Exploring the Non-Hormonal and On-Demand Contraceptives Value Propositions: Perspectives from End Users, Private Sector Healthcare Providers, and Stakeholders in Kenya and Uganda

Background

More than 230 million women in low- and middle-income (LMIC) countries still have an unmet need for modern contraceptives [1]. While supply side challenges continue to constrain uptake of modern contraceptives in many settings, several demand-side barriers also contribute to unmet need. Infrequent sex is among the largest drivers of contraceptive non-use, and the current range of contraceptive options are not meeting these women and girls' needs [2]. This is especially true for youth, adolescents, unmarried women, and those in long-distance partnerships. For other women, the hormonal profile, side effects, and dosing schedules of many contraceptives available on the market are barriers to initial adoption, adherence, or continuation of these methods. On-demand (defined as products taken either right before or after sex) and non-hormonal oral contraceptive pills represent new options in the product development pipeline. These new options have the potential to increase choice for the significant proportion of women who have current unmet need, particularly those who have infrequent sex or who prefer or require a non-hormonal method [3].

The on-demand pill, a Levonorgestrel (LNG1.5)-containing pill like the LNG emergency contraceptive pill (ECP) product currently on the market globally (including in Uganda and Kenya), is currently in the product development pipeline. It would represent one of the few woman-controlled, on-demand contraceptive products on the market. Though not yet through clinical trials, the on-demand pill would be intended to be taken as a single pill peri-coitally, either just before or within a defined period after sex (in comparison, the currently available LNG1.5 ECP is designed as a one or two pill regimen that should to be taken within 120 hours following unprotected sex) [4]. Non-hormonal contraceptive pills, such as Ormeloxifene, which has been in use in India since the early 1990s, are also under consideration for introduction in Uganda and Kenya.

Preliminary evidence has shown acceptability of on-demand and non-hormonal contraceptives among users [5,6]. However, little is known about end-user and provider perspectives on these new contraceptive options in Uganda and Kenya. While data from a variety of LMIC settings suggest that a segment of women are already using ECPs routinely or repeatedly as their main form of contraception, less is known about how common this "regular" use of ECP is; what the value proposition of a non-emergency, on-demand pill or non-hormonal pills might be for women and providers; and their perceptions and preferences for the range of product options that could be made available [7]. These perspectives are vital in informing the regulatory pathway donors, manufacturers, and other stakeholders involved in the process should pursue.

This research aims to lay the groundwork for bringing new contraceptive products, including the on-demand and non-hormonal contraceptive pills, to market in Kenya and Uganda.

Objectives

The primary objectives of this study are to explore the acceptability of on-demand and non-hormonal contraceptives among private sector providers and user preferences for on-demand and weekly non-hormonal products among adult women.

Aim 1: To understand motivators and barriers and support required for private healthcare providers (HCPs) to consider stocking/selling the LNG 1.5 on-demand/pericoital contraceptive pill or non-hormonal contraceptive pills.

Aim 2: To understand the benefits, challenges, and preferences for the on-demand pill and non-hormonal pills, including product naming and framing, perspectives on a standalone vs. EC+ on-demand pill, and stated preferences for product attributes including dosing schedule, side effects, and benefits, among potential end-users.

Methods

This is a mixed methods study conducted in Kenya and Uganda using semi-structured in-depth interviews (IDIs) and online surveys. The study was conducted in two urban sites (Nairobi & Nakuru) and a rural/peri-urban site (Kilifi) in Kenya and in one urban site (Kampala) and two peri-urban sites (Mbarara and Jinja) in Uganda. IDI participants (private sector providers and potential end users) were recruited from pharmacies and private health facilities affiliated with Maisha Meds, a health and technology organization. Facilities were purposively chosen based on ECP sales volumes during the previous year ("high" or "low/moderate" relative to country averages) to ensure representation of both high and low volume settings. E-survey participants (potential end users) were recruited through PSI's existing social media accounts as well as social media advertisements. Providers were eligible if they were currently employed at a selected facility, provided family planning services, and belonged to a selected provider cadre (pharmacist, nurse, nurse practitioner, clinical associate, general practitioner, or obstetrician gynecologist). Potential end users were eligible if they were female, of reproductive age (18 to 45 years old), were not currently or intending to become pregnant, were not currently using a long-acting modern contraceptive method, and had been sexual active in the prior year. All participants were 18 years or older.

Results

Data collection is currently underway, with full results expected by November 2024. The below presents preliminary findings from the Kenya end user (WRA) IDIs and e-survey.

Participant characteristics

Our Kenya sample included 48 end user IDIs and 356 end user e-surveys. Regarding the e-survey sample, the median age was 24 (IQR = 21, 26), most participants were married or in a relationship (67%, n=238), and most had never been pregnant (63%, n=223). Almost all participants had completed at least secondary school (98%, n=348), and the majority were unemployed (57%, n=202). The most common trusted sources of family planning information were medical providers (29%, n=103), the internet (21%, n=76), and friends (13%, n=47).

Family planning and emergency contraceptive (EC) use

Almost all participants reported ever use of modern contraceptives, with male condoms (56% ever using, n=201), ECs (47%, n=167), and oral contraceptive pills (41%, n=147) being the most

common. EC users reported a median of four lifetime uses (IQR = 2, 7), and two uses in the last year (IQR = 1, 4). Most EC users reported obtaining it from a pharmacy (79%, n=281) or drug shop (7%, n=23), and most (82%, n=220) reported ECs as being "somewhat" or "very" affordable. Interestingly, while most participants "somewhat" or "strongly" agreed that ECs are the main way they delay or prevent pregnancy (72%, n=205), the vast majority said that ECs should only be taken for emergencies and not as a regular contraceptive method (92%, n=324).

Most participants "somewhat" or "strongly" agreed that they don't have sex regularly enough to use other contraceptive methods (56%, n=198); that ECs are more affordable than other contraceptive methods (55%, n=196); that EC are easier to access than other methods (64%, n=228); that ECs are more private or discreet than other methods (68%, n=243); and that they face less stigma when accessing ECs compared to other methods (61%, n=217). However, just under half said ECs had fewer side effects than other methods (49%, n=171), while 16% (n=56) said they "strongly disagree" with the statement. Additionally, the majority "somewhat" or "strongly" agreed with the statement that taking emergency contraceptive pills too often may impact their ability to get pregnant in the future (66%, n=233), and the majority "somewhat" or "strongly" disagreed with the statement that EC pills are safe to take multiple times a month (65%, n=23).

<u>New on-demand product</u>

Participants were asked how likely they would be to take a new on-demand contraceptive pill that had the same medication as current EC pills, could be taken either right before or up to 24 hours after sex to prevent pregnancy, and could be used as a regular form of contraception (using it up to four times per month). The majority said they would be very likely (53%, n=169) or somewhat likely (33%, n=106) to use the product, with only 14% (n=41) saying they would be unlikely to use it.

Interest in a new on-demand product was further explored in the end user IDIs. Commonly cited potential advantages of an on-demand pill were ease of use (compared to, for example, injectable contraceptives); flexibility to use it before or after sex; discreetness of use; and flexibility to use it based on need, particularly for participants who engage in sex less frequently:

> *"[The new on-demand product] is not bad because for us whose husbands travel, he might pass by today, so I can take one and when he comes four times in the same month it will be okay, unlike taking [standard ECs] severally – that has effects." (WRA, Kenya)*

Common disadvantages included potential side effects and hormonal imbalance, short time windows for use, and people not understanding what "on-demand" and "peri-coital" mean in reference to contraceptives. Several respondents said they would need additional information on side effect profiles and availability in order to make an informed decision, with a few respondents also wanting to know more about costs and method efficacy.

Preferences were mixed when respondents were asked to pick between two potential new products: 1) a product with a new name and different label (but same medication as current ECs) which could be used up to 24 hours before or after sex; or 2) a relabeling current ECs as "EC+"

with the same window of use as current ECs (up to 120 hours after sex) but which would be promoted as a regular form of contraception for use up to four times per month. Some participants preferred the flexibility of the first option due to being able to use the product before or after sex, while others preferred the longer use window (120 hours versus 24) of the second option.

The first option was seen to potentially be more discreet, with one participant noting that:

> *"[T]he name would not be described as for emergency. You know even men know the name of these pills, so if the name is hidden, it's something that when you buy nobody will know, and you said the packaging will be different. The name description will be different. Yeah, so that's why I said option one. (WRA, Kenya)"*

Non-hormonal contraceptives

The e-survey and IDIs also explored perceptions of and interest in non-hormonal contraceptive products. Most EC users said they "strongly" or "somewhat" agreed with the statement that they do not like being exposed to hormones every day (76%, n=270) as might be the case if they took other contraceptive methods. In the IDIs, a number of respondents identified side effects, including irregular menstruation, headaches, impacts on libido and fertility, and hormonal imbalances, as primary disadvantages of hormonal contraceptives. When asked if they would prefer to take hormonal or non-hormonal contraceptives, most who chose non-hormonal contraceptives cited side effects as influencing their decision, with one participant noting that non-hormonal contraceptives "will not bring any changes in the body" (WRA, Kenya).

Conclusion

Our study adds to the evidence base showing both high acceptability of and routine use of ECs, with ECs being the second-most common form of contraceptive used by our sample. The majority of respondents reported that ECs are affordable, accessible, easy to use, and discreet. Most respondents reported infrequent sexual activity as a motivation for EC use. However, in line with EC use guidelines, most respondents agreed the ECs should not be used as a routine form of contraception. These findings suggest that a new Levonorgestrel (LNG1.5)-containing on-demand pill would be feasible, acceptable, and usable and would address users' contraceptive needs and preferences vis-à-vis flexible and discreet use. The vast majority of respondents indicated that they would be likely to try such a product.

Contraceptive side effects, including those associated with ECs, were a common concern among participants, and our findings suggest they play an important role in decision making regarding contraceptive choice and use. This suggests that non-hormonal contraceptive pills may address user concerns and fill a gap in the existing method mix.

References

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