclear	No	No	No	No
Have ethical issues been taken into consideration?	Yes	Yes	Yes	Unclear	Yes	Yes	Yes
Was the data analysis sufficiently rigorous?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Is there a clear statement of findings?	Yes	Yes	Yes	Yes	Yes	Yes	Unclear

^Walker 2011 reports quantitative and qualitative data and so has been assessed with both cohort and qualitative study tools.

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Quantitative Studies - CASP Checklists (1)

Element of CASP Tool	Amory 2007	Amouroux 2018	Anawalt 2019	Balswick 1972	Behre 2016	Brooks 1998	Eberhardt 2009	Glasier 2000	Gough 1979	Heinemann 2005 (a+b)	Jaccard 1981	Laird 1994	Marsiglio 1985/87
Did the study address a clearly focused issue?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was the cohort recruited in an acceptable way?	Yes	Yes	Yes	Yes	Yes	No	Unclear	Yes	Yes	Yes	No	No	Yes
Was the outcome accurately measured to minimise bias?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes
Have the authors identified all important confounding factors?	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No
Have they taken account of the confounding factors in the design and/or analysis?	Unclear	Yes	Unclear	Yes	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Was the follow up of subjects complete enough?	Yes	Unclear	Yes	Unclear	Yes	Unclear	Unclear	Yes	Unclear	Unclear	Unclear	Unclear	Unclear
Are the results believable?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Can the results be applied to another population?	Unclear	Yes	Unclear	No	Unclear	No	Unclear	Yes	Yes	Yes	Yes	No	Unclear
Do the results of this study fit with other available evidence?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	yes	yes	Yes

*Adapted from the CASP Cohort studies tool – some questions rephrased or omitted as not appropriate for study designs.

Quantitative Studies - CASP Checklists (2)

Element of CASP Tool	Martin 2000	Mbizvo 1992	Meriggiola 2006	O'Connor 2005	Peterson 2018	Roth 2014	Sjogren 2001	Skrzypulec 2006	Thompson 2007	Vera Cruz 2019	Walker 2011 [^]	Weston 2002	WHO 1982
Did the study address a clearly focused issue?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was the cohort recruited in an acceptable way?	Yes	Yes	Yes	No	Yes	Yes	Yes	Unclear	Yes	Yes	No	Yes	Yes
Was the outcome accurately measured to minimise bias?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes
Have the authors identified all important confounding factors?	Yes	Yes	Yes	No	No	Yes	No	Unclear	Yes	No	No	Yes	Yes
Have they taken account of the confounding factors in the design and/or analysis?	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Was the follow up of subjects complete enough?	Yes	Unclear	Yes	Unclear	Unclear	Unclear	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes
Are the results believable?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes
Can the results be applied to another population?	Yes	Yes	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Yes	Yes	Unclear	Unclear	Unclear
Do the results of this study fit with other available evidence?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

*Adapted from the CASP Cohort studies tool – some questions rephrased or omitted as not appropriate for study designs. [^]Walker 2011 reports quantitative and qualitative data and so has been assessed with both cohort and qualitative study tools.



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Title
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Abstract
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	2,3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3,4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	3
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	3,4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	4, S1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	n/a
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	n/a



PRISMA 2009 Checklist

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Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	n/a
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n/a
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6, fig 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Tables 1-6
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	n/a
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	n/a
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	n/a
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	n/a
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	15
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	16
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	16

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

Synthesis Without Meta-analysis (SWiM) reporting items

The citation for the Synthesis Without Meta-analysis explanation and elaboration article is: Campbell M, McKenzie JE, Sowden A, Katikireddi SV, Brennan SE, Ellis S, Hartmann-Boyce J, Ryan R, Shepperd S, Thomas J, Welch V, Thomson H. Synthesis without meta-analysis (SWiM) in systematic reviews: reporting guideline BMJ 2020;368:l6890 <http://dx.doi.org/10.1136/bmj.l6890>

SWiM is intended to complement and be used as an extension to PRISMA			
SWiM reporting item	Item description	Page in manuscript where item is reported	Other*
<i>Methods</i>			
1 Grouping studies for synthesis	1a) Provide a description of, and rationale for, the groups used in the synthesis (e.g., groupings of populations, interventions, outcomes, study design)	3	
	1b) Detail and provide rationale for any changes made subsequent to the protocol in the groups used in the synthesis	n/a	
2 Describe the standardised metric and transformation methods used	Describe the standardised metric for each outcome. Explain why the metric(s) was chosen, and describe any methods used to transform the intervention effects, as reported in the study, to the standardised metric, citing any methodological guidance consulted	5,6	
3 Describe the synthesis methods	Describe and justify the methods used to synthesise the effects for each outcome when it was not possible to undertake a meta-analysis of effect estimates	5,6	
4 Criteria used to prioritise results for summary and synthesis	Where applicable, provide the criteria used, with supporting justification, to select the particular studies, or a particular study, for the main synthesis or to draw conclusions from the synthesis (e.g., based on study design, risk of bias assessments, directness in relation to the review question)	5,6	
SWiM reporting	Item description	Page in manuscript	Other*

Synthesis Without Meta-analysis (SWiM) reporting items

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item		where item is reported	
5 Investigation of heterogeneity in reported effects	State the method(s) used to examine heterogeneity in reported effects when it was not possible to undertake a meta-analysis of effect estimates and its extensions to investigate heterogeneity	5,6	
6 Certainty of evidence	Describe the methods used to assess certainty of the synthesis findings	n/a	
7 Data presentation methods	Describe the graphical and tabular methods used to present the effects (e.g., tables, forest plots, harvest plots). Specify key study characteristics (e.g., study design, risk of bias) used to order the studies, in the text and any tables or graphs, clearly referencing the studies included	n/a	
<i>Results</i>			
8 Reporting results	For each comparison and outcome, provide a description of the synthesised findings, and the certainty of the findings. Describe the result in language that is consistent with the question the synthesis addresses, and indicate which studies contribute to the synthesis	7-12	
<i>Discussion</i>			
9 Limitations of the synthesis	Report the limitations of the synthesis methods used and/or the groupings used in the synthesis, and how these affect the conclusions that can be drawn in relation to the original review question	15	

PRISMA=Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

*If the information is not provided in the systematic review, give details of where this information is available (e.g., protocol, other published papers (provide citation details), or website (provide the URL)).