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Male Contraception is Coming: Who Do Men Want to Prescribe their Birth Control?

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Abstract

Objective: To assess men's preferences for type of healthcare provider from whom they would obtain hormonal male contraceptive (HMC) methods.

Study Design: We asked participants from three clinical trials of investigational hormonal male contraceptive methods—an oral pill (11β-Methyl-19-nortestosterone-17β-dodecylcarbonate, 11β-MNTDC), an intramuscular or subcutaneous injection (Dimethandrolone undecanoate, DMAU), and a transdermal gel (Nestorone® and testosterone, NES/T)—to rank their top three preferred HMC providers from a list including: men's health doctor (urologist/andrologist), hormonal doctor (endocrinologist), reproductive health doctor (OB/GYN), family planning clinician (community health worker, midwife, nurse practitioner), regular doctor (family medicine/internal medicine), and community pharmacist. We examined men's preferences based on their rankings and conducted bivariate analyses. Collapsing the various specialists (men's health doctor, hormonal doctor, reproductive health doctor, and family planning clinician) into a single provider type, we examined participant demographics against provider preference (regular doctor, pharmacist, or specialist).

Results: Participants across the three trials (n=124) ranked their regular doctor (44%) and community pharmacist (18%) as their most preferred HMC provider; these preferences did not

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differ significantly by trial and drug formulation. Specialists in family planning (13%), men's health (12%), reproductive health (10%), and hormones (4%) were least frequently ranked as their preferred provider. Older and higher educated participants more often preferred specialists over regular doctors and pharmacists (p=0.02 and p=0.01, respectively).

Conclusions: Despite receiving contraceptive steroid hormones and care from specialists in endocrinology and family planning in a clinical trial setting, participants in hormonal male contraceptive trials would prefer to obtain contraception from their regular doctor.

Keywords

male contraception; hormonal male contraception; male birth control; provider preference; prescription; primary care physician

1. INTRODUCTION

Research on hormonal male contraception continues to make progress towards a marketable method. In 2012, a combination hormonal injection of norethisterone enanthate and testosterone demonstrated contraceptive efficacy comparable to combined oral contraceptives for females in a phase II, multicenter clinical trial. Despite the trial's early cessation due primarily to the incidence of mild mood changes and injection site pain, more than 80% of participants reported satisfaction with the method and willingness to use a similar method [1]. More recent trials include a phase IIb contraceptive efficacy trial of a combination transdermal gel (Nestorone® and testosterone, NES/T) [2], and an injectable formulation of a novel progestogenic androgen (Dimethandrolone undecanoate, DMAU) [3] as well as dose-finding trials for two of the first oral pill prototypes consisting of the progestogenic androgens, Dimethandrolone undecanoate (DMAU) and 11β-Methyl-19-nortestosterone-17β-dodecylcarbonate (11 β-MNTDC), respectively [4, 5]. Given their promising effects on gonadotropin suppression while maintaining eugonadism [6], the success of these trials prompts the need to investigate how male contraceptives will be prescribed and/or provided when they enter the contraceptive market.

While multi-national surveys suggest that men would use hormonal male contraceptives (HMCs) [7], these findings stand in contrast to surveys showing that men underutilize preventive health services [8], inclusive of family planning services [9]. Nevertheless, contraception may incentivize men's concurrent use of healthcare, as has been historically seen with women [10]. Currently, women have many types of providers from whom they can obtain contraception, including obstetrician-gynecologists (OB/GYNs), primary care physicians (PCPs), internal medicine and family medicine physicians, pediatricians, and advanced practice clinicians (APCs) [11]. As some female contraceptive methods such as intrauterine devices (IUDs) or subdermal implants require procedures for placement and thus, additional training and resources, they are more commonly prescribed by OB/GYNs and specialized women's health APCs rather than PCPs [11]. Consequently, prescription methods (i.e., pills, patches, and rings) are prescribed by 75% of OB/GYNs, 50% of family medicine physicians, and 32% of pediatricians, whereas IUDs are provided by 92% of OB/GYNs, 16% of family medicine physicians, and less than 1% of pediatricians [11]. With respect to currently available methods of male contraception, condoms are purchased

over the counter, while vasectomies are primarily performed by urologists (82%), family practitioners (6.4%), and general surgeons among other physicians (11.6%) [12]. While the most appropriate provider for new HMCs may depend on the method's complexity, counselling requirements, mode of delivery, and safety profile, user provider preferences are also important to maximize uptake. Consequently, we surveyed men enrolled in three HMC clinical trials about their preferred contraceptive provider when HMCs become approved for the market.

2. MATERIALS AND METHODS

2.1 Study Design

Hormonal Male Contraceptive Clinical Trials—We evaluated provider preference data from surveys of subjects enrolled in clinical trials at the Lundquist Institute in Los Angeles, California and the University of Washington Medical Center in Seattle, Washington, as these were the only sites that conducted all relevant clinical trials. Participants included healthy men 18-50 years old with BMI ≤ 33 kg/m^2 showing no clinical or laboratory evidence of adverse medical conditions. Trials included phase 1 evaluations of a daily, oral 11β-MNTDC prototype pill, an injectable DMAU formulation, as well as a phase IIb evaluation of the NES/T transdermal gel (Clinical Trials Registration Numbers: NCT03298373, NCT02927210, NCT03452111). In the 11β-MNTDC clinical trial, participants took capsules of varying dosages of active drug or placebo for 28 consecutive days. During the injectable DMAU trial, participants received varying dosages of a single intramuscular or subcutaneous injection containing DMAU or placebo. Lastly, during the phase IIb NES/T gel study, participants use the transdermal gel daily for a suppression phase lasting six to sixteen weeks, and an efficacy phase lasting up to fifty-two weeks. All participants completed acceptability questionnaires at their exit visit or during recovery follow-up. Acceptability surveys from the 11β-MNTDC oral pill study have previously been published without inclusion of provider preferences [13].

2.2 Survey Instrument

Each participant completed an acceptability questionnaire querying their attitudes towards and experience with the specific HMC. The questionnaires included the item: "Where would you prefer to go or who would you prefer to go to see for the male birth control pill/injection/gel?" Response options included: men's health doctor (urologist, andrologist), hormonal doctor (endocrinologist), reproductive health doctor (OB/GYN), family planning clinic (community health worker, midwife, nurse practitioner), your regular doctor (family medicine, internal medicine), and community pharmacist. Of these six options, participants ranked their top three choices from 1 (most preferred) to 3 (less preferred); the remaining three options were left unranked.

2.3 Descriptive and Statistical Analysis

We present the data on provider preference in two ways—their most preferred option (Figure 1) and a weighted representation of general provider preference where healthcare provider options marked as first, second, and third choice received three, two, and one point(s), respectively. We included the latter method, acknowledging that men will need a wide

range of provider options rather than their preferred provider to ensure male contraceptive access. We additionally examined for any associations between respondent demographic characteristics (age, race/ethnicity, marital status, and education level) and provider preference. We collapsed provider categories into broader groups to facilitate a more robust bivariate analysis—specialist (men's health doctor, endocrinologist, reproductive health specialist, and family planning clinician), regular doctor (family medicine and internal medicine), and community pharmacist (Table 2). We conducted Chi-square tests of independence and Fisher's Exact tests as appropriate, setting our significance level at $p<0.05$. We performed analyses using the Stata 14.2 (College Station, Texas, USA) statistical analysis package.

3. RESULTS

We collected questionnaire data from 124 men: 35 from the 11β-MNTDC oral pill trial, 55 from the DMAU injection trial, and 34 from the NES/T transdermal gel trial.

3.1 General Opinions and Responses Across Various Methods

We noted significant differences in the participants' HMC provider preference for both ratings of most preferred provider ($p<0.01$) and weighted preference rankings ($p<0.01$). Across all trials, participants most frequently selected their regular doctor (43.5%) as their most preferred prescriber of male contraception, followed by their community pharmacist (17.7%), and family planning clinician (12.9%) (Figure 1). Examining the weighted rankings, we noted a similar finding with 32.8% of participants preferred a regular doctor, 16.1% preferring a community pharmacist, and 16.2% preferring a men's health doctor. Individuals ranked and selected an endocrinologist least frequently, consisting of 7.6% of weighted provider preference.

With respect to provider preference by male contraceptive method, participants from each trial consistently reported preferring their regular doctor most (40.0% 11β-MNTDC, 43.6% DMAU, and 47.1% NES/T); hormonal doctor was least selected as the participants' most preferred provider (0%, 7.3%, and 2.9%, respectively) (Figure 1). In analyzing weighted preference, participants preferred to see their regular doctor for male birth control (33.3%, 33.3%, and 31.4%, respectively) and few preferred to go to a hormonal doctor (8.1%, 6.7%, 8.3%, respectively). In an analysis of both highest preference and weighted preference, there was no significant variation in provider preferences across the three drug formulations ($p = 0.97$, $p = 0.81$, respectively).

3.2 Demographic Differences Across Provider Preference

Examining differences in provider preferences by participant demographic characteristics, we noted significant associations of provider preference with participant socio-demographic characteristics (Table 2). While noted to be a statistically significant difference ($p=0.016$), variations in provider preference by age were not particularly meaningful between regular doctors (28.1 years), pharmacists (30.7 years), and specialists (31.7 years). Provider preference varied significantly by education level with those who completed high school

or less showing higher interest in a specialist and those who completed a graduate degree showing higher interest in a regular doctor (p=0.009) (Table 2).

4. DISCUSSION

Understanding the landscape of men's contraceptive access preferences prior to the release of a commercial product is a critical issue. In this survey of 124 participants from three hormonal male contraceptive trials, we found an overwhelming preference for obtaining hormonal male contraceptives from the participant's regular doctor. Despite their experience with specialists and experts in endocrinology and family planning in the clinical trial setting, these provider types were among the least preferred by participants.

These findings mirror results from a survey conducted on a convenience sample of men in the United Kingdom in 1998, where 50% of respondents preferred their general practitioner as opposed to a family planning clinic or a pharmacist [14]. These findings suggest that the familiarity or convenience of a provider may influence men's preference. In qualitative, semi-structured interviews with 22 men reporting interest in male contraception in England, researchers highlighted men's valuation of a reliable source with whom they had developed trust [15], possibly built by longitudinal relationships developed with their PCPs. Alternatively, for men who receive primary care from a healthcare network, rather than an established, individual PCP, their preference for a regular doctor may reflect perceptions of PCP availability and accessibility. Thus, the acceptability and uptake of HMCs may rely on future education and counseling of PCPs [13, 14]. Concurrently, as men see their PCPs on a more regular basis to receive HMCs, these increased visits may include a positive impact on men's broader health outcomes.

Participants also showed great interest in community pharmacists as HMC prescribers. Given the convenience and cost-effectiveness of obtaining female hormonal contraceptives directly from pharmacists [16, 17], a nationwide survey explored this option in 2006, finding that the majority (68%) of women would consider going to their pharmacist for contraception directly [18]. Following these findings, seventeen US jurisdictions and the District of Columbia currently allow direct pharmacy provision [19]. Semi-structured interviews with US men highlighted the need to see a doctor to obtain contraception as a disadvantage [20], thus developing male contraception with attention to its eventual provision by pharmacists directly may help to ensure widespread uptake. Given that pharmacists' ability to prescribe and provide oral contraceptive pills has been linked to contraceptive continuation among women, pharmacists' provision of male contraception would likely benefit men's contraceptive continuation similarly [21]. Of note, as testosterone-containing products are currently classified as Schedule III controlled substances, the range of potential hormonal male contraceptive providers may be limited [22].

The participants' preference for a less-specialized provider is surprising given the intensive clinical trial expectations experienced by the participants. We anticipated that routine visits with endocrinologists and family planning specialists, and the measures necessary to determine efficacy might lead participants to think they need to seek care from a specialist.

While physicians who specialize in OB/GYN are also considered PCPs for female patients, men may not be fully aware of specialists for male reproductive health such as urologists and andrologists [23]. Men may also be wary of the increased cost and time associated with seeing a specialist. A report published by the Endocrine Society in 2014 reported that the average wait time for new patients seeking a non-emergent consult with an endocrinologist was 37 days [24], which may prove too burdensome for most men, particularly those needing to obtain a prior referral.

With respect to participant characteristics linked to provider preference, we noted that more educated participants preferred regular doctors. This finding might be related to the lack of established care with regular doctors among individuals with less education [25], as compared to those with higher education who more frequently report having recently seen a doctor for a wellness visit [26]. Accordingly, data from the Kaiser Family Foundation highlight that approximately 25% of men do not have a personal doctor or healthcare provider [28]. With respect to a specialist preference among older participants, this finding might be related to their familiarity with specialists, as men tend not to see a urologist (specialist) until later in life [27].

While exploratory in nature, this study is one of the first to provide important insights regarding expectations for male contraceptive providers. We noted similar findings across three different formulations, routes of delivery, and trials. Nevertheless, the study is limited in its survey of trial participants from urban regions of the United States who may represent a healthier, more health-interested, and health-literate population. Those living in rural areas may have more limited options with respect to accessible contraceptive providers. We note that in our response options for preferred provider, we refer to regular doctors with the possessive adjective “your,” suggesting that those who preferred this option had an established relationship with their doctor, though this was not assessed explicitly in the survey. Further, we did not include APCs or online prescription services in this survey; these options should be included in future surveys as APCs are a growing part of the healthcare workforce and men may show interest in using online prescription services. Lastly, our findings are limited to men over the age of 18. As young men in the U.S. initiate sex on average at age 16 years [29], they will need to be considered in future research, with the additional assessment of pediatricians and adolescent medicine specialists as potential providers.

The history of female contraception has been defined by barriers to access and reproductive autonomy--issues that will be similarly relevant to men and male partners when a male option becomes available. The choice of their regular doctor or PCP as men’s preferred HMC provider will require an effort to not only expand insurance coverage for men to include contraception among preventive health services, but also re-emphasize the role of PCPs in screening for and managing men’s sexual and reproductive health needs at annual physical examinations [30]. Future studies should survey primary care providers about their preparedness for and attitudes towards providing male contraceptives. While men should not be required to obtain routine health examinations to obtain male contraception, HMCs may encourage men to access preventive care services at an earlier age and stimulate a paradigm shift in men’s healthcare. Should the development of HMCs mirror that of female

contraception, HMCs may encourage men to access preventive care services at an earlier age and stimulate a needed paradigm shift in men's healthcare. With many men also preferring pharmacists as prescribers, development efforts following initial widespread HMC approval should consider a role for direct provision from pharmacists [21]. While men within our study had an overwhelming preference for PCPs as their HMC provider, ensuring the education and engagement of a wide range of providers will be just as important as the development of a wide range of male contraceptive methods.

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APPENDIX A.: Relevant section of acceptability questionnaire used for 11β-MNTDC oral hormonal male contraceptive pill trial

FUTURE INSIGHTS: The next questions ask about your preferences for male birth control in the future.

Please rank your top THREE choices from 1 (most preferred) to 3 (less preferred).

1. If the following **MALE BIRTH CONTROL METHODS** were available, which **THREE** would you prefer to use? **Write 1 (most preferred) to 3 (less preferred).**

_____ Daily pills by mouth
_____ Daily gel applied to the skin
_____ Monthly injections
_____ Three month injections
_____ Yearly injections
_____ Vasectomy or sterilization
_____ **Does not apply** (no need for birth control, no sexual partner, or no female sexual partner

2. **WHERE** would you prefer to go or **WHO** would you prefer to see for the male birth control pill? Please select **THREE** options and rank them from **1 (most preferred) to 3 (less preferred).**

_____ Men's health doctor (Urologist, Andrologist)
_____ Hormonal doctor (Endocrinologist)
_____ Reproductive health doctor (Ob/Gyn, Family Med)
_____ Family planning clinic (Community health worker, Midwife, NP)
_____ Your regular doctor (Family medicine, Internal medicine)
_____ Community pharmacist
_____ **Does not apply** (no need for birth control, no sexual partner, or no female sexual partner)

3. Did you ever **WISH YOU HAD NOT** participated in the trial? How often did you think about it?
☐ Never ☐ Rarely ☐ Sometimes ☐ Very often ☐ Always

4. If you ever wished that you had not participated in the trial, **WHY**?

_____

_____

5. What are some things **YOU WOULD LIKE TO CHANGE** about the pill?

_____

_____

_____

APPENDIX B.: Relevant section of acceptability questionnaire used for DMAU hormonal male contraceptive injectable trial

FUTURE INSIGHTS: The next questions ask about your preferences for male birth control in the future.

Please rank your top THREE choices from 1 (most preferred) to 3 (less preferred).

1. If the following **MALE BIRTH CONTROL METHODS** were available, which **THREE** would you prefer to use? **Write 1 (most preferred) to 3 (less preferred).**

_____ Daily pills by mouth
_____ Daily gel applied to the skin
_____ Monthly injections
_____ Three month injections
_____ Yearly injections
_____ Vasectomy or sterilization
☐ **Does not apply** (no need for birth control, no sexual partner, or no female sexual partner)

2. **WHERE** would you prefer to go or **WHO** would you prefer to see for the male birth control injection?
Please select **THREE** options and rank them from **1 (most preferred) to 3 (less preferred).**

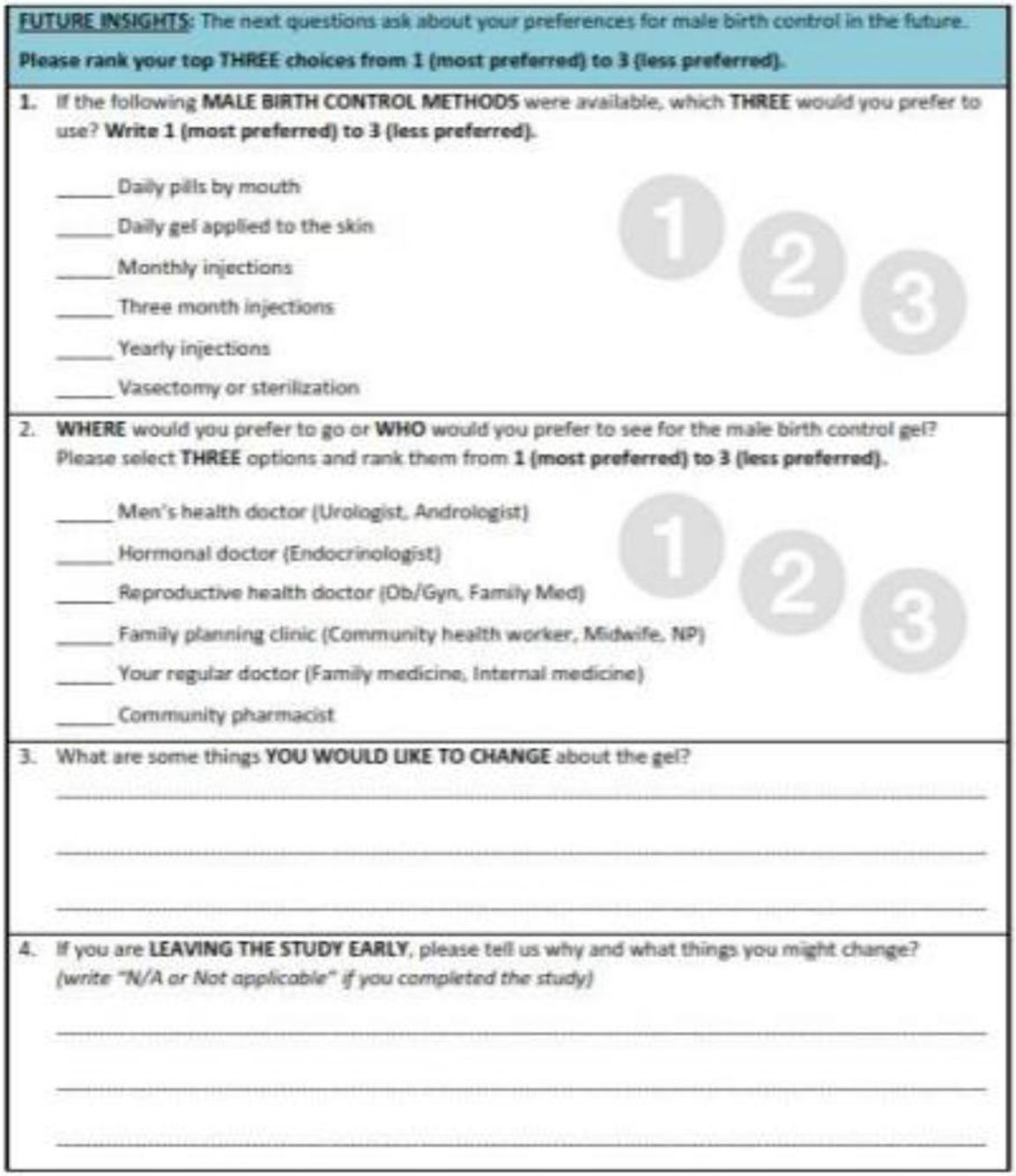
_____ Men's health doctor (Urologist, Andrologist)
_____ Hormonal doctor (Endocrinologist)
_____ Reproductive health doctor (Ob/Gyn, Family Med)
_____ Family planning clinic (Community health worker, Midwife, NP)
_____ Your regular doctor (Family medicine, Internal medicine)
_____ Community pharmacist
☐ **Does not apply** (no need for birth control, no sexual partner, or no female sexual partner)

3. Did you ever **WISH YOU HAD NOT** participated in the trial? How often did you think about it?
☐ Never ☐ Rarely ☐ Sometimes ☐ Very often ☐ Always

4. If you ever wished that you had not participated in the trial, **WHY**?

_____
_____
_____
_____

APPENDIX C.: Relevant section of acceptability questionnaire used for the Nestorone/Testosterone transdermal hormonal male contraceptive gel trial



FUTURE INSIGHTS: The next questions ask about your preferences for male birth control in the future.

Please rank your top THREE choices from 1 (most preferred) to 3 (less preferred).

1. If the following **MALE BIRTH CONTROL METHODS** were available, which **THREE** would you prefer to use? **Write 1 (most preferred) to 3 (less preferred).**

_____ Daily pills by mouth
_____ Daily gel applied to the skin
_____ Monthly injections
_____ Three month injections
_____ Yearly injections
_____ Vasectomy or sterilization

2. **WHERE** would you prefer to go or **WHO** would you prefer to see for the male birth control gel? Please select **THREE** options and rank them from **1 (most preferred) to 3 (less preferred).**

_____ Men's health doctor (Urologist, Andrologist)
_____ Hormonal doctor (Endocrinologist)
_____ Reproductive health doctor (Ob/Gyn, Family Med)
_____ Family planning clinic (Community health worker, Midwife, NP)
_____ Your regular doctor (Family medicine, Internal medicine)
_____ Community pharmacist

3. What are some things **YOU WOULD LIKE TO CHANGE** about the gel?

_____
_____
_____

4. If you are **LEAVING THE STUDY EARLY**, please tell us why and what things you might change? *(write "N/A or Not applicable" if you completed the study)*

_____
_____
_____

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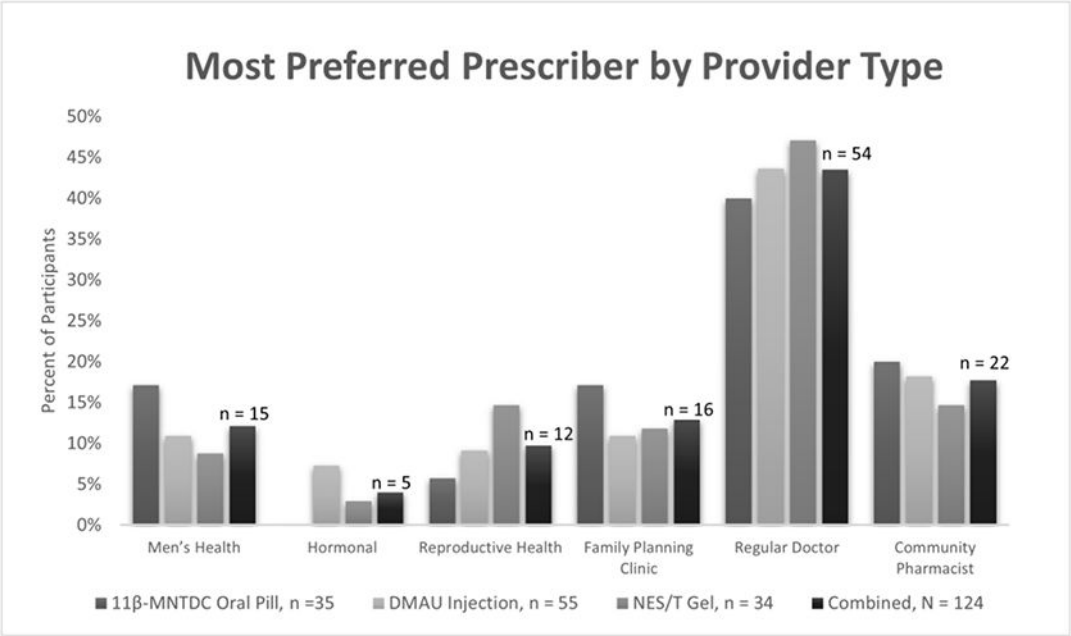
Implications:

As most men expect to obtain hormonal male contraceptives from their regular doctor when commercially available, primary care physicians should become familiar with hormonal male contraception and be prepared to provide counseling and options accordingly.



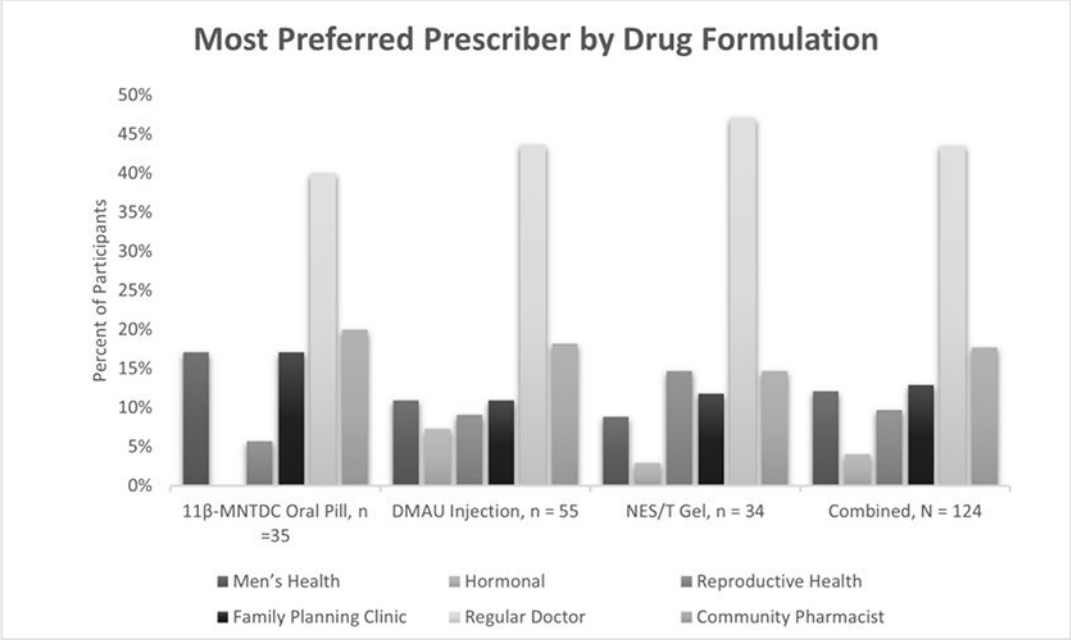


Figure 1: Most preferred hormonal male contraceptive prescriber by provider type and trial drug formulation, N=124

Top: Percentage of participants reporting preference for each provider type, by drug formulation; n=total number of participants reporting preference for the given provider across all drug formulations combined. Bottom: Percentage of participants reporting preference for various providers from each clinical trial, by provider type

Table 1:

Preference for hormonal male contraceptive provider across participants

All Subjects	Men's health specialist, n (%)	Hormonal specialist, n (%)	Reproductive health specialist, n (%)	Family planning clinician, n (%)	Regular doctor, n (%)	Pharmacist, n (%)	p
Most preferred provider N=124 *	15 (12.1)	5 (4.0)	12 (9.7)	16 (12.9)	54 (43.5)	22 (17.7)	**<0.01**
Weighted provider preference N=741 +	120 (16.2)	56 (7.6)	85 (12.8)	117 (15.7)	243 (32.8)	120 (16.1)	**<0.01**

*Total number of participants;

+Total weighted preference score where 1st preference = 3 points, 2nd = 2 points, 3rd = 1 point, and remainder = no points; total of 741 possible points

Table 2.

Participant demographic characteristics by 1st preference provider

Question	Specialist n=48	Regular Doctor n=54	Pharmacist n=22
Age *			
Mean	31.8	28.1	30.7
Race/Ethnicity, n (%)			
Non-Hispanic Asian	7 (38.89)	6 (33.3)	5 (27.8)
Non-Hispanic Black	9 (47.4)	6 (31.6)	4 (21.1)
Non-Hispanic White	18 (54.6)	12 (36.4)	3 (9.09)
Hispanic	12 (25.0)	26 (54.2)	10 (20.8)
Other/Multiracial	2 (33.3)	4 (66.7)	0 (0.0)
Marital Status, n (%)			
Never Married	32 (36.4)	41 (46.6)	15 (17.1)
Married	13 (43.3)	12 (40.0)	5 (16.7)
Divorced	3 (50.0)	1 (1.9)	2 (9.1)
Education Level, n (%) *			
High school grad or less	8 (53.3)	3 (13.3)	5 (33.3)
Some college, no degree	5 (22.7)	13 (59.1)	4 (18.2)
College graduate	27 (45.8)	27 (45.8)	5 (8.5)
Graduate degree	7 (25.9)	12 (44.4)	8 (29.6)

* $p<0.05$