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Estimating the market size for a dual prevention pill: adding contraception to pre-exposure prophylaxis (PrEP) to increase uptake

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ABSTRACT

Introduction Uptake of oral pre-exposure prophylaxis (PrEP) remains low. The objective of this analysis was to estimate the potential market size in priority sub-Saharan African countries for a 28-day dual prevention pill (DPP) regimen containing the active pharmaceutical ingredients in oral PrEP and oral contraceptive pills (OCPs) for the prevention of HIV and unintended pregnancy.

Methods We selected 15 countries in sub-Saharan Africa for analysis. Population estimates were based on United Nations Population Division data from 2017. Low, medium and high rates (range 0.25% to 25%) of estimated conversion from current contraceptive method to the DPP were applied by country based on HIV prevalence ($\geq 10\%$ vs $< 10\%$), current contraceptive method (OCP, condom or unmet need for contraception) and age group (15–24 or 25–49 years).

Results In these 15 countries, between 250 000 and 1.25 million women could switch from their current contraceptive method to the DPP. Given that current PrEP use in the 15 countries combined is estimated to be 113 250 (women and men), the most conservative market size estimate would more than double the number of women currently using PrEP.

Conclusions By leveraging the existing market for OCPs and assuming modest conversion from condom users and women with an unmet need for contraception, the DPP could lead to a 2- to 10-fold increase in PrEP usage in these 15 sub-Saharan African countries, expanding the broader public health benefit of this proven HIV prevention strategy.

INTRODUCTION

Oral pre-exposure prophylaxis (PrEP) is a highly effective method of HIV

Key messages

- ▶ The Population Council is developing a dual prevention (DPP) pill regimen by co-formulating a tablet combining emtricitabine and tenofovir disoproxil fumarate, approved for pre-exposure prophylaxis (PrEP) in sub-Saharan Africa, and generic oral contraceptive pills containing levonorgestrel and ethinylestradiol for the prevention of HIV and pregnancy.
- ▶ A DPP will likely increase uptake of PrEP.
- ▶ There is a significant potential market for such a product in the 15 sub-Saharan African countries evaluated, suggestive of a large global market.

prevention, yet uptake of and adherence to PrEP in high-risk countries remains low.^{1 2} This is especially true among adolescent girls and young women, who account for two-thirds of new HIV infections in sub-Saharan Africa.³ Clinical studies, market research and acceptability studies suggest women would prefer an HIV prevention method that also prevents unintended pregnancy.^{4–9} Therefore, combining a contraceptive with HIV prevention could increase uptake of PrEP among women.

Currently, the only available modern multipurpose prevention technology (MPT) that is protective against both pregnancy and HIV is the condom. Condoms are not an ideal MPT because they are male controlled (or require a man's acceptance in the case of the female condom), non-discreet (meaning both partners know it is in use) and have a 13% contraceptive failure rate with typical use.^{10–12} Several products are currently under



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development to address the need for a new contraceptive MPT, including intravaginal rings, micro-array patches and implants; however, most are a decade or more away from market launch.¹³ A dual prevention pill (DPP) regimen, which combines two marketed and approved products, is likely to be the fastest pathway to contraceptive MPT introduction.¹⁴ The Population Council is developing a DPP regimen by co-formulating a tablet combining emtricitabine and tenofovir disoproxil fumarate, the active pharmaceutical ingredients in oral PrEP approved for use in sub-Saharan Africa, and generic oral contraceptive pills (OCPs) containing levonorgestrel and ethinylestradiol.¹⁵ This DPP regimen would require a relatively simple development plan, as a bioequivalence study should be sufficient for product approval. The DPP has the potential to reach the market by 2024, far earlier than any other contraceptive MPT currently under development.

An estimate of the market size is important for generating support among stakeholders, including donors, commercial partners and programme implementors, and for informing the development process to ensure production capacity meets the market demand for the product. The objective of this study was to estimate a baseline market size in select sub-Saharan African countries for a 28-day OCP regimen that also provides PrEP to women at risk for HIV. The key assumption underlying this analysis was that current OCP users would be the earliest adopters of the DPP.

METHODOLOGY

Data sources

Two publicly available data sources were used to assess the market size for the DPP; Demographic and Health Surveys (DHS) data on current contraceptive method use and United Nations Population Division 2017 estimates for total population by broad age groups.^{16 17} The United Nations Population Division data were accessed in February 2019. At that time, the most recent population estimates available were the 2017 revisions. Since DHS data from Nigeria do not include HIV information, HIV prevalence for Nigeria was supplemented by Joint United Nations Programme on HIV and AIDS (UNAIDS) data.¹⁸

Patient and public involvement

No patients were involved in this analysis.

Target population

The population in this market analysis included all HIV-negative women of reproductive age (15–49 years) in countries with HIV prevalence among women above 3% who were current OCP users, male condom users or women with an unmet need for contraception (defined as women who do not want to become pregnant but are not using contraception). Countries included with HIV prevalence among women of reproductive age greater than or equal to 10% were:

Lesotho, Malawi, Mozambique, Namibia, South Africa, Zambia and Zimbabwe. Countries included with HIV prevalence among women of reproductive age under 10% but greater than 3% were: Cameroon, Congo, Cote d'Ivoire, Kenya, Nigeria, Rwanda, Tanzania and Uganda.

In order to calculate the total number of women using each method, we multiplied percentages of women who were OCP users, male condom users or had an unmet need for contraception by the total population of women living in each country aged 15–24 or 25–49 years.^{16 17} The population of women living with HIV was uniformly calculated and removed, assuming relatively equal distribution of women living with HIV across the method mix, as research suggests there is no significant difference in contraceptive method selection by HIV status.¹⁹

Conversion rates

The term 'conversion rate' is defined as the estimated percentage of women who may switch from their current contraceptive method to the DPP. There is limited published, publicly available literature on how to calculate appropriate conversion rates for low- and middle-income country contraceptive markets. We created a wide range of high-, mid- and low-range estimates to account for this level of uncertainty (table 1). Our assumptions included applying different conversion rates by country based on HIV prevalence, contraceptive method and age group. We defined 'high HIV prevalence' as countries with HIV prevalence above 10%, as it fell within the UNAIDS definition of 'high' prevalence.²⁰ Although UNAIDS considers countries with HIV prevalence greater than 5% as high-burden, we conservatively raised this cut-off to 10%, as it played a major role in the conversion rates we applied by country.

The highest conversion rate used in countries with high HIV prevalence was 25%, applied only to adolescent girls and young women currently using OCPs. The highest conversion rate used in countries with lower HIV prevalence was 12.5%, applied only to adolescent girls and young women currently using OCPs. Both of these rates were used only in the most ambitious, or high-range, conversion scenario. We used more conservative rates to generate the low- and mid-range market estimates. Our decision to use higher conversion estimates for countries with a significant HIV burden (prevalence above 10%) was based on our assumption that interest may be greater in these countries due to perceived HIV risk, and more resources and funding may be available to be directed towards promoting the DPP as an option to women.

Contraceptive use

We applied conversion rates to current OCP users, male condom users and women with an unmet need for contraception. Current OCP users were included

Table 1 Estimated conversion rates

Total HIV-negative population	Low-range conversion		Mid-range conversion		High-range conversion	
	15–24	25–49	15–24	25–49	15–24	25–49
HIV prevalence <10%						
Age group (years)	15–24	25–49	15–24	25–49	15–24	25–49
HIV-negative oral contraceptive pill users	2.5%	1%	5%	2.5%	12.5%	6%
HIV-negative male condom users	1%	0.5%	2.5%	1%	5%	2.5%
HIV-negative women with an unmet need for family planning	0.5%	0.25%	1%	0.5%	2.5%	1.5%
HIV prevalence ≥10%						
Age group (years)	15–24	25–49	15–24	25–49	15–24	25–49
HIV-negative oral contraceptive pill users	5%	2.5%	10%	5%	25%	12.5%
HIV-negative male condom users	2.5%	1%	5%	2.5%	12.5%	6%
HIV-negative women with an unmet need for family planning	1.5%	0.75%	2.5%	1.25%	6%	2.5%

as they are likely to be the quickest adopters of the DPP, as the transition will not require a behaviour change and will provide the added benefit of HIV prevention. Women who report their primary method of contraception as the male condom were included based on their potential interest in a new dual protective method. Finally, women with an unmet need for contraception were included as they may be enticed to uptake this new contraceptive product with added benefit, and providers will likely be motivated to encourage women with an unmet need to try a new method with added HIV protection.

We assigned current OCP users the highest conversion rates because they are likely to be the earliest adopters of the DPP based on their demonstrated interest in a daily pill regimen. This assumption is strengthened by the findings of the TRIO placebo MPT acceptability study among young Kenyan and South African women, which found that women were more likely to select an MPT in oral tablet form over other dual prevention formulations if they were familiar with a daily pill regimen.⁶

Women who report using male condoms as their primary method of contraception may be interested in converting to the DPP based on the added benefits of the DPP being in a woman's control and its lack of interference during sex. Further, condoms have a high discontinuation rate and women may be inclined to switch to a new method.²¹ Since this conversion requires a behaviour change from a coitally dependent barrier method to a daily pill, we applied 50% lower conversion rates to condom users than OCP users.

We assigned the lowest conversion rates to women with an unmet need for contraception because these women have a diverse set of reasons why they are not using contraception and it is unclear if the DPP would appeal to them.

Age groups

We applied the highest conversion rates to adolescent girls and young women (aged 15–24 years) because

they have the highest HIV incidence and are a high priority target for PrEP roll-out.²² Young women in sub-Saharan Africa also use short-acting methods, predominantly condoms, pills and injectables, at higher rates than long-acting methods like intrauterine devices or implants.²³ The market strategy for the DPP will likely be aimed at adolescent girls and young women, given their heightened HIV risk, with targeted counselling and demand creation activities. The conversion rates we used for women aged 25–49 years were roughly 50% lower than the conversion rates we applied to adolescent girls and young women given their lower HIV risk.

RESULTS

The total number of HIV-negative OCP users, condom users and women with an unmet need, as well as the HIV prevalence and conversion estimates by country, can be found in [table 2](#). The countries with the largest number of potential new users of the DPP according to our analysis were South Africa, Nigeria and Zimbabwe. According to PrEP Watch data among our 15 countries, the most successful PrEP roll-out has been in Kenya, South Africa and Uganda.²⁴

In these 15 countries alone, there are roughly 5.4 million HIV-negative OCP users, of whom 1.27 million are adolescent girls and young women.^{16 17} When reviewing the three most recent DHS results for each country, we found only four of our 15 countries (Namibia, South Africa (only two available DHS surveys, from 1998 and 2016), Tanzania and Uganda) demonstrated a decline in the percentage of women using OCPs, with all other countries either holding steady or increasing the percentage of women using OCPs.¹⁶ The countries with the largest populations of female OCP users are Zimbabwe, Nigeria and Kenya.

The calculated low-, mid- and high-range market size estimates for each population of HIV-negative women by broad age group (15–24 or 25–49 years) can be found in [table 3](#). By the most conservative

Table 2 Country estimates of HIV prevalence, population by contraceptive method, and dual prevention pill uptake

Country	HIV prevalence among women aged 15–49 years*	Total female population of HIV-negative oral contraceptive pill users (000s)	Total female population of HIV-negative condom users (000s)	Total population of HIV-negative women with an unmet need for family planning (000s)	Conversion range estimates (000s)		
					Low-range	Mid-range	High-range
HIV prevalence among women <10%							
Cameroon	5.6	82	553	896	8.5	18.8	44.4
Congo	4.1	29	175	161	2.3	5.2	12.1
Cote d'Ivoire	4.6	314	257	1210	11.1	24.2	59.4
Kenya	8.0	601	339	1398	14.7	32.7	81.0
Nigeria	3.0†	762	1805	5095	41.0	89.9	219.8
Rwanda	3.6	132	62	354	3.0	6.6	16.8
Tanzania	6.2	481	457	1971	16.4	35.8	89.1
Uganda	8.3	125	258	1695	9.5	20.3	51.3
HIV prevalence among women ≥10%							
Lesotho	29.7	37	77	51	3.0	6.1	14.8
Malawi	10.8	63	97	562	9.8	17.8	41.8
Mozambique	15.4	350	222	1049	28.2	53.0	127.6
Namibia	16.9	24	103	63	3.2	6.4	15.6
South Africa	27.3	546	1278	1300	49.7	99.1	239.5
Zambia	14.2	260	114	542	15.4	29.3	70.6
Zimbabwe	16.7	922	143	270	34.1	67.9	168.1
Conversions among all HIV-negative women aged 15–49 years (000s)					250	513	1252

*The Demographic and Health Surveys (DHS) Programme STATcompiler. Funded by USAID. Accessed 10 February 2019. <http://www.statcompiler.com>.

†Nigeria. UNAIDS data. Accessed 6 February 2019. <https://www.unaids.org/en/regionscountries/countries/nigeria>.

estimate, ranging from 0.25% to 5% conversion across subpopulations, 250 000 women in 15 sub-Saharan countries might switch to using the DPP regimen. By the mid-range conversion estimate, ranging from 0.5% to 10% conversion across subpopulations, 513 000 women might switch to using the DPP regimen. Finally, by the high-range conversion estimate, ranging from 1.5% to 25% conversion across subpopulations, 1.25 million women might switch to using the DPP regimen. These results represent a potential market for the DPP, which will require robust multi-year demand creation and training activities to achieve.

DISCUSSION

By leveraging the existing market for OCPs and assuming modest conversion from condom users and

women with an unmet need for contraception, the DPP could significantly increase the number of women using PrEP in sub-Saharan Africa. Given that current PrEP use in the 15 countries combined is estimated to be 113 250 women and men,²⁴ the most conservative low-range conversion estimate of 250 000 women would more than double the number of women using PrEP.

The efficacy of PrEP is dependent on adherence to the daily pill regimen. Trials of PrEP among women, such as the FemPREP and VOICE trials, demonstrated low adherence among women, resulting in low efficacy of PrEP.^{4 25 26} A dual protective method could improve motivation among users by simultaneously addressing multiple health needs.⁶ In a study of MPT acceptability in Malawi and Zimbabwe, women indicated

Table 3 Estimates of dual prevention pill uptake by method

HIV-negative female population	Low-range conversion (000s)		Mid-range conversion (000s)		High-range conversion (000s)	
	15–24	25–49	15–24	25–49	15–24	25–49
Age group (years)						
Oral contraceptive pill users	45	59	89	129	223	317
Male condom users	41	21	93	49	206	119
Women with an unmet need for family planning	46	38	84	70	205	183
All HIV-negative women aged 15–49 years (000s)	250		513		1252	

if they could protect themselves against unintended pregnancy and HIV simultaneously, without requiring the inclusion of their male partners, both acceptability and adherence would improve.²⁷ This suggests that the typical-use efficacy of both methods individually will be lower than the efficacy of the methods combined, a secondary and important benefit of this combined product.

Poor PrEP adherence has been associated with stigma around perceived fears of being seen as promiscuous or HIV-positive, as well as fear of disapproval from family members and sex partners.^{28 29} The DPP regimen has the potential to overcome adherence challenges related to PrEP stigma because it would also be a contraceptive.² Multiple studies have demonstrated women report greater ease negotiating contraceptive use with their male partners over HIV prevention, which can be seen as a source of distrust.^{14 27} With the DPP, women would have the option to only disclose the pill's contraceptive benefit to their male partners, thereby avoiding or downplaying the stigma associated with HIV prevention.

Perception of low risk for HIV acquisition has also been cited as a reason for limited uptake of and adherence to PrEP.^{2 26 28} By contrast, contraceptives are more widely used and valued among women due to high perceived, and actual, risk for unintended pregnancy.⁸ Marketing the DPP as a contraceptive with the added benefit of HIV protection could aid to alleviate risk perception-related barriers to PrEP uptake, supported by findings that women are more interested in a dual prevention method over PrEP alone.⁸

The current status of PrEP adoption displays wide variation by country.²⁴ These wide variations illuminate the challenges associated with HIV prevention product roll-out, such as risk perception, stigma, and the importance of product champions. Donor investments and government support play a critical role regarding achieving market size, especially for adolescent girls and young women. Although the successful PrEP roll-out in countries like Kenya, South Africa and Uganda may be associated with better DPP uptake in these countries, there are key differences between PrEP and the DPP that will likely differentiate the latter's market uptake from that of PrEP.²⁴ The roll-out of the DPP will ideally bypass the challenges of stigma and risk perception associated with PrEP since it will be positioned as a new contraceptive method with added benefit, not primarily as an HIV prevention product; this positioning may help avoid the barriers associated with PrEP roll-out.

This analysis has several limitations. First, there is a high level of uncertainty around creating conversion rates, as there is little existing, publicly available literature on contraceptive market uptake in low- and middle-income countries. One other study employed a similar strategy to estimate the market size for the Sayana Press, making various assumptions and using a

range of low-, mid- and high-range estimates to account for uncertainty.³⁰ Second, the analysis was limited to only 15 countries in sub-Saharan Africa; further investigation is required to understand the global market for the DPP, including countries in Eastern Europe and populous countries in Asia, such as India, that have high HIV incidence among certain groups. Third, we may have underestimated the market by assuming zero conversions from long-acting reversible contraceptive (LARC) users. While there may be potential interest in the DPP among LARC users, we conservatively assumed that with a shared decision-making approach users would likely initiate PrEP for HIV prevention rather than transition to the DPP in order to continue their chosen formulation and the benefits of their current long-acting method. Furthermore, women using long-acting methods have lower rates of discontinuation and therefore may be less likely to convert to the DPP.²¹ However, this assumption should be reassessed when the DPP becomes available. Fourth, this analysis did not incorporate patient access, regulatory requirements, distribution networks, procurement, discontinuation rates, licensing or branding options to define the multi-year uptake timeline before achieving market size. Finally, the size and packaging of the DPP will be an important factor regarding women's uptake and must be evaluated for acceptability, as it will look different than the standard OCPs in terms of pill size and packaging. The product package must be believable as an oral contraceptive to avoid stigma. Despite these limitations, this analysis was an important first step toward understanding the market potential of the DPP and the potential impact on increasing PrEP uptake.

CONCLUSIONS

Several formulations of multipurpose prevention technologies are under development, including long-acting implants. However, the DPP is likely the fastest pathway to contraceptive MPT introduction.¹⁴ While longer-acting PrEP formulations may overcome adherence barriers, many women desire short-acting user-controlled formulations, especially women who desire to conceive in the near future.³¹ Furthermore, despite the increasing number of options for effective contraception, OCPs have remained an important method of family planning with a significant market share globally, including in high HIV prevalence countries.¹⁶ Therefore, the potential global market for a DPP is likely larger than what was found in this analysis and will likely be sustained with the introduction of alternative combined HIV and pregnancy prevention technologies. Additional research is needed to explore demand in other settings and plan for a market introduction strategy. Further investment will be essential to meet the many product development requirements necessary for successful product launch. The DPP regimen would increase women's choice within

the contraceptive method mix, an important goal for achieving improved sexual and reproductive health outcomes worldwide.

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