

Modeling the impact of novel male contraceptive methods on reductions in unintended pregnancies in Nigeria, South Africa, and the United States

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Abstract

Objective: We modeled the potential impact of novel male contraceptive methods on averting unintended pregnancies in the United States, South Africa, and Nigeria.

Study design: We used an established methodology for calculating the number of couple-years of protection provided by a given contraceptive method mix. We compared a “current scenario” (reflecting current use of existing methods in each country) against “future scenarios,” (reflecting whether a male oral pill or a reversible vas occlusion was introduced) in order to estimate the impact on unintended pregnancies averted. Where possible, we based our assumptions on acceptability data from studies on uptake of novel male contraceptive methods.

Results: Assuming that only 10% of interested men would take up a novel male method and that users would comprise both switchers (from existing methods) and brand-new users of contraception, the model estimated that introducing the male pill or reversible vas occlusion would decrease unintended pregnancies by 3.5% to 5.2% in the United States, by 3.2% to 5% in South Africa, and by 30.4% to 38% in Nigeria. Alternative model scenarios are presented assuming uptake as high as 15% and as low as 5% in each location. Model results were sensitive to assumptions regarding novel method uptake and proportion of switchers vs. new users.

Conclusion: Even under conservative assumptions, the introduction of a male pill or temporary vas occlusion could meaningfully contribute to averting unintended pregnancies in a variety of contexts, especially in settings where current use of contraception is low.

Implications: Novel male contraceptives could play a meaningful role in averting unintended pregnancies in a variety of contexts. The potential impact is especially great in settings where current use of contraception is low and if novel methods can attract new contraceptive users.

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Keywords: Male contraception; Reversible vas occlusion; Male pill; CYP; Unintended pregnancy; Mathematical model

1. Introduction

In 2012, an estimated 40% of pregnancies were unintended, totaling 85 million unintended pregnancies

worldwide [1]. Unmet need for contraception (defined as the number of sexually active, fecund people who wish to limit or postpone births, but are not currently using contraception) varies globally. In 2010, women’s unmet need was estimated at 5.9% in the United States and 23.2% in Africa [2]. In three West African countries, estimates for wife-only unmet need (33%–40%) tended to be greater than

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husband-only unmet need (15%–23%). This latter figure represents a sizeable need and suggests that men could be an underutilized entry point for contraceptive use in couples [3].

Globally, both women's and men's preferences for family size are shrinking, but many exceed their desired family size [4]. Even in countries that tend toward pronatalist attitudes, desired family size among men is decreasing [5].

As women bear the physical responsibility of pregnancy and often an unequal share of childrearing, it is critical that they have access to the existing variety of female-controlled, safe, effective, acceptable and affordable contraceptive methods. Existing male-controlled methods are limited to condoms, withdrawal and vasectomy, which are used by approximately 11.6%, 4.6% and 10.8% of men in the United States and by 2.4%, 1.3% and 0% of men in sub-Saharan Africa, respectively [6].

Clinical trials using actual products, such as gels or injectables, have assessed the acceptability of novel male contraceptive methods [7–11]. Surveys or qualitative studies have also assessed acceptability of hypothetical products described to participants [12–14]. Clinical trial data suggest that certain novel male methods would be acceptable to some users. Of 38 men who completed a trial involving a topical testosterone gel and injection combination, 50% reported being “satisfied or very satisfied” with the regimen and 45% said that they would use it if it were commercially available [7]. In a trial evaluating a testosterone injectable, 61% of the 44 participants who completed the 1-year exposure period rated the method as excellent or good and 79% indicated that they would use it if it were available [10].

Hypothetical acceptability of male contraceptive pills or injections is high in some groups but shows wide variability. Despite reported skepticism over factors such as safety and efficacy, in one study, hypothetical willingness to try a male pill ranged from 44% (men in Hong Kong) to 83% (white men in Cape Town), and willingness to try an injectable ranged from 32% (men in Edinburgh) to 62% (white men in Cape Town) [13]. A survey including 9000 men aged 18–50 years from nine countries found that willingness to try a novel male hormonal contraceptive ranged from a low of 28.5% of men in Indonesia to a high of 71.4% of men in Spain, with daily oral dosing being the preferred route across all countries surveyed [12]. Willingness to use such methods in the United States was estimated to be 49.3%. Features likely to impact the acceptability of novel male methods include efficacy, delivery route, timing of onset of effectiveness, side effects, requirements for use (i.e., semen analysis or regular clinic visits), reversibility, female partner perspectives, sociodemographic characteristics of the user and expense [12].

Studies have also assessed women's attitudes toward use of a novel contraceptive method by their male partner [14–17]. In a survey of almost 2000 women in Scotland, South Africa, and Shanghai, over 70% of participants would be willing to rely on their partner's use of a hormonal male contraceptive and only 2% of the sample would not trust

their partner to use it [16]. A study by Audu et al. [15] in Northeast Nigeria found that 54% of 417 women would prefer a male partner to use contraception instead of themselves (although this likely pertained to current male methods).

Given high unintended pregnancy rates and unmet need for contraception in many regions of the world and promising acceptability data for novel male contraceptive methods, we sought to model the hypothetical impact on unintended pregnancy rates with the introduction of a new, effective and reversible male contraceptive method.

2. Materials and methods

We estimated the impact of an effective, reversible male contraceptive on unintended pregnancies averted in three diverse settings: the United States (relatively high contraceptive use, including substantial long-acting and permanent method use), South Africa (relatively high contraceptive use, particularly of injectables) and Nigeria (relatively low contraceptive use). We used Microsoft Excel to build a model comparing annual unintended pregnancies in a “current scenario” (based on the current contraceptive method mix) against a “future scenario” in which one of two effective, reversible male contraceptive methods was introduced, either a pill, or a reversible vas occlusion procedure. We chose these two methods because many researchers around the world are working to develop various types of male contraceptive pills, and several researchers are working on different approaches to reversible vas occlusion [18–22]. While regulatory approvals are many years away, a male pill and/or a reversible vas occlusion procedure may become real options.

Estimation of unintended pregnancies averted was based on couple-years of protection (CYP) calculations following the methodology published by MEASURE Evaluation [23] (see Appendix A for details). By multiplying the total CYP by the proportion of pregnancies that are unintended (0.288 per CYP in our model) [24], we estimated unintended pregnancies averted based on a given method mix. Perry et al. [25] used a similar approach to estimate the public health impact of increased vasectomy uptake in eight low-resource countries. In that work, Perry et al. used National Demographic and Health Survey data from each of the target countries as well as contraceptive commodity cost estimates [26,27] to calculate the cost per CYP of the nations' current contraceptive method mix. The analysis then compared the cost-effectiveness of the current method mix to a method mix that included a 5% increase in vasectomy use by the year 2020. In addition, the analysis estimated the increase in the number of averted unintended pregnancies, maternal and infant deaths, unsafe abortions and case fatalities due to increase overall CYP of a method mix that included greater vasectomy use.

Table 1 presents the required modeling inputs to establish the “current” scenario, including number of current users

Table 1
Current use, annual discontinuation rates and CYP conversion factors for the United States, South Africa, and Nigeria

	United States		South Africa		Nigeria		
Women aged 15–49 years in marriage or unions (2016) [28]	37,901,000		5,027,000		29,284,000		
Proportion of infecund women	15.5% [29]		32% [30]		31.3% [31]		
Fecund women aged 15–49 years in marriage or unions (calculated, used in model)	31,402,735		3,418,360		20,324,208		
	% Using [6]	Annual in-need discontinuation rate [32] ^a	% Using [6]	Annual in-need discontinuation rate [33] ^{a,b}	% Using [6]	Annual in-need discontinuation rate [33] ^{a,b}	Units per CYP [23]
Short-term methods							
Female pill	16	0.400	11.6	0.367	2.1	0.367	15
Male condom	11.6	0.844	4.9	0.479	2.5	0.479	120
Injectable	0	0.580	30.3	0.262	3.8	0.262	4 ^c
Long-term methods							
IUD	5.1	NA	1.1	NA	1.3	NA	CYP per procedure [23] ^d
Implant	1	NA	0.2	NA	0.5	NA	1
Female sterilization	21.8	NA	15.3	NA	0.4	NA	1
Vasectomy	10.8	NA	0.7	NA	0	NA	1

Abbreviations: NA, not applicable.

^a In-need discontinuation refers to discontinuation occurring among women who continue to be in-need of contraception (i.e., sexually active and seeking to avoid pregnancy).

^b Based on in-need discontinuation rates from Kenya DHS data.

^c Based on Depo Provera.

^d Long-term methods conservatively assumed to provide only 1 year of protection given the 1-year time horizon of the modeling exercise.

(restricted to married or coupled, fecund women aged 15–49 years), current use of modern methods in each geography, annual discontinuation rates for users still in-need of contraception (i.e., trying to avoid pregnancy) and CYP conversion factors for each method (Appendix A). We based in-need discontinuation rates for Nigeria and South Africa on discontinuation rates from DHS data in Kenya, as no discontinuation data were available specific to these countries. The list of contraceptives considered is not exhaustive but includes most commonly used methods for which necessary data were available.

Calculating the future scenario CYP required data on use of existing and novel methods, discontinuation rates for novel male methods and CYP conversion factors for novel male methods. We used corollaries from existing female contraceptive methods as proxies to determine discontinuation rates and CYP conversion factors for novel male methods. We assumed that the male pill would have the same discontinuation rate and CYP conversion factor as female pill. For all long-acting or permanent methods (both existing and the hypothetical reversible vas occlusion method), the years of coverage provided by each method was assumed to be 1, given that our analyses were concerned with the impact on annual unintended pregnancy rates.

No existing corollary or historic uptake data were available as a proxy to estimate the number of novel male method users (or, for the purposes of the CYP methodology, the number of women likely covered by a novel male method). Thus, we estimated the uptake of novel male method users based in part on survey data [12,13] from key geographies of interest.

Since only a subset of men who express willingness to try a novel method would likely do so, we conservatively assumed the annual number of users for both novel male methods in each country to be 10% of men who expressed a willingness to try one. In the United States, 49.3% of men reported willingness to try a new form of male contraception (daily oral pill, monthly injectable or annual implant) [12]. In South Africa, willingness to use a male pill varied from 55% (black men) to 83% (white men) [13], so we conservatively used the lowest figure (55%). Thus, the number of novel method users was estimated at 4.9% and 5.5% for the United States and South Africa, respectively.

According to the 2013 Nigeria national DHS, only 16% of married women have an unmet need for contraception — 12% for spacing and 4% for limiting — despite a low prevalence of contraceptive use [34]. We chose a cap of 3.8% uptake for a novel male method because (a) no country-specific acceptability data were available for Nigeria, and (b) 3.8% is the level of the most-used existing

Table 2
Modeling inputs for future scenarios

		United States, % using [6]			South Africa, % using [6]			Nigeria, % using [6]	
Short-term									
Female pill		14.8			10.8			2	
Male condom		10.8			4.6			2.4	
Injectable		0			28.3			3.7	
Long-term									
IUD		4.7			1			1.3	
Implant		0.9			0.2			0.5	
Female sterilization		21.8			15.3			0.4	
Vasectomy		10.8			0.7			0	
Novel male method	% Using	Annual in-need discontinuation rate [32]	CYP conversion factor [23]	% Using	Annual in-need discontinuation rate [33] ^a	CYP conversion factor [23]	% Using	Annual in-need discontinuation rate [33] ^a	CYP conversion factor [23]
Male pill	4.9 ^b	0.400	Units per CYP 15 ^c	5.5 ^a	0.367	Units per CYP 15 ^c	3.8% ^d	0.367	Units per CYP 15 ^c
Reversible vasectomy		NA	CYP per procedure 1.0 ^e		NA	CYP per procedure 1.0 ^e		NA	CYP per procedure 1.0 ^e
Totals for future scenarios									
% Switchers		2.5			3.2			0.4	
% New users		2.5			2.4			3.4	

Percent using: all existing contraceptive options are reduced (compared to the “current scenario”) to reflect switching between existing and novel options.

^a Based on South Africa data from Martin et al. [13], assuming that 10% of those willing to use male methods would become users.

^b Based on US data from Heinemann et al. [12], assuming that 10% of those willing to use male methods would become users.

^c Assumed the same as the female pill (closest corollary).

^d Capped at the maximum usage of a current method to maintain face validity.

^e Long-term methods conservatively assumed to provide only 1 year of protection given the 1-year time horizon of the modeling exercise.

Table 3
Main model results for current and new scenarios

	United States			South Africa			Nigeria		
	Current scenario	Male pill scenario	Reversible vas occlusion scenario	Current scenario	Male pill scenario	Reversible vas occlusion scenario	Current scenario	Male pill scenario	Reversible vas occlusion scenario
No. of unintended pregnancies averted per year	5,264,035	5,450,208	5,538,839	559,470	577,363	587,299	533,716	695,859	736,675
% Change from current scenario		3.5	5.2		3.2	5		30.4	38
Absolute change from current scenario		186,173	274,804		17,893	27,829		162,143	202,959

method (female injectable). In the Nigeria analyses, we applied a cap to ensure that the uptake of a novel male method did not exceed the current usage of the most prevalent existing method (injectables).

Table 2 presents inputs used in the “future scenarios,” in which the male pill or reversible vas occlusion is introduced. We assumed the projected number of novel male method users would be composed of some “switchers” (currently covered by existing methods) and some “new users” (not currently using contraception). For each geographic area, switchers were determined based on the proportion of current reversible-method users (i.e., those who could discontinue their current method in favor of a new one), and new users were determined based on the proportion of those not currently using contraception. We proportionally drew switchers in each geographic area from the current users of all reversible methods, so there are slightly fewer users of reversible methods in the inputs for future scenarios (Appendix A).

3. Results

Our model suggests that introduction of the male pill or reversible vas occlusion would avert an additional 3.5% to 5.2% unintended pregnancies in the United States, and 3.2% to 5% unintended pregnancies in South Africa, respectively (Table 3). In Nigeria, the estimates would be substantially higher, at 30.4% to 38% more unintended pregnancies averted for the two methods, respectively (Table 3). Such results compare favorably with the real-world decrease in unintended pregnancy rates of 2% achieved per year in Africa from 2008 to 2012 [1].

Our model estimates that introducing reversible vas occlusion will avert more unintended pregnancies than a male pill in all countries, even when assuming that reversible vas occlusion would confer only 1 year of contraception. The differences in the current method mix of each country can largely explain the difference in magnitude of impact by country. In the United States and South Africa, introduction of novel male methods would decrease unintended pregnancies, but impact would be mitigated by the high prevalence of other methods already in use. In Nigeria, where current use of contraception is very low, even a 3.8% uptake of a novel male contraceptive method could have a dramatic impact.

Model results were robust to variation in discontinuation rates but were more sensitive to assumptions around male method uptake (Table 4). However, even assuming that only 5% (instead of the model’s 10% assumption) of men who indicated interest in using a novel male method would actually adopt the method, the increase in unintended pregnancies averted still ranges from 1.6% to 2.6% in the United States and South Africa, and between 22% to 27.5% in Nigeria. When assuming 15% of men who indicated interest would adopt a novel male method, results for the United States and South Africa climb to 7.8% and 7.5%. If all users of novel male methods were assumed to be new users (instead of some new users and some switchers from other methods, as in our main model), more unintended pregnancies would be averted, ranging from a 6.7% increase in the United States (male pill scenario) to a 41.7% increase in Nigeria (reversible vas occlusion scenario). Although these scenarios seem unlikely, they help to illustrate the potential upper bound of impact that novel male methods could provide.

4. Discussion

To our knowledge, this is the first attempt to quantify the potential impact of novel male contraceptive methods on unintended pregnancy across countries. We used a standardized approach to calculate number of unintended pregnancies averted in each country. Where possible, we leveraged existing data for female methods (such as discontinuation rates and units per CYP) and used conservative assumptions for our main model while exploring variation in sensitivity analyses.

Limitations of this analysis include the need to rely on assumptions (due to the hypothetical nature of the research question) and limitations of available data. Substantial uncertainty exists around hypothesized “uptake” of novel male contraception in each country. Data from acceptability studies conducted in 1995–1996 and 2002, respectively, informed our assumptions, but these data may not reflect current attitudes. Furthermore, it remains unclear how precisely these studies can predict actual behavior with the contraceptive methods in our model. We assumed similar acceptability across methods, although real preferences may vary according to various factors described earlier [12] and by administration schedules and formulations [13]. Service

Table 4
Sensitivity analysis: projected change from current scenario in number of unintended pregnancies averted under alternative assumptions

No.	Parameter	Main model	Alternative assumption	% Change from current scenario					
				United States		South Africa		Nigeria	
				Male pill scenario	Reversible vas occlusion scenario	Male pill scenario	Reversible vas occlusion scenario	Male pill scenario	Reversible vas occlusion scenario
1	In-need discontinuation rates	United States: Trussell et al. [32]	All discontinuation rates varied by +20%	3.6	4.9	3.3	4.7	30.8	36.7
		South Africa and Nigeria: assumed to have the same discontinuation rates as observed in Kenya DHS survey data	All discontinuation rates varied by -20%	3.5	5.6	3.1	5.3	30	39.4
2	Proportion of “accepting” men projected to adopt a novel male method	10% of accepting men would use a novel male method	5% of accepting men modeled to use a novel male method	1.8	2.6	1.6	2.5	22	27.5
		United States: 4.9% South Africa: 5.5% Nigeria: 3.8% (capped at current highest usage)	United States: 2.5% South Africa: 2.8% Nigeria: 2.8% 15% of accepting men modeled to use a novel male method	5.3	7.8	4.8	7.5	30.4	38
3	New users vs. switchers	Novel male method users composed of both switchers and new users	Novel male method users composed of new users only	6.7	8.4	7.9	9.7	34	41.7

delivery and cost coverage may also limit fulfillment of preferences and continuation of use. In a similar way, women may be unable to access their preferred contraceptive due to lack of insurance, high co-pays and/or a myriad of other political, structural, cultural and social barriers [35,36]. Similarly, without data to inform an alternative approach, our model assumed that current users of reversible methods switch to using novel male methods in equal proportions, which may not reflect real-world nuances of method preference and switching behavior. For example, women may derive noncontraceptive benefits from their current hormonal method and may therefore switch to relying on a novel male method at different rates than, for instance, women who currently rely on male condoms. In the absence of concrete target product profiles, we assumed that novel male methods would have analogous efficacy and discontinuation profiles as current female-controlled options. Finally, our model captures the impact of novel male methods only among married or partnered women, for whom the necessary data on current contraceptive use were available, which likely underestimates the population of contraceptive users and potential impact on averting unintended pregnancies.

The CYP indicator itself was another limitation in our analysis. CYP does not capture the fact that a novel male method could prevent pregnancies in multiple partners per male user. In addition, CYP indicators reflect the contraceptive effectiveness of a single contraceptive unit [e.g., oral pill packet, male condom, intrauterine device (IUD), etc.]. In our model, we rely on cross-sectional data to estimate contraceptive use for each method. We then estimate the number of units used in a given year by factoring in discontinuation of short-term methods (pills, condoms and injectables). However, we do not factor in potential discontinuation of long-term nonpermanent methods (IUDs and implants) within a 12-month period. Our estimates assume that one long-term nonpermanent method procedure contributed one CYP to the contraceptive effectiveness of the method mix. Discontinuation rates of long-acting methods range widely worldwide. A 2011 World Health Organization report suggested an all-cause, 12-month IUD discontinuation rate in 14 developing countries to range from 9.6% to 37.3% [37]. Discontinuation of long-term nonpermanent methods in our model would reduce their estimated contraceptive contribution. However, our model is not sensitive to potential switching that may occur within a year after discontinuation, which may mitigate any reduction in overall CYP of the method mix.

Furthermore, broader contraceptive choice for men may impact dual use of contraception. Dual use could increase, especially among individuals who continue to use condoms for disease prevention, or decrease as contraceptive options for men expand beyond condoms. The CYP indicator cannot capture the implications of such dynamics; a new statistical methodology may be required to fully capture the dynamics of a landscape including novel male methods. Other

potential challenges relevant to the success of a novel male method that fall outside the scope of the current analysis include time, development costs, training needs, regulatory hurdles and the lack of delivery systems that address the reproductive health needs of men. Additional investigations of these factors will be critical.

We intentionally narrow our discussion to the impact of a novel male method on unintended pregnancies averted, but funders and policy makers must also consider potential ancillary benefits (i.e., increased male reproductive autonomy, potential decreased burden on women to shoulder contraceptive responsibility) and potential risks (potential condom displacement, or potential for reproductive coercion by men who falsely claim to be using male contraception). In addition, some novel male methods might require men and their partners to use alternative contraception until sperm counts fall sufficiently low. Other novel oral agents target sperm function or sperm transport rather than sperm production. These methods would not require sperm counts and their onset of action would be more rapid. Effective counseling can shape how men and their partners establish open communication about these risks and how to confirm that the method is working effectively if confirmation was required.

In conclusion, novel male methods could substantially reduce the number of unintended pregnancies in a variety of settings. Among women, research shows that making more methods available increases use [38]. The same may be true for men. The current analysis is limited due to data gaps and the dearth of statistical models capable of capturing male and female participation in contraception. These projections warrant additional research into (1) the potential role of male contraception and (2) the development of new male contraceptives.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.contraception.2017.08.015>.

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