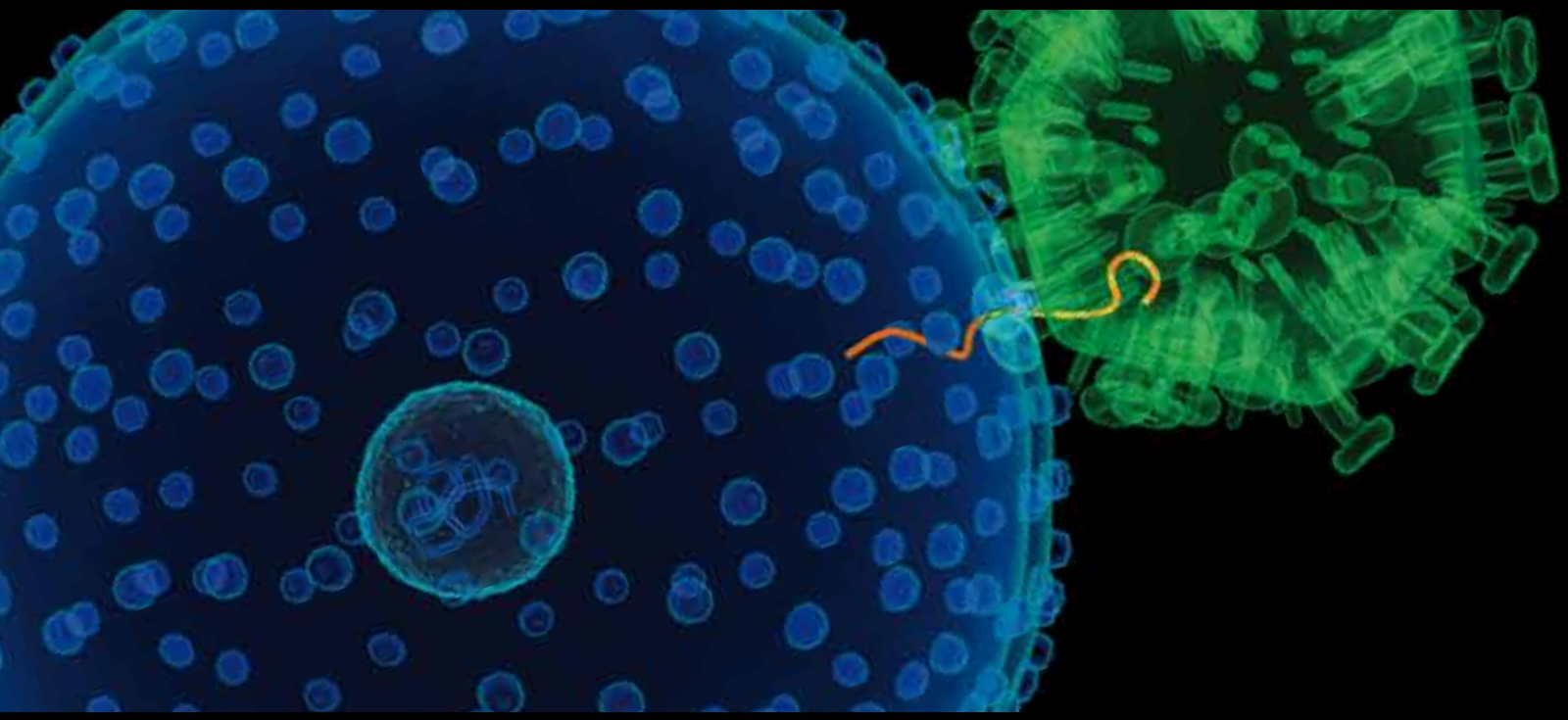
AIDS Research and Treatment

Intersection of HIV and Reproductive Health

Guest Editors: Craig R. Cohen, Elizabeth Bukusi, Helen Rees, and Kelly Blanchard



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Editorial

Intersection of HIV and Reproductive Health

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The HIV epidemic is integrally linked to reproductive health. Indeed HIV itself, which is predominantly a sexually transmitted infection, is a key reproductive health issue. In women, HIV can have adverse impact on pregnancy, childbirth, and breastfeeding. HIV status also affects conception and parenting choices. Both HIV and poor reproductive health share common drivers, including poverty, gender inequality, and social marginalization of vulnerable populations [1]. Responses to both health issues should therefore be closely linked and mutually reinforcing. The 2006 Political Declaration on HIV/AIDS that called for greater linkage between HIV/AIDS and reproductive health as an additional approach to curb the epidemic [2].

Furthermore, new approaches are needed to ensure that long-term, high-quality health services can meet both the HIV and broader reproductive health needs of women and men [3]. These innovative approaches include integrated services or a "one-stop shop," where both services are provided in a single clinic with the same health provider during a single visit. As we approach the deadline for meeting the Millennium Development Goals in 2015 [4] and as the global health community debates the new Sustainable Development Goals for the post-2015 era [5], it is clear that greater integration of HIV and reproductive health research and service provision will be critical to achieve these goals.

The intersection between family planning and HIV services for women living with HIV is a central theme of this special issue. An estimated 13 million HIV-infected women live in sub-Saharan Africa [6]. Improved access to family planning among HIV-infected women will decrease maternal morbidity and mortality and improve neonatal outcomes [7]. Yet among HIV-infected women in this region, unintended pregnancy has been reported to range from 62% to 93%, including women on antiretroviral therapy [7, 8]. Despite current guidelines and best practice, contraceptive provision is not routinely offered as part of HIV services [9]. Even when it is offered, women and men frequently do not have information about or access to the full range of effective methods, and long-acting methods like intrauterine devices and contraceptive implants are often unavailable in high-HIV prevalence settings [10]. In addition, more attention is needed for drug interactions between antiretroviral drugs and hormonal contraceptives and for promotion of dual-method use. HIV-positive and -negative women need better information about and greater access to proven contraceptive methods.

For HIV negative women, there is a need to integrate HIV counselling and testing with contraceptive services, so that access to both services is increased. While pregnancy is known to increase the risk of HIV acquisition, antenatal services often fail to offer male or female condoms and safer sex counselling to pregnant women. In countries where there are high rates of teenage pregnancy and of HIV among adolescent girls, there are very few examples of effective integrated services for young women.

We hope that the papers in this special issue will bring additional attention to the intersection of HIV and reproductive health. A renewed focus on this intersection by populations, public and private health systems, country ministries of health and finance, and international donors, as well as attention by the larger global health research community, remains essential to continue to advance women's health. Such attention can also help promote gender equality,

especially for those affected by and at risk of HIV. Readers will find a number of papers on providing comprehensive sexual and reproductive health services, including abortion care, to HIV-infected women from sub-Saharan Africa and Asia, prevention of gender-based and intimate partner violence, and the need to develop female-controlled multipurpose technologies designed to prevent pregnancy, HIV, and STI transmission.

Acknowledgments

We thank the authors for their excellent research and look forward to the discussions that will be catalyzed by the findings included in this special issue.

Craig R. Cohen
Elizabeth Bukusi
Helen Rees
Kelly Blanchard

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Research Article

Providers' Perspectives on Provision of Family Planning to HIV-Positive Individuals in HIV Care in Nyanza Province, Kenya

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Objective. To inform an intervention integrating family planning into HIV care, family planning (FP) knowledge, attitudes and practices, and perspectives on integrating FP into HIV care were assessed among healthcare providers in Nyanza Province, Kenya. *Methods*. Thirty-one mixed-method, structured interviews were conducted among a purposive sample of healthcare workers (HCWs) from 13 government HIV care facilities in Nyanza Province. Structured questions and case scenarios assessed contraceptive knowledge, training, and FP provision experience. Open-ended questions explored perspectives on integration. Data were analyzed descriptively and qualitatively. *Results*. Of the 31 HCWs interviewed, 45% reported previous FP training. Few providers thought long-acting methods were safe for HIV-positive women (19% viewed depot medroxyprogesterone acetate as safe and 36% viewed implants and intrauterine contraceptives as safe); fewer felt comfortable recommending them to HIV-positive women. Overall, providers supported HIV and family planning integration, yet several potential barriers were identified including misunderstandings about contraceptive safety, gendered power differentials relating to fertility decisions, staff shortages, lack of FP training, and contraceptive shortages. *Conclusions*. These findings suggest the importance of considering issues such as patient flow, provider burden, commodity supply, gender and cultural issues affecting FP use, and provider training in FP/HIV when designing integrated FP/HIV services in high HIV prevalence areas.

1. Introduction

Unmet need for contraception and unintended pregnancy are prevalent among the estimated 13 million HIV-positive women in sub-Saharan Africa [1–3]. Unintended pregnancies account for 14–58% of all births in countries where the burden of HIV is the greatest [4]. In South Africa, a recent cohort study of women attending antiretroviral (ART) clinics found that 62% of pregnancies were unintended [5], while a cross-sectional study of pregnant women obtaining services for prevention of mother-to-child transmission (PMTCT) reported that 84% of pregnancies were unintended [6]. In a cohort of Ugandan women starting ART, 17% became pregnant over the two-year follow-up period, despite 93% not wanting or planning pregnancy [1].

Prevention of unintended pregnancy among HIV-positive women is one of the World Health Organization's four

cornerstones of preventing mother-to-child transmission of HIV (PMTCT) [7]. In many settings in sub-Saharan Africa, contraceptive services are provided in family planning (FP) clinics separate from clinics providing ART and related care for HIV-infected individuals [8]. Recognizing the structural barriers associated with this model of care, at least six international statements have recommended integrating family planning and HIV services in order to increase access among HIV-positive individuals to contraceptive counseling and services [2]. The US President's Emergency Plan for AIDS Relief (PEPFAR), the largest commitment from a single country to eradicate HIV, has identified decreasing unintended pregnancies among HIV-positive individuals as one of its four most essential strategies towards creating an AIDS-free generation [9]. Improved access to family planning among HIV-positive individuals is not only expected to decrease vertical transmission of HIV but also maternal morbidity and mortality, poor neonatal outcomes [10–12], and various other health and societal cost outcomes related to unintended pregnancies and vertical transmission of HIV [4, 13–15].

The Kenyan government has been working towards implementing integrated family planning and HIV services throughout the country for several years. In 2007 the Reproductive Health (RH) HIV Integration Technical working group, a Ministry of Health-led task force cochaired by representatives from the Division of Reproductive Health and the National AIDS and STI Control Program, was created and has been critical in advancing family planning/HIV integration efforts throughout the country. In 2009 this multidisciplinary group developed a National RH and HIV and AIDS Integration Strategy [16] which provided a framework for the integration of RH and HIV services. Recently, in 2012, the RH-HIV Integration Technical working group created a blueprint for national implementation of integrated family planning and HIV services [17]. In order to add to the evidence needed to support such national integration efforts in Kenya and in other sub-Saharan African countries, members of this taskforce from the Kenya Medical Research Institute, University of California, San Francisco, and Ibis Reproductive Health initiated a cluster randomized trial evaluating the impact of FP/HIV integration on contraceptive prevalence and unintended pregnancy [18].

Health care providers are at the forefront of defining, offering, and/or modifying integrated HIV and family planning services, yet little research has been done in Kenya and elsewhere exploring the perspectives of health care providers with regard to integrated reproductive health and HIV services [19–23]. In preparation for the cluster randomized trial we sought to explore the viewpoints of health care providers working in public sector HIV care and treatment clinics in rural, western Kenya (Nyanza Province) with respect to providing family planning services within HIV care settings.

In Nyanza, the overall HIV prevalence is 14 percent, the highest in the country and double the level of the next highest provinces—Nairobi and Western—at 7 percent each. Gender differences in HIV prevalence exist here; it is estimated that 16 percent of women and 11.4 percent of men are HIV-positive [15]. The total fertility rate in Nyanza is 5.4 and the contraceptive prevalence rate for modern methods is 33%, despite the fact that 75% of married men and women in Kenya age 15–49 years report a desire to delay fertility for at least two years or cease childbearing all together. Among married women of reproductive age, approximately 18% report using depot medroxyprogesterone acetate, 6% female sterilization, 3% oral contraceptives, 4% condoms, and less than 2% intrauterine or subdermal methods [15]. Unmet need for contraception among HIV-positive women in Kenya appears even higher than that of the general population [8].

Our study aimed to assess providers' knowledge and attitudes regarding family planning provision for HIV-positive individuals, as well as their perceptions of benefits and barriers to integrating contraceptive provision into HIV care. This preliminary work was conducted to explore whether providers felt integrated FP/HIV services were feasible and sensible within HIV clinics and to inform the design of the intervention component of a cluster randomized controlled trial (RCT) evaluating the impact of integrating family planning into HIV care.

2. Methods

We conducted a mixed-method study between November 2007 and October 2008 at thirteen government-run HIV care and treatment clinics "patient support centers" in the Migori, Rongo, and Suba districts of Nyanza Province, Kenya. The study sites selected were supported by Family AIDS Care and Education Services (FACES), a collaboration between the University of California San Francisco (UCSF) and the Kenyan Medical Research Institute (KEMRI). FACES provides training, clinical mentorship, and logistical support for public sector HIV care and treatment clinics in these districts in western Kenya [24].

The 13 study sites included public sector dispensaries, health centers, and subdistrict and district hospitals, 11 of which were sites to be included in the RCT and two of which were district hospitals that had already begun to integrate family planning services into HIV care. All study sites provided comprehensive HIV care to their clients, including ART. The study participants included 31 paid healthcare workers at these sites, over half of whom had a clinical diploma (nurses and clinical officers), while the others were counselors or clinic assistants who had regular contact with patients. The decision to include lay healthcare workers, also called community clinic health assistants (CCHAs), was purposeful. In a response to a shortage in healthcare workers, FACES staff has implemented "task-shifting" [25] and has trained lay healthcare workers to conduct the majority of counseling regarding medication adherence, side effects, and HIV prevention at these health facilities. CCHAs were part of the healthcare workforce at all study sites and it was anticipated that they would be involved in patient screening and education for family planning services after integration was implemented.

The study participants were selected through purposive sampling, with the goal of interviewing 30–40 providers where the intended family planning and HIV care intervention would occur. At each study site, an interviewer approached healthcare workers present that day and invited

them to participate in the study. The interviewer explained that the purpose of the study was to learn about HIV providers thoughts on and experience with providing family planning to HIV-positive men and women as well as their thoughts on if and how family planning should be provided for this population. The interviewer asked if they would be willing to participate in an approximately one-hour interview. All 31 providers approached for the study agreed to participate. Two to three providers were interviewed from each site. The number of study participants is equivalent to approximately one-third of the healthcare workforce at the thirteen sites. Participants were offered a book voucher worth 350 Kenyan shillings (about USD $4) after the interview.

The study instrument consisted of two parts: a structured, quantitative survey and an open-ended interview. Structured questions and case scenarios were used to assess contraceptive knowledge, training, and provision experience, while open-ended questions provided the opportunity to discuss opinions about the reproductive intentions of their clients and about the possibility of integrating family planning into HIV care. The case scenarios were included to explore providers' knowledge regarding the safety of different contraceptive methods with respect to HIV and whether or not their practice patterns would differ based on fertility intentions, age, and other sociodemographic factors. Providers were presented with three clinical scenarios in which HIV-positive women with differing parities, ages, comorbidities, and fertility intentions desired contraception. In each scenario all contraceptive methods are considered to be clinically safe for use in the context of HIV infection and disease, according to WHO medical eligibility for contraception guidelines [26]. They were asked method-by-method (which included condoms, oral contraceptives, depot medroxyprogesterone acetate, and intrauterine, subdermal, and permanent contraception) if each method was safe for the patient and if they would recommend that method to the patient. The quantitative portion of the study instrument was modeled after an evaluation of a family planning and antiretroviral therapy integration pilot in Mbale, Uganda [27]. The instrument was reviewed by and piloted with nonstudy participant Kenyan HIV healthcare providers and subsequently revised prior to finalization and data collection.

The qualitative portion of the instrument was informed by questions used in an open-ended interview guide from a study of providers' perspectives on the reproductive intentions of HIV-positive individuals in Cape Town, South Africa [28]. Domains included providers' views on childbearing among and current provision of family planning for HIV-positive individuals and thoughts on integrating family planning into HIV care. The interviews were conducted in English in a private room in the healthcare facility and lasted approximately one hour. With participant consent, the interviews were audio-recorded and subsequently transcribed. No identifying information was recorded in the audio recordings or interview notes.

All quantitative data were analyzed using Stata 9.2 (College Station, TX, USA). Frequencies were generated and appropriate comparisons were made using Fisher's exact and Chi-square tests. Qualitative data were analyzed using a grounded theory approach [29]. Initial thematic categories were drawn from the literature and the interview transcripts and then subcategorized once the full range of themes and patterns was developed. Participant responses to questions were coded manually by SN and KM. Trends and crosscutting themes were identified and further explored during the final analysis. Any coding discrepancies were resolved through discussion and consensus.

This study was approved by the Ethical Review Committee at KEMRI and the Committee of Human Research at UCSF. All participants gave written informed consent prior to study participation.

3. Results

3.1. Demographics and Clinical Context. Of the 31 providers, 18 were clinicians (clinical officers or nurses) and 13 were HIV/VCT (voluntary counseling and testing) counselors, community clinic health assistants, or health worker volunteers who had regular contact with patients in HIV care. The median number of years as a healthcare provider was 3 (range: 1–26) and of HIV care experience was 1 (range: 1–11).

Twenty-four of the respondents reported that condoms were available at their health facility in general, not necessarily at the HIV clinic, and 17 reported the availability of at least one non-barrier contraceptive method, such as oral contraceptive pills, depot medroxyprogesterone acetate (DMPA), or subdermal or intra-uterine contraception (IUC) (Table 1). Eight respondents reported that at least one long-acting reversible contraception method (subdermal or intra-uterine contraception) was available at their site, and only two of these eight reported availability of subdermal implants. Half of the providers reported working at a site where there was a provider trained in IUC insertion.

Two-thirds (19) of the respondents reported that they desired additional family planning training. Fourteen providers reported receiving some family planning training outside of their initial schooling during the previous two years. The respondents with recent family planning training were more likely to be working at a larger facility, for example, subdistrict or district hospital, than at a health center or dispensary ($p = 0.03$).

3.2. Main Themes

3.2.1. Theme I: Choice-Based Perspective regarding Fertility in the Context of HIV. In order to explore potential biases among providers with respect to HIV and pregnancy, participants were asked about their personal views regarding an HIV-positive women becoming pregnant and whether they think it is appropriate for HIV-positive men and women to bear children. All providers stated that an HIV-positive person has a right to have a child. However, their personal views about HIV-positive people bearing children differed depending on client sex. In general, providers viewed HIV-positive women as having the right to bear children. However, they qualified this choice by stressing that an HIV-positive woman's health should be optimized for pregnancy and if she is not in good physical condition, they would not recommend

Table 1: Demographics and clinical context of HIV care providers ($N = 31$).

Clinical experience	
Age in years (median, range)	33 (30–35)
Clinicians (clinical officers or nurses)	18 (58%)
Community clinic health assistants	13 (42%)
Number of years worked as provider (median, range)	3 (1–26)
Number of years worked in HIV care (median, range)	1 (1–11)
Clinical site for family planning availability	
Worked at sub-district or district hospital	15 (48%)
Worked at site where condoms were available	24 (80%)
Worked at site where at least one nonbarrier method was available [OCP's, DMPA, implants, or IUC]	17 (57%)
Worked at site where implants or IUC was available	8 (26%)
Family planning training	
Received training in family planning outside of school, during the past two years	14 (45%)
Desires additional family planning training	19 (61%)

OCP: oral contraceptive pills.
DMPA: depot medroxyprogesterone acetate.
IUC: intrauterine contraception.

conception. Their concern appeared to lie mainly with the potential maternal health risks associated with HIV disease and pregnancy and less commonly with the risk of maternal-child transmission. One nurse said,

> *"Generally, her health should be good. Her CD4 should be high; her viral load should be low…because (pregnancy) can do her more harm if her health is not optimized…"*

A woman's choice of pregnancy was further qualified by her marital status and by the number of children she already had. Most providers commented that the woman should be married if she planned to get pregnant and she should not have many children already.

A few providers acknowledged that they are rarely faced with an HIV-positive female client who desired pregnancy and that thinking about their reactions to such a client was hypothetical. They said they usually encountered HIV-positive women who were already pregnant or wanted to prevent pregnancy, not women who desired pregnancy.

When asked about their views on HIV-positive men fathering children, providers tended to think about the man in the context of his marriage, family, and community, rather than his health. Providers spoke more frequently about the importance of partner agreement regarding having a child. One nurse said,

> *"I'll just tell him…to bring the wife, to talk to the wife, and do consultation with each other and see if they have one conclusion."*

In addition to concerns about family size, providers expressed concerns about the familial and social impacts of an HIV-positive man fathering a child, especially in the situation of limited resources. They stated concerns about men being able to financially support their families and to continue to work and be productive members of society.

Providers almost unanimously expressed views about family planning that reflected a focus on reproductive choice and family health. One community clinic health assistant said,

> *"Family planning to me means…planning the number of children you want to have and (when) you want to have them…there is a way of giving birth to the number of children you can take care of."*

The survey portion of the interview additionally revealed a rights-based perspective. Twenty-seven (87%) respondents said that HIV-positive people were free to have sex if they wanted. These views did not differ if the respondent was a clinician or nonclinician.

When asked their views on appropriate family planning counseling for HIV-positive men and women, most providers said it was important for women to consult their partners prior to using family planning; however, this was not expressed for men. For men, they often stressed the importance of dual protection, while for women this was less commonly mentioned. When asked about what they would recommend if an HIV-positive man or woman knew they did not want to have any more children, most providers recommended female sterilization for both hypothetical male and female clients. Few providers mentioned male sterilization.

3.2.2. Theme 2: Views regarding Hypothetical Integration of HIV Care and Family Planning: Facilitators and Barriers. When they were asked about integrating family planning and HIV services, several barriers and facilitators were mentioned. Most providers were supportive of the idea and felt it would improve patient care. One community clinic health assistant said,

> *"I think it would be good to integrate services so that clients are not being transferred from one place to the other, they might even disappear on the way…"*

A nurse said,

> *"When the patients come to the clinic all these services can be given there instead of seeing the patient partially and then referring the patient for family planning services. . ."*

Several providers reflected on the current situation in which they felt HIV-positive women were given few family planning options. They reflected on male resistance to condom use and how often providers had nothing to give women other than condoms, but if her partner refused to use this method, then they really were not providing family planning. They also expressed concerns about staffing issues, method supply, space, and training limiting their ability to provide family planning. One nurse said,

> *"If all we have are condoms, we may tell a woman to use a condom. . .And then the partner does not want to use the condom. . .so when she comes back we tell her can we give you more condoms? She says no because the husband does not want to use. . .And if she wants another family planning method that is not within the facility. . .then she will not get the service. And also if she needs the service that is inside (the facility) and the provider is not there, she will not get it. . ."*

One clinical officer said,

> *"We do not have enough drugs. You can counsel somebody. . .but how are you going to (provide family planning) if you do not have the pills? If you do not have private space? Or if you cannot insert an IUC or do a tubal ligation?"*

Providers also voiced concerns about method-related fears among clients. Most spoke about women's concerns about side effects such as irregular bleeding. When asked what family planning myths exist in their communities, providers mentioned misperceptions about contraceptive safety and potential teratogenicity. Among various myths mentioned, providers said that intrauterine contraception is believed to sometimes travel to the brain or the heart, and some people believe that men *"will be disturbed psychologically"* after vasectomy. Providers felt that societal myths about family planning served as significant barriers to use regardless of HIV status and efforts to overcome these misperceptions should be incorporated into integration plans.

Despite their concerns about the logistics of integration and family planning misperceptions, there were several social factors that they thought might facilitate the success of integration. Providers talked about stigma, both toward people with HIV and toward people using family planning, as factors that would be better addressed through integration. With regard to HIV stigma, providers felt that having family planning services available within the HIV clinic would protect HIV-positive clients from unnecessary discrimination and feelings of shame due to discomfort with disclosing one's HIV status outside of the HIV clinic. One community clinic health assistant said,

> *"If a client is HIV positive and needs family planning methods. . .she should get it within (the HIV clinic). . .not be referred to another place and be given that service outside. . .because she may go there and she may not say that she is HIV positive.."*

Several providers also mentioned stigma against women attending family planning clinics and the assumption that women who do so are promiscuous. One nurse said,

> *"Family planning uptake is still low because. . .the community feels those people who go for family planning. . .have many sexual partners so one would wonder why she has to go for family planning if she only has one sexual partner with whom she can easily organize."*

Participants felt that having family planning available at the HIV clinic would minimize the impact of HIV-related and family planning-related stigma and increase contraceptive use. Providers felt the HIV clinic was a good place for family planning because they *"understand their (patients') problems better (than the staff at the family planning clinic)."*

Most providers mentioned roles that men play in family planning. Two salient and pervasive themes emerged. Providers discussed how currently men seemed to play a prohibitive role against using family planning, but how incorporating men more effectively into family planning decision-making through integrated services might be beneficial. Providers expressed views that even in their absence men dictate women's choices of family planning and influence the way in which providers counsel women. They talked about how most women choose DMPA because it is a covert form of contraception. One nurse said,

> *"In our community, the Luos, most. . .use Depo because. . .they know their husbands will not be able to realize very fast." Providers also felt "we can improve (family planning) by including the males."*

They felt that incorporating men into family planning counseling and decision-making could decrease clandestine behavior and increase awareness of partners' needs, thereby creating a situation that is more conducive to family planning continuation. They felt integration of family planning into HIV care would facilitate inclusion of men since men are generally more comfortable coming to the HIV clinic, where there are other men or where they might be a patient themselves, than accompanying their partner to the family planning clinic, almost exclusively attended by women.

3.2.3. Theme 3: Knowledge and Providing Patterns among Providers regarding Contraceptive Safety in HIV-Positive Individuals. Correct knowledge regarding the safety of family planning methods and what providers would recommend to HIV-positive clients was low (see Figure 1). Despite the safety of DMPA, IUC, and contraceptive implants for use by the women in the clinical scenarios, only 19.4%, 35.5%, and

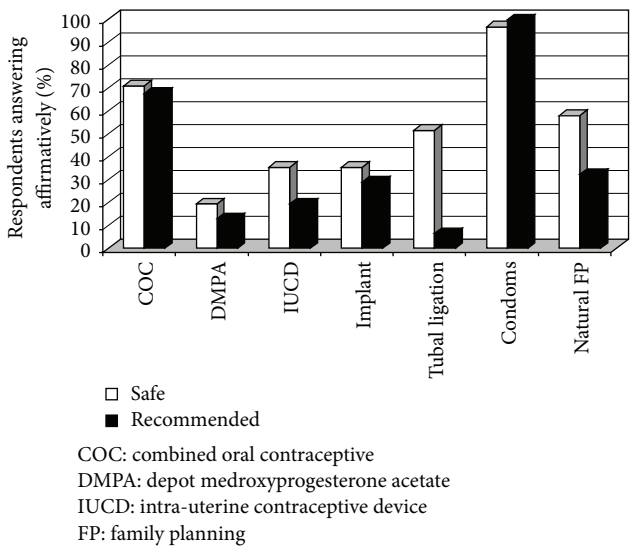

Figure 1: Contraceptive safety knowledge and recommendation of contraceptive methods among HIV care providers in Nyanza Province, Kenya ($N = 31$).

35.5% of respondents, respectively, thought these methods were safe. Clinicians were significantly more likely than nonclinicians to correctly report the safety of combined oral contraceptives and tubal ligation ($p = 0.02$ and $p = 0.01$, respectively). Tubal ligation was least recommended, with only 6.5% of respondents reporting that they would recommend it. Condoms were deemed the safest and the most recommended method. Only four participants (13%) erroneously thought that condoms were the only family planning method an HIV-positive person can use.

With the exception of the differences in family planning safety knowledge, differences in responses according to the respondent's role in the clinic (nurse, clinical officer, or CCHA) were not observed. Overall response themes were quite uniform, and there were few outliers with respect to the themes described above.

4. Discussion

Similar to other studies from sub-Saharan Africa [26, 27], we found that the majority of providers viewed pregnancy as a basic right for people living with HIV. However, they reported in their experience that HIV-positive women more commonly wanted to limit or end childbearing rather than conceive. They stated that HIV-positive people should have access to all contraceptives. Providers were enthusiastic about integrating family planning into HIV care and felt integration could improve access to contraception and reduce stigma related to both family planning and HIV. However, we found that the providers interviewed had extremely limited knowledge and uncertainty about the safety of contraceptive methods, hormonal and nonhormonal, and whether or not to recommend contraception to people living with HIV. Our study findings portray the enthusiasm and hypothetical acceptability among HIV providers for FP/HIV integration. Our findings also reveal the dire need to comprehensively educate HIV providers about the safety of FP methods with respect to HIV and to increase their ability to incorporate sensitivity to complex gendered power differentials that influence contraceptive choice and use into their counseling. These data informed the development of the FP/HIV intervention in Nyanza, Kenya, used in the cluster randomized trial which is now being used as a model to guide national integration efforts in Kenya and will be useful in similar resource-poor settings in sub-Saharan Africa.

Providers identified several sociocultural barriers with respect to contraceptive uptake. They spoke about the need for partner approval before using family planning and how as a result of this gendered power dynamic most women in Kenya choose to use DMPA [15], the most easily concealable contraceptive. These findings of male partner influence on contraceptive choice and use, while uncovered in the context of a study on FP/HIV integration, are issues that have long been recognized in the literature and among practitioners as obstacles to FP use among women in the general population. Previous research in Kenya demonstrated that the strongest predictors of female contraception use were male fertility preference [30] and partner disapproval which predicted use of less effective family planning methods or, more commonly, none at all [31–33]. Providers felt that involving men in fertility decision-making could potentially help promote women's and their families' health.

We found that providers were more likely to counsel men to use dual protection and to tell women to consult their partners before using family planning, implying that perhaps there was a perception that men are at greater risk of transmitting HIV than women are and/or that men have more agency in protecting themselves from acquiring HIV or impregnating a woman than women do with respect to HIV and pregnancy prevention. The majority (approximately 80%) of patients seen at the HIV clinics participating in the cluster RCT are married, with approximately a fifth of them reporting being in polygamous relationships [18]. Given these statistics, integrating family planning into HIV care could have a major impact on contraceptive use among married men and women since it enables the counseling and provision of family planning to be done in an environment where men are expected to be, different from the maternal-child health clinics generally attended only by women. However, issues related to stigma associated with coming to an HIV clinic in general must be recognized.

Male involvement in family planning needs to be implemented in a way that promotes joint and equitable decision-making about family planning and does not reinforce gendered norms about men as decision makers. In order for increased male involvement in family planning to occur in a way that is safe and constructive for women, gender-sensitive approaches to training of HIV care providers with respect to HIV and pregnancy prevention need to be used. As part of the family planning integration intervention we implemented couples family planning counseling at integrated sites. However, couples counseling will only be appropriate for a portion of HIV-positive individuals who present for HIV care as it requires agreement on behalf of both partners to engage in joint counseling and assumes a level of acceptance that

joint decision-making is important and feasible. In order to engage a broader population of HIV-positive men and women in family planning, further development, implementation, and evaluation of interventions that promote gender-equitable reproductive health behavior and decision-making are important in order to create family planning and HIV integrated services that are effective and will decrease unintended pregnancies among HIV-positive individuals.

As it has been found in many countries [34] regardless of HIV infection, providers identified widespread community and personal misperceptions regarding side effects and safety of contraception to be a barrier to contraceptive provision and uptake. Accurate training is needed on the provider level with respect to family planning in order for HIV providers to feel comfortable counseling and providing FP methods to HIV-positive patients. Education is also needed on the community level, in and outside of the clinics, in order to help dispel many of the socially perpetuated myths that exist about contraceptive use. As a result of these interviews, FP educational curricula and job aids were developed to be used in the FP/HIV intervention in order to dispel contraceptive misperceptions and to train community clinic health assistants and certified health care providers to provide FP group education, counseling, and methods [35]. These tools are now being used nationally to scale up the implementation of FP/HIV.

Participants expressed concerns about lack of staff, space, and methods as barriers to integrating family planning into HIV care; similar concerns have been voiced by providers elsewhere in Kenya and Uganda [26, 36]. The HIV epidemic has fueled a major crisis in the healthcare workforce, especially in sub-Saharan Africa. The rapid expansion of people needing treatment for HIV-related illness has overwhelmed healthcare systems globally [37]. The WHO has responded to this shortage in the healthcare workforce with recommendations for "task-shifting," [25]. Task-shifting has been found to be cost-effective in several African countries [38] and has been successfully implemented for ART provision in urban regions of Kenya [33]. Given the growing patient volume and health needs of HIV-positive individuals, implementing task-shifting within integrated services appears essential [34].

Most research on family planning and HIV has not focused on providers but rather on the physiologic effects of hormonal contraception and antiretroviral therapies [39–41] and on the unmet need for contraception and fertility desires among HIV-positive clients [1, 42–45]. We found that knowledge about the safety and appropriate use of family planning methods among HIV-positive individuals was limited as it has also been found in Uganda [26]. We also found that providers were more likely to counsel men to use dual protection and to tell women to consult their partners before using family planning. Further research into the ways in which preconceived ideas regarding gender roles and gendered power differences influence HIV care providers is essential in order to create effective family planning training programs for providers.

This study has several limitations. The most important limitation is that the providers were asked hypothetical questions about integrated services. None of the participants had significant experience providing integrated services and thus provided theoretical responses. Multiple issues, such as logistic and financial factors, that are important to the provision of integrated services may not have been thoroughly discussed and responses were not reflective of actual experiences with integration. The study was conducted in a limited number of facilities, each of which had a small number of providers. Additionally, it was conducted only in clinics that are currently supported by FACES and would be participating in the FP/HIV integration cluster RCT. Although the RCT had not begun and providers were not aware of the plans for the RCT, it is possible that providers in these clinics have different views on family planning compared to providers in non-FACES-supported clinics. While the findings are likely representative of these districts, they may not be representative of providers in Kenya as a whole. Another difficulty relates to the tragic postelection violence that occurred in Kenya in late 2007 and early 2008. During this time all data collection ceased for nine months. Despite discontinuous data collection, we observed no important differences in participants' responses before and after this period.

HIV-positive women in sub-Saharan Africa have a significant unmet need for contraception [1–3, 8, 42, 43], and unintended pregnancy among HIV-positive women is prevalent [1, 4–6, 44, 45]. Although more data on clinical outcomes are needed, integration of family planning into HIV care will likely improve access to family planning for HIV-positive individuals and reduce stigma. Given the growing evidence base supporting a focus on family planning as an integral component of decreasing vertical transmission and eradicating HIV, as well as recognition of the reproductive rights of HIV-positive individuals, resources must be devoted to address the challenges identified by HIV health care providers regarding training, staffing, clinic space, commodity distribution, and gender-based fertility decision-making identified here.

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Research Article

Overcoming Barriers to Family Planning through Integration: Perspectives of HIV-Positive Men in Nyanza Province, Kenya

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This study explored barriers to and facilitators of using family planning services among HIV-positive men in Nyanza Province, Kenya. From May to June 2010, in-depth interviews were conducted with 30 men receiving care at 15 HIV clinics. The key barriers to the use of family planning included concerns about side effects of contraceptives, lack of knowledge about contraceptive methods, myths and misconceptions including fear of infertility, structural barriers such as staffing shortages at HIV clinics, and a lack of male focus in family planning methods and service delivery. The integration of family planning into HIV clinics including family planning counseling and education was cited as an important strategy to improve family planning receptivity among men. Integrating family planning into HIV services is a promising strategy to facilitate male involvement in family planning. Integration needs to be rigorously evaluated in order to measure its impact on unmet need for contraception among HIV-positive women and their partners and assure that it is implemented in a manner that engages both men and women.

1. Introduction

Many studies have demonstrated the diversity and complexity of reproductive intentions among people living with HIV in sub-Saharan Africa, which are influenced by personal, health-related, sociocultural, socioeconomic, and gendered factors [1–6]. Often HIV infection changes but does not eliminate fertility desires [1]. Some HIV-positive individuals believe that having children gives them reasons to live [1, 7, 8], and some bear children to avoid raising suspicions of HIV infection [8, 9]. Still others want to replace children who have died due to HIV [1, 8, 10]. However, many HIV-positive individuals want to avoid pregnancy due to financial reasons and being satisfied with the number of children they have [6]. Other deterrents to having children include fears of orphaning a child, of vertical transmission of HIV, and of infecting a negative partner during conception [1, 6, 7]. Several studies have shown that fertility desires differ by gender, that one partner's fertility intentions can impact the other's, and that men and women are influenced differently by community opinions regarding HIV and reproduction [1, 5, 8, 11, 12].

Unmet need for contraception and unintended pregnancy are prevalent among HIV-positive women and couples in sub-Saharan Africa [13, 14]. Based on evidence of cost-savings and demonstrated effectiveness of contraception in averting HIV-positive births [15, 16], the World Health Organization/United Nations Population Fund Glion Call to Action emphasizes family planning as one of four critical elements of a comprehensive prevention of mother-to-child transmission (PMTCT) of HIV strategy [17]. Integrating family planning into HIV care and treatment is being promoted by international public health agencies, local organizations, and some governments, including the government of Kenya,

to ensure that HIV-positive individuals have access to comprehensive contraceptive counseling and services [18].

Traditionally, family planning programs have been directed towards women, since it is women who become pregnant and the majority of family planning methods are used by women. Moreover, women are more frequently in contact with the health care system because of their overall responsibility for family health, especially for the health of infants and children under five years of age. However, men are key decision-makers around use of contraceptives [6], and studies have shown that men usually want to be involved in reproductive decision-making [6, 19]. It has been shown that when men are involved in family planning, there are improvements in uptake of contraception [20]. Furthermore, reproductive health programs that target couples have been shown to be more effective at increasing contraceptive use than those directed to individuals [19, 21]. The move toward integrating family planning services into HIV care and treatment may offer an opportunity to engage with men and their partners to increase contraceptive uptake. Despite the growing body of literature about the complex reproductive desires of people living with HIV [8], there exist few in-depth studies about patient perspectives of integration of family planning and HIV services and even fewer focused solely on HIV-positive men.

The Kenyan government, in accordance with international policy, has demonstrated a strong commitment to improve linkages between reproductive health and HIV/AIDS services, reflected in its recently developed national strategy for reproductive health and HIV/AIDS integration [18]. This qualitative study was conducted in Nyanza Province, the region in Kenya with the highest prevalence of HIV and high unmet need for family planning, as part of formative research for a cluster-randomized controlled trial (RCT) evaluating the impact of integrating family planning services into HIV care and treatment clinics on contraceptive prevalence (http://clinicaltrials.gov/, NCT01001507). We sought to explore the barriers and facilitators to the use of family planning services among HIV-positive men accessing HIV care and treatment in public sector clinics in rural Kenya. Our aim was to gain a better understanding of HIV-positive men's experience with and needs for family planning in order to guide efforts to integrate family planning into HIV care and reduce unmet need for contraception among people living with HIV.

2. Material and Methods

2.1. Sites. This qualitative study was conducted between May and June 2010 as part of baseline data collection for a cluster randomized controlled trial evaluating the impact of integrating family planning into HIV services on contraceptive prevalence. Participants were recruited from 15 public sector HIV treatment clinics taking part in the RCT in the Kisumu East, Nyatike, Rongo, and Suba Districts of Nyanza Province including two dispensaries, eight health centers, three subdistrict hospitals, and two district hospitals. All sites were supported by Family AIDS Care and Education Services (FACES), a collaboration between the University of California, San Francisco (UCSF) and the Kenyan Medical Research Institute (KEMRI) [22]. All sites provided comprehensive HIV care and treatment including the provision of antiretroviral therapy (ART). At the time of this study, none of the sites were offering specific couples-based counseling or ART services, although such services may have been provided on a case-by-case basis. The study was approved by the Committee on Human Research at UCSF and the Ethical Review Committee at KEMRI.

2.2. Eligibility. Eligible participants were nonsterilized, HIV-positive men 18 years and older accessing care at one of the participating HIV clinics. A convenience sample of two men per site was selected to participate. The interviewer screened male patients after they completed their clinical visit and invited the first eligible and willing participant to complete the interview. After the first interview was completed, this process was repeated to identify the second participant. Each participant provided voluntary written informed consent and received a reimbursement of approximately $2.50 USD.

2.3. Open-Ended Interviews. Thirty open-ended interviews were conducted to explore male clients' family planning preferences in the context of integration of family planning into HIV care and treatment services. Interviews were conducted in participants' first language (Dholuo) by a trained interviewer. Each interview lasted approximately 60 minutes and was based on a semistructured interview guide. The domains covered in the interview guide included reproductive intentions, perceived barriers to obtaining and using effective contraception, and acceptability of various family planning services, including integrated with HIV care and home-based services. All interviews were audio recorded.

2.4. Data Analysis. Interviews were transcribed and translated into English. Data were managed in Atlas-ti 6.0 (Scientific Software Development, Berlin), and transcripts were coded and analyzed using a grounded theory approach [23]. Two investigators independently conducted the initial coding of a sample of transcripts according to a codebook constructed from the interview guide content and a preliminary content analysis of the raw data; inductive codes based on the data were developed as concepts emerged. Discrepancies were resolved through discussion and consensus. An iterative process was used to develop the final qualitative analysis codebook which allowed for refinement of our analysis and thematic concepts. In the final analysis, codes and quotations were grouped to identify thematic trends and variant views. Quotes presented here are identified by the age of the participant, the number of living children, disclosure of HIV status to the primary partner, and the HIV status of the primary partner. These characteristics were chosen as they may impact use of contraception and decisions about accessing family planning services in an HIV clinic.

3. Results

The demographic characteristics of participants are shown in Table 1. For those whose age was known, about half were 35

Table 1: Participant characteristics ($N = 30$).

	N (%)
Age, mean (range)	33.5 (27–42)
18–34	12 (40%)
35–42	12 (40%)
Missing*	6 (20%)
Marital status	
Married	29 (97%)
Unmarried	1 (3%)
Education	
Primary school or less	19 (63%)
Secondary school or higher	7 (23%)
Missing*	4 (13%)
Literacy	
Reads with difficulty or not at all	13 (43%)
Reads easily	14 (47%)
Missing*	3 (10%)
Disclosure of HIV status to wife or main partner	
Disclosed	24 (80%)
Did not disclose	3 (10%)
Not applicable (no wife or partner)	1 (3%)
Missing*	2 (7%)
HIV status of wife or main partner	
HIV-positive	21 (70%)
HIV-negative	3 (10%)
Unknown to male participant	4 (13%)
Not applicable (no wife or partner)	1 (3%)
Missing*	1 (3%)
Number of living children, $N = 29$, median (range)*	4 (0–11)
Time since HIV diagnosis (years), $N = 26$, mean (range)*	2.0 (<1–7)
Currently on ART ($N = 27$)*	16 (59%)
Current contraceptive use—self or partner ($N = 30$)	
Injectable contraceptives	8 (27%)
Combined oral contraceptives	2 (6%)
Female sterilization	1 (3%)
Condoms	21 (70%)
Condoms only	13 (43%)
Condoms + other method	8 (27%)
No modern method	3 (10%)
Abstinence	3 (10%)

*Data were missing for some participants.

or older, and half younger. All but one was married. Most had primary school education or less, and about half were literate. The median number of living children was four. On average, men had been diagnosed with HIV two years previously, and the majority was on antiretroviral therapy. Nearly half of men (43%) reported using condoms alone and another 27% reported using condoms with another method of family planning, and a minority (36%) said their partner was using a modern method of contraception (Injectable, combined oral contraceptives, or female sterilization). Among the 30 participants, 21 (70%) reported their wife or main partner was HIV+, three (10%) reported she was HIV−, four (13.3%) reported that they did not know the status of their wife or main partner, and the remaining were missing or not applicable. The majority of the individuals reported having disclosed their HIV status to their wife or main partner ($n = 24$, 80%). Three men had not yet disclosed their status and three had missing data or were not applicable.

3.1. Relevance of Family Planning. Many HIV-positive men, independent of their fertility desires, understood the importance of planning one's family to improve the health of the mother and child, to enable them to better care for their children, and for financial reasons. For instance, one man stated that "*...it [family planning] enables you to plan your family and only have a child when you want, that enables you to take good care of the child...*" (29 years, 3 children, disclosure missing, HIV+ partner). The importance of child-spacing was a common theme. One man described it in the following way: "*in the culture of the Luo community if a child is closely followed by another pregnancy then the child will grow weaker and sicker.*" (42 years, 7 children, disclosed to partner, HIV+ partner.) Another man discussed spacing children in the following manner: "*...we needed a break to first take care of the other children we have and push them ahead before getting another child. Having several of them would make it difficult to meet all their needs at once, for instance one needs clothing, another one school fees, hospital fees...*" (30 years, 5 children, disclosed to partner, HIV+ partner).

3.2. Barriers to Family Planning. Despite the fact that many participants understood the importance of planning one's family, the use of more effective contraception, such as hormonal, intrauterine, or permanent methods, was low. Several barriers to family planning use emerged as predominant themes in the interviews, including concerns about side effects of contraceptives, lack of knowledge about contraceptive methods, myths and misconceptions, structural barriers such as staffing shortages, and a lack of male focus in family planning methods and service provision. Some of the concerns and perceived barriers mentioned are based on actual experiences or their partner's experiences, while others are hypothetical concerns or based on common attitudes and beliefs in the community.

3.2.1. Side Effects of Contraceptives. Side effects of contraceptives were a common concern, specifically irregular bleeding. One man said: "*I have heard that at times when a woman is on family planning medications they have longer periods and the flow of blood never ceases... As a man, at times you want to have sex, but you realize she has blood, yet she was on her period just the other day.*" (Age missing, 4 children, disclosed to partner, HIV+ partner.)

3.2.2. Lack of Knowledge and Myths and Misconceptions. Family planning educational talks were routinely given in the waiting area of the HIV clinic where these men received HIV services. Most men were able to name at least two family planning methods. However, many men were not aware of long acting reversible contraceptives and permanent methods. There remains a particularly large gap in knowledge related to vasectomy, an infrequently utilized form of contraception in this community. Fear of infertility due to nonpermanent forms of contraception was a concern repeated by some men, "*I have also heard rumors that the drugs can make somebody never able to get pregnant again*." (Age missing, 4 children, disclosed to partner, HIV+ partner.) However, some men were more knowledgeable about the variety of contraceptive options available, including the importance of dual protection. For instance, one man said: "*the condom helps to protect against many other things and not just pregnancy. Therefore, as much as my wife uses injections, we also use condoms*." (29 years, 3 children, disclosure missing, HIV+ partner.) Throughout the interview, this man stated that he and his wife have achieved their desired family size. He also stated: "*my wife is also infected and whenever we have sex we do what we were told at the hospital to reduce the effect of HIV…we must use condoms to avoid injuring the other person by adding more HIV…*" Many other men with both HIV-positive and HIV-negative partners discussed the importance of condoms for HIV prevention and as illustrated here, "to avoid adding HIV" or acquiring a second strain of the virus.

3.2.3. Structural Barriers. A few men were aware of challenges that their partners may be facing in accessing family planning services. One challenge that was repeated a few times was shortage of staff to provide services. One man stated: "*on the day she went, she didn't get the services as the provider was away. When she went the next time she was still away, that happened on four different times then on the fifth visit she got the services*." (42 years, 7 children, disclosed to partner, HIV+ partner.) Another mentioned that when there are stockouts of commodities, his wife must go to the pharmacy to buy the medication and have someone administer the injection. Another man reported that condoms are sometimes out of stock at the health facility, and he must buy them.

The cost of the services did not appear to be a barrier for most men because family planning services are often provided for free or a small fee. One stated: "*I think it is just okay, because they must use a syringe; however the medicine is only 30 shillings [$0.35]*" (36 years, 2 children, disclosed to partner, HIV+ partner). When referring to the cost of condoms, one man said: "*there are condoms that are sold; they are the ones I have paid for, however most of the times I use the ones given for free at the health centers*." (37 years, 4 children, disclosed to partner, HIV− partner.)

Although the majority of men reported that they lived close by and are able to walk to the health facility, distance to the clinic was reported by a few men as a barrier. "*The clinic is a bit far from us, such that if I come on foot, it takes about 2 1/2 hours to reach here*." (37 years, 4 children, disclosed to partner, HIV− partner.) Another said: "*the terrain is what complicates it, you see this place has a lot of hills*." (42 years, 7 children, disclosed to partner, HIV+ partner.) Wait time at the clinic was reported as a barrier for one individual. Only one of the men interviewed had accompanied his spouse to get family planning services, and therefore they, unlike the female clients, were not accustomed to going to two separate clinics to receive family planning and HIV/AIDS care services.

3.2.4. Lack of Male Options for Family Planning. Other than male condoms, the most common contraceptive methods are used by women. Several HIV-positive men noted that they would like to have their own methods for birth control. Lack of male options for family planning services was reported as a barrier for a few men in this population. One man said: "*you see us as men, our options are limited, it is the women who have a variety of options to choose from…*" (37 years, 4 children, disclosed to partner, HIV− partner). Another man stated: "*there are times I hear presentations over the radio on family planning services and where the services are, however personally I have not gone to see for myself since it is mostly women who visit those clinics..*." (29 years, 3 children, disclosure missing, HIV+ partner). Several men mentioned they would like to accompany their partner to access family planning services so that they could learn more about the services.

3.3. Facilitators of Family Planning Related to Integration of Family Planning and HIV Services

3.3.1. A Sense of Belonging and Community at the HIV Clinic. When men were asked about the possibility of receiving family planning services in the HIV clinic, there was a general agreement among most men that integration would improve access to family planning services among HIV-positive men and their partners. Convenience and improved continuity of care were mentioned as supportive reasons for integration of family planning services. One man stated: "*since we are already HIV-positive and getting our medication at the PSC [HIV clinic], if those services [family planning] can be offered at the PSC then I would prefer to get them from the PSC*." (Age missing, 6 children, disclosed to partner, HIV+ partner.)

Men appeared to feel a sense of belonging at the HIV clinic. One said: "*personally I would prefer to go to the patient support center [HIV clinic] because it is our clinic; I wouldn't want to go to the maternity clinic. It is at the patient support center that I will have to tell them my problems because it is my place and they are our people*." (30 years, 5 children, disclosed to partner, HIV+ partner.) Another said: "*I thought the clinic for children is only meant for those carrying small children*." (Age missing, 11 children, disclosed to partner, HIV− partner.) "*I like it there [HIV clinic] because I am used to that place, the care providers at the clinic also talk to us freely and are concerned about our health, the other clinic only deals with women and children's issues, but here I will find fellow men and women, and we can talk freely*." (42 years, 11 children, disclosed to partner, HIV+ partner.) Access to service providers and speed of services also seemed to be a facilitator for receiving family planning services at the HIV

clinic. "*Because here [the HIV clinic] is a busy place, and when you come you are likely to find people. But in the other clinics. . .you may even find it closed and there are times when patients go back home without treatment because both the nurse and the doctor are away.*" (42 years, 7 children, disclosed to partner, HIV+ partner.)

A few men's opinions about integration of family planning and HIV services were indifferent, as one stated that: "*these are wings of the hospital; PSC [HIV clinic] is one of them so it is just the same as going to the maternal and child health clinic.*" (Age missing, 7 children, disclosed to partner, HIV+ partner.) While a few preferred family planning services to be delivered at the family planning clinic, the great majority of men were supportive of receiving family planning services in the HIV clinic.

3.3.2. Faith in and Comfort with HIV Care Providers. Many men reported trust and confidence in the providers at the HIV clinic. One stated: "*I have confidence in the people working there [HIV clinic]. Again they have the qualifications and experience hence would give me good advice.*" (38 years, 1 child, disclosed to partner, HIV− partner.) Another said: "*because when one is HIV-positive, they need close attention, and if your wife gets pregnant and you are both positive, you get to know that the child needs to be given birth to at the hospital. . .*" (29 years, 3 children, disclosure missing, HIV+ partner). Another stated: "*because they are the ones who know and will understand my problems and hence will handle me well.*" (27 years, 1 child, disclosed to partner, HIV+ partner.)

Men often said that health care providers influenced their opinions about family planning. One man stated: "*it is mainly due to the counseling we receive here at the hospital and as a result of that I have realized that I am able to decide on the number of children to have and when to have them.*" (42 years, 11 children, disclosed to partner, HIV− partner.) Another man when discussing receiving family planning counseling said: "*you see when people openly discuss something, then stigma reduces and there is more acceptance as you realize you are not alone in your situation.*" (Age missing, 6 children, disclosed to partner, HIV+ partner.)

3.3.3. Opportunity for Couples Counseling at the HIV Clinic. Family planning couple counseling provides an opportunity for a facilitated discussion to enable both partners to make an informed choice about contraceptive options that satisfies their personal, reproductive, and health needs. Integration of HIV and family planning services could facilitate couple counseling. A few men reported that health care providers could counsel couples who disagreed about their fertility preferences and family planning use. When asked about differences in fertility preferences, one man said that "*I had brought my wife to the clinic and the doctor talked to us together, we were counseled and she accepted the idea of family planning.*" (36 years, 3 children, disclosed to partner, partner HIV+.) Another man discussed his desire to accompany his partner to her family planning visit by saying "*I would like that because it gives us an opportunity to both talk to the doctor, she can give her opinion and I can also give my opinion as we get advised together.*" (30 years, 5 children, disclosed to partner, HIV+ partner.) Although this desire to accompany one's partner to a family planning counseling session was echoed by many men, only one man reported previously attending the FP clinic with his wife. Several men were informed that if they want to have a child they should speak with the health care provider before conceiving so that they can appropriately time the pregnancy and prevent mother-to-child transmission of HIV.

4. Discussion

Our study qualitatively explored views among HIV positive men in western Kenya about the idea of integrating family planning into HIV care and treatment. Despite commonly cited barriers to uptake and use of contraception, such as insufficient knowledge about contraceptive methods, fear of social disapproval, and fear of side-effects and health concerns [24–26], we found that most men in this exploratory study felt that integrating family planning into HIV care would be a preferable way to receive family planning information and services compared to separate services at the maternal and child health or family planning clinics. We found that many expressed a desire to learn more about family planning and felt that integrating family planning into HIV services would increase their knowledge about and involvement in family planning. Many also expressed feelings of confidence in the HIV care providers and a sense of belonging in the HIV clinic which may facilitate the likelihood that men and their partners would access family planning services, such as education and counseling, and personally adopt or encourage their partner to adopt new contraceptive methods if provided at the HIV clinic.

Men accessing HIV care and treatment reported theoretical ways in which integrating family planning into HIV care would make access to information and use of family planning easier for them and their partners. Many men in this study wanted to cease or delay having children, and as a result they were receptive to information that they received during the family planning educational talks about the various contraceptive methods. Although the majority of contraceptive methods are used by women, studies have shown that when men are involved in family planning discussions, there are improvements in uptake of contraception among women [20]. There is also a potential for HIV-positive men to gain knowledge about and access to vasectomy services. The impact of integration of family planning and HIV/AIDS services and the effect of health care provider counseling and education appeared to positively impact male acceptance and potential utilization of family planning by them and their partners.

Based on information gathered during the baseline interviews with male and female patients accessing HIV care, we designed the intervention to attempt to meet their family planning needs. The intervention included the provision of a range of family planning services within the HIV clinic. The services included family planning education, counseling, and contraceptive method provision including condoms, oral and injectable contraceptives, implants, intrauterine devices, and referral for tubal ligation and vasectomy services. Prior to

the intervention, condoms were available in the HIV clinic, and clients interested in other methods were referred to the family planning clinic. Several months prior to the in-depth interviews, lay counselors had begun to deliver family planning educational talks in the waiting area of the HIV clinic.

Among this population of HIV-positive men, the most common barriers to supporting their partner's use of contraception included concerns over side effects, lack of knowledge of contraception methods, and myths and misconceptions including fear of infertility. Some, but not all, of the barriers to family planning uptake cited by men could be addressed through strengthened family planning education, counseling, and service provision within the HIV clinic. A related baseline study conducted among HIV-positive women at the same HIV clinics in Kenya found that women reported similar barriers to family planning. The main difference was that women often stated that they did not use family planning or used it clandestinely due to partner opposition to family planning [27]. However, surveys of men and couples show that men are more likely to report contraceptive use than women, and men and women often have similar attitudes about family planning [28]. Misperceptions by women of husbands' attitudes, indicating absence of discussion, might be a more significant barrier to use.

Currently condoms, withdrawal, periodic abstinence, and vasectomy are the only options that require use or cooperation by men. These methods, with the exception of vasectomy, do not require interaction with the family planning service delivery system or a provider. A few men reported the need for more male-focused approaches and talked about the frustration that there were no more reversible male-controlled methods. The fact that we are still far from the development of a widely used, effective, and acceptable reversible male contraceptive [29] perpetuates male exclusion from family planning services and utilization of family planning. Additionally, the perception that the maternal and child health clinic is only for women and children has been raised as a barrier for male involvement in a variety of reproductive health services, including family planning and PMTCT [30]. Integration of family planning into HIV care may prove to be a way to allow more men to receive family planning education and counseling in a more neutral, less gender-biased way.

Family planning education provided in the waiting area of the HIV clinics reached both men and women. When HIV and family planning services are integrated, couples accessing HIV care in the same clinic could also attend family planning couple counseling sessions within the HIV clinic. We believe this has the potential to increase the number of men who participate in family planning discussions with their partners; however, since this is a baseline study, we do not know how it will impact use of contraception. Unfortunately, couple-based ART services are not routinely provided in this setting, unless upon request. We did not measure the extent that couples were accessing ART services together.

Inclusion of men in family planning counseling and education, however, is not enough to overcome the gendered power dynamics that impact contraception use. Differences in perceptions of gender equitability and gendered-power based differentials within relationships have been found to impact contraception use by women in western Kenya [31]. In order to successfully involve men in integrated family planning and HIV services, programs must be developed that take into account men's fears and vulnerabilities related to family planning. As has been seen in the field of HIV prevention [32, 33], it is not enough to focus on the empowerment of women to use condoms, or more effective contraception in this case, but programs must work towards transforming traditional gender roles and expectations in order to create a more egalitarian and supportive basis from which men and women can be empowered to make family planning decisions together.

Many of the study findings are relevant to all Kenyan men living in the region, independent of one's HIV status, such as concerns over side effects, lack of knowledge of contraceptive methods, and myths and misconceptions. Gendered-power-based differentials within relationships are also common in the general population. However, HIV infection may impact fertility desires, and concerns over HIV infection to children and partners may influence contraceptive choices. Of course, one important difference is that HIV-positive men accessing HIV care and treatment are already having regular contact with a clinical service, which may not be the case for HIV-negative men. We were particularly interested in whether these HIV-positive men in care would be receptive to receiving education about family planning, as well as services for them and their partners, in this setting.

Although providing family planning services in a location where men are already accessing HIV services will increase the likelihood of reaching men, a more couple-oriented approach to family planning is also needed. Many men reported their interest in attending their partner's family planning clinic visit, but it is yet to be seen if integrated services will improve couple-based counseling and decision making.

Additional strategies to improve the number of men who engage in family planning services include recruiting males as family planning providers and offering more family planning counseling for couples at home. HIV-positive men and women who are using contraceptive methods could be invited to contribute to family planning education talks at the clinic and in the community to promote female-oriented methods with men and vice versa. This is particularly important given that although clinic staff might be respected for their technical competence, the experiences of friends and family with contraceptive methods are far more influential [34, 35]. Additional efforts are also needed to provide balanced education and counseling, recognizing varying fertility desires. It is also important to recognize that some men and couples may need services to help them get pregnant using safer conception practices, noted by one man regarding his wife's repeated miscarriages and pregnancy complications. Although the majority of men in this study had disclosed their HIV status to their primary partner or spouse and majority of the men were in seroconcordant relationships, it is critical to tailor educational and counseling message to the individual couple's needs because disclosure and the HIV serostatus of the couple may impact their fertility desires and interest and use of contraception.

This exploratory study has several limitations. There may be a sample selection bias, and the men interviewed here may have differed in their attitudes towards accessing or utilizing family planning services within the HIV clinic than other men. Most men in our study had never accompanied their spouse to a family planning visit, and therefore most of the concerns and perceived barriers stated are hypothetical or based on actual experiences reported by their spouse. Furthermore, our participants were already accessing HIV care; we did not include HIV-positive men from the community not in care, or men of unknown HIV status, who may have different perspectives. Given that these men were recruited from clinic sites and might have associated interviewers with care providers, there is a risk that their responses were influenced by social desirability bias. Though theoretical saturation was reached around all main themes, some concepts could not be fully developed due to the small sample size. For example, since the majority of participants had not accessed formal family planning services, we could not fully assess perceived provider attitudes and/or family planning-related stigma. Finally, nuances of language and nonverbal communication strategies may have been lost or misinterpreted during the process of data transcription and translation.

Integration is a promising strategy that needs to be rigorously evaluated to measure the impact on unmet need for contraception among HIV-positive women and their partners. This study supports integrating family planning into HIV care and suggests that men would like family planning services available in the HIV clinic and that the HIV clinic provides a unique environment by which to facilitate male involvement in family planning. As countries roll out family planning integration into HIV clinics, it will be important to ensure that these programs develop in a manner that reaches both men and women with family planning information and services and provides a space for couples to discuss fertility intentions and contraception.

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Research Article

A Community-Supported Clinic-Based Program for Prevention of Violence against Pregnant Women in Rural Kenya

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Objective. Pregnant women are especially vulnerable to adverse outcomes related to HIV infection and gender-based violence (GBV). We aimed at developing a program for prevention and mitigation of the effects of GBV among pregnant women at an antenatal clinic in rural Kenya. *Methods*. Based on formative research with pregnant women, male partners, and service providers, we developed a GBV program including comprehensive clinic training, risk assessments in the clinic, referrals supported by community volunteers, and community mobilization. To evaluate the program, we analyzed data from risk assessment forms and conducted focus groups ($n = 2$ groups) and in-depth interviews ($n = 25$) with healthcare workers and community members. *Results*. A total of 134 pregnant women were assessed during a 5-month period: 49 (37%) reported violence and of those 53% accepted referrals to local support resources. Qualitative findings suggested that the program was acceptable and feasible, as it aided pregnant women in accessing GBV services and raised awareness of GBV. Community collaboration was crucial in this low-resource setting. *Conclusion*. Integrating GBV programs into rural antenatal clinics has potential to contribute to both primary and secondary GBV prevention. Following further evaluation, this model may be deemed applicable for rural communities in Kenya and elsewhere in East Africa.

1. Introduction

Gender-based violence (GBV) is a major source of preventable mortality and morbidity for women globally [1–3]. In Kenya, 47% of ever-married women report having ever experienced emotional, physical, and/or sexual violence from their spouse—among the highest rates in the world [4, 5]. Violence towards pregnant women in Kenya is estimated to be 13.5% [6], a higher prevalence than many conditions routinely screened for during pregnancy [7]. Global research suggests that when pregnant women experience GBV, there is a higher likelihood of miscarriage [3, 8], premature labor [9], low birthweight [8, 10, 11], and infant death [12]. Demographic Health Survey data from Kenya suggests that experiencing lifetime GBV is associated with child stunting and under-2 mortality [12].

GBV is also a driver of the global HIV epidemic, particularly in sub-Saharan Africa where women are disproportionately at risk of both GBV and HIV infection. GBV increases risk of HIV acquisition [13, 14], and HIV-positive women are more likely to experience GBV than their HIV-negative counterparts [15]. Pregnant women are especially vulnerable to the intersecting risks and adverse outcomes related to HIV infection and GBV. There is evidence that pregnant women have a higher risk of HIV acquisition and transmission than other women [16, 17].

In addition to direct effects of GBV on maternal and child health, GBV may indirectly worsen health by reducing pregnant women's uptake of essential maternity and HIV services. In Kenya, women who anticipated partner stigma or violence were more than two times more likely to refuse HIV testing during antenatal care [18]. HIV-positive women who fear violence or a relationship breakup are less likely to enroll in HIV care [19] and may choose not to deliver at health facilities for fear of violence triggered by HIV testing or unwanted disclosure [20, 21]. A pregnant woman is often the first family member to be tested for HIV due to her contact with health services, putting her at disproportionate risk of suffering from HIV-related stigma and discrimination, in some cases leading to violence [22]. We have found that important triggers of GBV experienced by pregnant women in rural Kenya are testing for HIV without the husband's permission and disclosure of HIV-positive status during pregnancy [23].

Despite growing recognition of the urgent need for primary and secondary prevention of GBV, there are few best practices for integrating GBV services into primary healthcare settings in low- and middle-income countries [24]. Of the existing healthcare interventions for GBV identified in recent systematic reviews, none are located in sub-Saharan Africa [25, 26]. The knowledge base is especially limited for rural settings, as existing GBV services are generally urban and hospital-based [24, 27, 28].

There is an urgent need to integrate GBV programs into health services in rural areas and to link them with existing community structures and support services [24, 29]. In "systems-level integration," basic services, such as screening and medical care, are delivered at one facility, with external referrals to other facilities for specialized services [24]. Our team developed and piloted such a systems-level integrated program at the primary-care level. The integrated program aimed at (a) offering risk assessment, medical care, and supported referrals for pregnant women experiencing violence at the clinic-level (secondary prevention) and (b) influencing social norms at the community level to prevent GBV (primary prevention). Findings from the formative research conducted to inform creation of the program are presented elsewhere [23]. Here, we describe the integrated GBV program conducted at a rural primary-care facility in Nyanza Province, Kenya, and present data for evaluation of the program.

2. Methods

2.1. Setting. Kenya is one of the sub-Saharan African countries greatly affected by HIV and AIDS [30]. Nyanza Province has the highest HIV prevalence in Kenya, with 15% of persons 15–49 years of age testing HIV positive [31]. It also has the highest reported prevalence of physical violence against women in the nation, with 57% of women in Nyanza aged 15–49 reporting having ever experienced physical violence since age 15, and 36% of these women reporting physical violence in the past 12 months [4]. Sixty percent of ever-married women aged 15–49 in Nyanza report ever having experienced emotional, physical, or sexual violence committed by their husband partner (39% reported emotional, 51% physical, and 22% sexual) [32]. This study was conducted in collaboration with Family AIDS Care and Education Services (FACES), a PEPFAR-funded program that supports over 100 government health facilities in Nyanza Province in HIV prevention, care, and treatment efforts. The program was carried out at a government primary healthcare clinic, which provided all standard primary healthcare services (including antenatal care) as well as HIV care and treatment.

2.2. Program Approach. We followed the six-step process recommended by the WHO for implementing intimate partner violence (IPV) and sexual violence prevention programs [29]. As illustrated in Table 1, we first conducted formative qualitative research, including focus groups with pregnant women and male partners and in-depth interviews with a range of service providers, to learn about pregnant women's experiences of GBV in this rural Kenyan setting [23]. We then convened key stakeholders (representatives from the Ministry of Health, Ministry of Gender and Social Services, nongovernmental organizations (NGOs), faith-based organizations (FBOs), FACES, the police, the judiciary, political leaders, and local community leaders) to review existing models and obtain guidance for developing a GBV program for the rural primary healthcare setting. The insights gained from stakeholders were then used to adapt several existing GBV curricula [33–36] and create a cohesive program package that included (1) building the capacity of health workers, (2) bolstering multisectoral linkages, and (3) enhancing community GBV awareness, with a special focus on reaching men.

We conducted a pilot of the program in one community in rural Nyanza Province, during the period November 2010–February 2011. The pilot program was carried out in four phases (see Figure 1) and included both clinic- and community-based activities. No GBV screening or referrals were being conducted at the facility prior to the initiation of this program.

In Phase 1, we built the skills of local community partners (administrative, religious, social, and traditional leaders) to respond to GBV. In a two-day workshop, local partners learned about GBV and effects on health, mapped out their neighborhood, discussed existing (often informal) services that could be supportive of GBV victims, and established a local referral tree.

In Phase 2, we trained all clinic staff (including administrative staff, community volunteers, and lay health workers) through a 40-hour training program. Topics covered in the training included gender and human rights, GBV sensitization, links between GBV and HIV, HIV-related stigma, role of the health sector, privacy and confidentiality, IPV screening tools and techniques, sexual violence and postrape care, supported referral protocols, provider safety and self-care, and communication skills. Two new program tools were developed to facilitate links between the clinic and community. The first was a "risk assessment form," based on formative research and existing GBV screening tools from South Africa and the United States [37–39]. This form was used to collect data on GBV cases and referrals and served

Table 1: Approach for implementing an integrated community-supported clinic-based GBV program.

Implementation steps*	Methods	Key findings
(I) Establish relationships with key partners	Conducted initial discussions with key stakeholders	Local Ministry of Health and FACES leadership were interested in developing methods to address GBV within health services
(II) Define the nature of the problem	(i) FGDs† with pregnant women ($n = 4$ groups) and male partners or relatives of pregnant women ($n = 4$ groups) (ii) IDIs† ($n = 20$) with Ministry of Health, Ministry of Gender and Social Services, NGOs, FBOs, health service providers, police, judiciary, and community leaders	(a) Specific types of GBV commonly experienced by women in this setting: beating, forced sex, verbal abuse, denial of reproductive choice, neglect, and being kicked out of their homes (b) Triggers for GBV include woman making decisions (e.g., HIV testing) without partner consent, woman failing to perform household duties, man for misallocating money, woman disclosing HIV status, either partner using alcohol, and either partner is suspected of infidelity (c) Help-seeking behaviors: women were often reluctant to press formal charges, and in many cases preferred to use more informal community and family mechanisms. (d) Local resources do exist for GBV, but those that do exist tend to be weak or inefficient and lack linkages to one another (e) Primary healthcare workers are trusted service providers, already being accessed by pregnant women in rural areas, and are a potential resource for primary and secondary prevention of GBV.
(III) Identify potentially effective programs	Convened stakeholders to review existing GBV curricula	Relevant portions of GBV curricula for health workers from Kenya, India, South Africa, and Latin America were identified.
(IV) Develop policies and strategies	Designed locally relevant program using formative research and stakeholder input	Components of an effective program, as defined by stakeholders, were as follows: (a) building capacity of health workers, (b) bolstering multisectoral linkages, (c) enhancing community sensitization and awareness (with a special focus on reaching men)
(V) Create an action plan	Established program model	(See Figure 1)
(VI) Evaluate learning	Conducted a mixed-method evaluation using focus groups ($n = 2$ groups) and clinic data on screening and referral	(See Section 3)

*Adapted from the WHO [29].
†FGDs: focus group discussions; IDIs: in-depth interviews; NGOs: nongovernmental organizations; FBOs: faith-based organizations.

as a guide for healthcare providers on appropriate counseling and referral strategies. The second tool was a specialized "referral tree" containing guidance and contact information for community partners and local resources. Community-based activities during this phase included organization of a local baraza (community meeting held by a local chief) where anti-GBV messages adapted from the Raising Voices curriculum [40] were communicated through posters, speeches, and skits by community groups.

In Phase 3, the clinic staff began to screen all pregnant women visiting the antenatal care clinic, where women are also tested for HIV and received prevention of mother-to-child transmission (PMTCT) interventions. In lieu of providing all necessary GBV services in the clinic, community volunteers were trained to offer "supported referrals" to services that already existed in the province. Supported referrals are distinct from ordinary referrals because community volunteers offer concrete assistance for reaching referral services in the community or the nearest town, including provision of transport costs, personally escorting women to services, telephoning ahead and offering emotional support. Existing resource persons included medical professionals trained in GBV, community elders, chiefs, counselors, church leaders, police, and a probono lawyer. The community volunteers, called Community Referral Persons (CRPs, 2 women and 3 men), assisted with phoning ahead, escorting women to services, and facilitating reimbursement for transport fare (often a key barrier to accessing support in rural areas). Limited funds were available to support transport costs for clients and CRPs to reach referral agencies in the nearest town, cell phone costs for health workers, and CRPs to communicate with each other and referral agencies and for biweekly meetings of the CRPs led by FACES Coordinators. Throughout this phase, community mobilization events in different parts of the clinic catchment area were conducted by members of the FACES team and the CRPs.

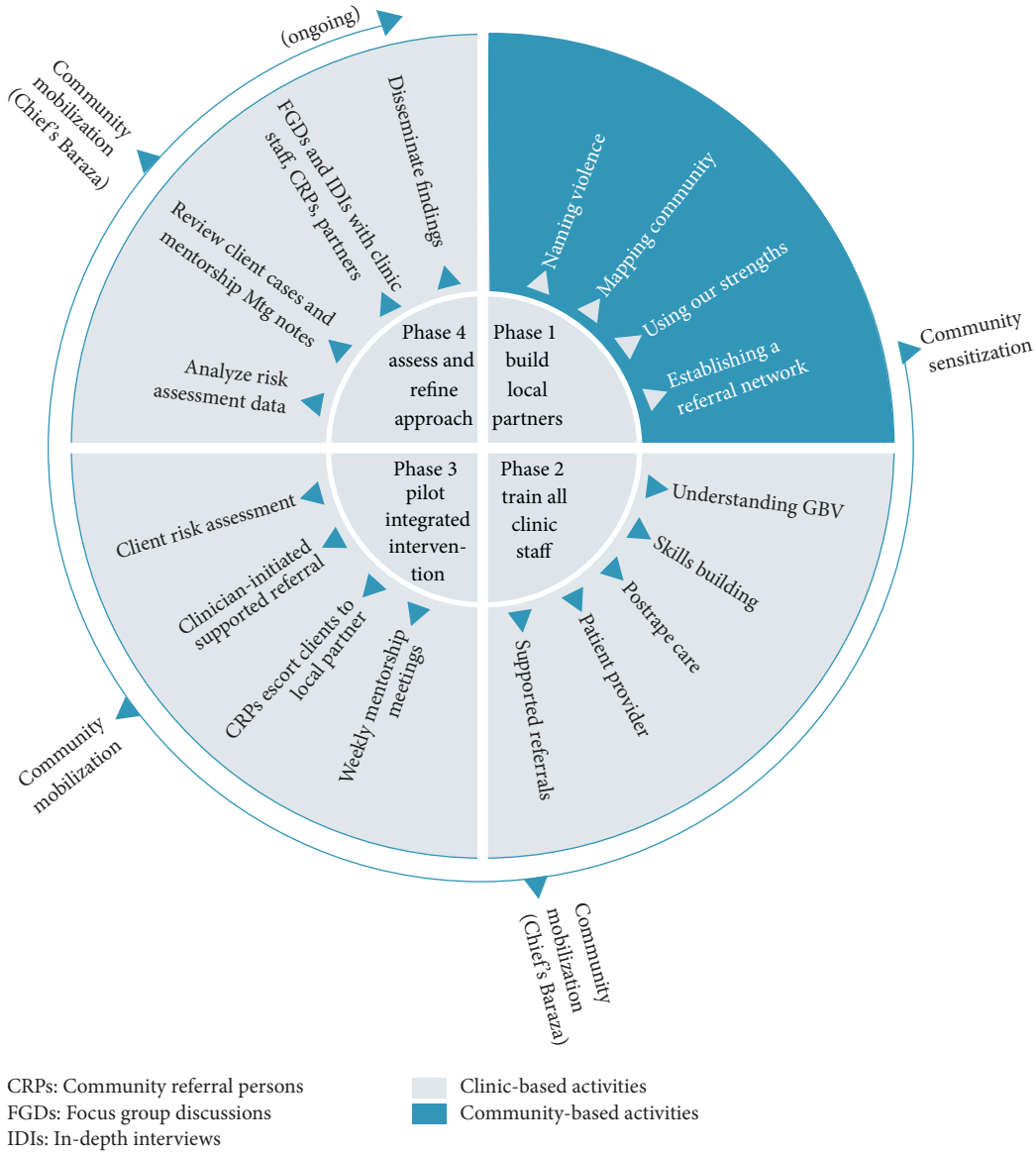

Figure 1: GBV program components.

During Phase 4, we conducted an evaluation of the pilot program by examining risk assessment forms and conducting focus groups and in-depth interviews with community and clinic participants. Evaluation methods and findings are described in detail below.

2.3. Evaluation Methods. Due to limited resources and ethical considerations, we conducted a small-scale mixed methods evaluation using anonymous screening from data and qualitative research methods. Although we collected significant data from pregnant women at baseline to inform the design of the program [23], we were not able to trace women who reported violence to collect quantitative data on the outcomes of GBV referrals. In order to avoid putting women at any additional risk due to research procedures [41], we chose to collect stories of the women assisted during confidential in-depth interviews with the community referral persons and other service providers.

Quantitative. GBV risk assessment questions routinely asked of antenatal clients during the pilot included the following. (1) If you told your partner that you came here for health services today, would s/he react angrily or negatively? (2) Has your partner or another person close to you: *(a) Pushed, grabbed, slapped, choked hit or kicked you? (b) Threatened to hurt you, your children or someone close to you? (c) Taken away money/resources that you/your children need to survive? (d) Sent you back to your maternal home, (e) Forced you to have sex when you did not want to?* (3) Has your partner tried to get you pregnant when you did not want to be? (4) If you

wanted to use a condom or another family planning method, would you be afraid to ask your partner? (5) Are you worried your partner (or another person close to you) will be angry and/or hurt you if s/he finds out you were tested for HIV? (6) Do you feel unsafe returning to your home today? Clients answering "Yes" to any of these questions were considered to be at risk of or experiencing GBV. These anonymous risk assessment forms were completed by the health providers (clinical officers and nurses, both male and female) during antenatal visits at the clinic. The healthcare providers read the questions to the women (in her preferred language) and women orally provided answers that were recorded on the form. Risk assessments took place in a private room in the antenatal clinic, and no other staff or patients were present. Data from these forms ($n = 134$) were examined and simple descriptive statistics were conducted to identify monthly numbers and trends in screening, cases identified, and referral after the initiation of the program activities.

Qualitative. Focus groups with clinic staff and community members were conducted after the program had been active for two months. Participants (2 groups; $n = 17$ participants, both genders) were purposively selected from those who participated in or were affected by the GBV program and included health workers from the clinic, the CRPs, FACES Coordinators, local administrators, church and community leaders, elders, and local nongovernmental organization representatives. Each focus group included a mixture of participants from these target groups. The groups were led by an experienced qualitative researcher in Dholuo or English language (both languages are widely spoken in the district) using a moderator's guide and were audio-recorded after obtaining permission from the participants. Topics included feedback on the overall GBV program approach, the training received, the process of supported referrals; the impact of the program on the clinic, clients, and community; and suggestions for improvement.

In addition, 5-6 months after the program activities were initiated, we conducted a series of in-depth interviews with key informants (6 women and 19 men) who had been involved in the program. Types of informants included health workers at the clinic ($n = 5$); Ministry of Health, police, and other community, district, and service leaders ($n = 10$); CRPs ($n = 5$); and FACES staff ($n = 5$). These interviews were conducted in English by an experienced qualitative researcher using an in-depth interview guide developed by the research team and were audio-recorded after obtaining permission from the participants. Topics in the interview guide included the participant's role in the community and their overall impression of and role in the program; experiences with GBV risk assessment and the referral process; views on addressing GBV in the community; and facilitators and barriers to program success.

Audio files were transcribed in the original language (Dholuo or English) and then translated to English if necessary by experienced translators based in Kenya. The English transcripts were coded by two researchers in QSR NVivo 9, using a thematic approach to data analysis [42]. An initial coding framework was developed based on several sources: the research questions, data collection themes, and the current literature. Following the development of this initial framework, two authors coded all transcripts according to the identified "broad codes," which represent wide thematic baskets of ideas [43]. Next, the research team held a series of phone meetings to jointly develop "fine codes" using a grounded theory approach [44]. Two authors then applied the final list of "fine codes" to two separate QSR NVivo databases. A preliminary research report was created by printing out excerpts related to each code, reviewing the text for any divergence of opinion and summarizing the views of participants alongside illustrative quotes.

Ethical Considerations. All participants were taken through an informed consent process and provided verbal informed consent to participate in the research. Ethical approval for this study was obtained from the Kenya Medical Research Institute (KEMRI), the University of California, San Francisco (UCSF), and the University of Alabama at Birmingham (UAB).

3. Results

3.1. Screening and Referrals. A total of 134 women were screened in the ANC clinic during the months December 2010 from April 2011. Forty-nine women (37%) reported some type of violence or risk of violence (physical, sexual, and/or psychological). Of the 134 forms, 24 (18%) included a report of physical violence (pushing, grabbing, slapping, choking, hitting, and kicking), 23 (17%) sexual violence (forcing sex), 26 (19%) psychological violence (threatening own safety or children/persons close to you), and 15 (11%) economic violence (forcing out of home or taking away money/resources you or your children need to survive).

Of those reporting violence, 26 (53%) accepted referrals to support resources in the province (not all women reporting violence wanted to take any action). Support was provided for these women to access these support resources including referrals to community referral persons (23 women), police in the nearest town (4 women) (for filing paper work—the P3 form—to make a formal complaint against the perpetrator of the violence), local government administrators (3 women) (to help with needs for shelter and food), nongovernmental organizations working on women's rights (2 women) (for counseling), a probono lawyer (1 woman) (for those who wanted to pursue legal action), and village elders (1 woman) (for help with communication with the husband and family).

Examination of numbers of risk assessment forms, including the two months after the initial pilot period ended in February, indicated that the volume of screening in the ANC clinic declined over time, although the number of ANC visitors remained relatively stable (Figure 2). Characteristics of the GBV cases described by the CRPs during in-depth interviews are presented in Table 2.

3.2. Evaluation Focus Groups and In-Depth Interviews with Healthcare Providers and Community Service Providers. The major themes that emerged from the qualitative data analysis

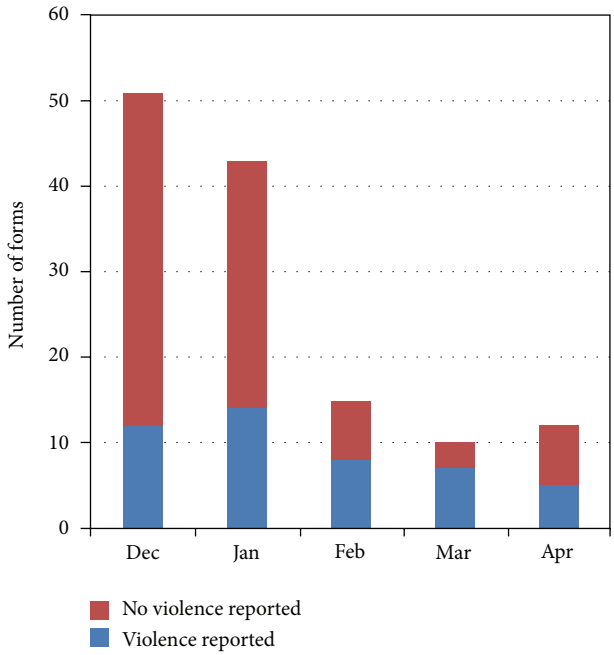

Figure 2: GBV screening by month, December 2010–April 2011.

Table 2: GBV cases handled by community referral persons (n = 33).

Characteristic	Number of cases
Gender	
Female	30
Male	3
Who referred to CRP	
Clinic	10
Local administrator	8
Village elders	2
Client came directly to CRP	13
Type(s) of violence	
Physical only	12
Sexual only	6
Emotional only	1
Economic only	6
Physical and emotional	1
Physical and economic	5
Physical and sexual	1
Supported referral made to	
District hospital	3
Counselor at women's NGO	9
Probono lawyer	3
Local clinic	6
Local administrator	5
Police	1
Pastor	2

included: changes in community GBV awareness, the role of screening at the health facility in facilitating women's access to GBV services, the importance of community collaboration, social risks in the community for persons working to prevent and address GBV, and challenges to program success.

3.2.1. Theme 1: The Community Gained Awareness of GBV Services and Consequences for Perpetrators. The participants felt that the GBV program had begun to make a difference in the community. Victims of violence had become aware that there was a way to get help, and perpetrators of violence were learning that there were consequences of partner violence. Several interviews and focus group discussions highlighted the benefit of simply knowing where to receive GBV-related services:

> *At least they know there are people somewhere who are out for women. At least there is somewhere where women can file their cases when they are battered, so at least there is a change, they are getting to know that they should do the right thing at the right time, it is not like those days when they use to beat us. (Focus Group #2, Respondent #4)*

One participant explained that the program raised awareness of the consequences of perpetrating violence, creating a disincentive for men to use physical GBV towards their partners:

> *It's not the same, because now men fear beating women or doing such violence because they know they may be arrested or there may be steps taken for them if they do that. (In-Depth Interview participant #11)*

3.2.2. Theme 2: Screening for GBV at the Health Facility Opens the Door to Accessing Services. Participants saw benefits to screening at the health facility in rural areas, as women commonly access health clinics but may be less familiar with other available services for GBV. In several focus group discussions, participants explained that GBV screening offered a crucial first step for assisting women with violence:

> *This program can be so nice such that at every health facility, any woman walking there can be able to be screened and then any gender-based violence can be identified and then they can be helped... And that can only be generated from the screening and when the screening is not done at that [health] facility level, then you cannot get the other proceedings. (Focus Group #1, Respondent # 5)*

3.2.3. Theme 3: Community Collaboration Can Help GBV Victims in Low-Resource Settings. The involvement of community partners in the GBV program resulted in the ability to find local solutions to help victims, even in this rural setting where there is no battered woman's shelter and limited formal resources for GBV. One participant in a focus group explained how they leveraged space in the chief's home as a way to provide a woman safety while she decided on her next move:

> *We accommodated the lady I think for two to three days in the chief's home. He is a simple man, so that is where she stayed, she took a bath she was feeling good... The same lady came back to me and then I found for her shelter with a neighbor, ... so I went and talked to that lady and she stayed with her for three days. (Focus Group #1, Respondent #9)*

3.2.4. Theme 4: Those Working to Prevent GBV May Face Negative Community Judgment. Although the health workers and CRPs felt empowered by the training and felt they were doing good in the community, some found the work challenging and were criticized by other community members (especially men) because of their new role:

> *So when somebody is saying that women are not supposed to be beaten, that... they should go to somebody and take some action, in the community it is like that person is acting against the will of the community. To the men it is like he is an outcast in the community, an outlaw who is not supposed to be there.... In social places you will hear them saying that he is not a good person because if he is preaching to our ladies and women to take action against us, then it is like he wants to bring a revolution, women are going to overpower us and then we are going to be voiceless. (Focus Group #1, Respondent #8)*

In order to carry out this work more effectively, most participants stressed the need for repeated refresher trainings and sensitization for service providers and local partners (including local administration and police) as well as additional counseling skills for CRPs and health workers.

3.2.5. Theme 5: Despite the Gains, Structural Challenges Remain. Despite their successes, the participants discussed many continuing challenges to addressing GBV in their community. They explained that socioeconomically disempowered women were reluctant to press charges against a violent husband for fear of "breaking the family" and subsequently being left without a home or resources. Some service providers mentioned that they, as well as the women, often preferred to "solve things at home" instead of seeking outside help. Extended family members and village elders (those who had not participated in the local partners meeting) in some cases supported the violent man over the woman. Several participants explained that criminal and legal procedures for reporting GBV cases could not be completed locally but had to be carried out in the nearest town, resulting in difficulties in pressing charges and delays in action:

> *Sometimes you get a woman has been beaten by her husband. And when she comes here to report, she reports the matter. Then you start to give her P3 [official violence reporting form]. When she goes home, she's threatened by the family of the husband: "If you go ahead with that case, you are not going to stay. You'll not be here. We will chase you away, if our brother is arrested. (In-Depth Interview participant #20)*

The forms of resistance to this type of program underscore the need to include local partners and community-level education in order to facilitate acceptance of a clinic-based approach to GBV.

4. Discussion

The current study suggests that an integrated program in a rural primary healthcare setting in Kenya is acceptable and feasible to both healthcare providers and the surrounding community. Initial assessment suggests that the program has potential to contribute to both primary and secondary prevention of GBV. The program addressed many of the barriers that have been cited as inhibiting the health sector response to GBV, including lack of provider knowledge, insufficient staff training, few existing policies, poor management support for GBV response, and a lack of coordination between the health sector and other services [24, 45]. We found that healthcare providers and community members were motivated to address the issue of GBV and the program was perceived as a positive contribution to their community.

The program harnessed an important "window of opportunity" among pregnant women attending a rural antenatal clinic. Women in their reproductive years use medical services more frequently than at any other time [7]. This places healthcare providers in a position to build on-going relationships with pregnant women, a prerequisite for identifying and supporting women experiencing violence [46].

The 40-hour training program for all clinic staff and the community volunteers seemed to provide the necessary skills for this type of GBV risk assessment and referral work, although periodic refresher trainings would be necessary to address gaps in skills and maintain these tasks over time. As has been found elsewhere [47], data from the risk assessment forms and the focus groups indicated screening in the ANC clinic declined over time after the training. The focus group and in-depth interview findings indicate that clinicians ultimately may have used more of a "case finding" approach, assessing some clients and not others. Case finding, based on the presentation of specific signs or symptoms of abuse, may be preferable for resourced-constrained settings [48]. Larger systems and structural factors, such as regulations requiring forms for reporting violence (P3 form) to be obtained in the nearest town, were difficult to tackle in this small local pilot.

We also found that community collaboration was crucial to the success of the program in this low-resource setting without any shelters or other formal resources for victims of violence. It is recognized that effective GBV referral services need to offer more support than simply handing women a sheet of paper with a list of potential resources [49]. The necessity of engaging the broader community in GBV is increasingly recognized as an essential addition to sub-Saharan African programming [40] and represents an important adaptation from resource-rich settings, who have

historically created clinic-only approaches to GBV during pregnancy [50, 51].

Certainly this program did not address all the challenges to primary and secondary prevention of GBV in this setting. A preference among both service providers and clients to "solve things at home" and use "family mediation" approaches to help the couple to live peacefully may be problematic, especially in severe situations when the woman's life is in danger [52]. This finding is consistent with global GBV research showing that women often prefer informal, family-based mechanisms to formal, legal responses [53, 54]. Importantly, as program service providers began to see GBV as a health issue within their scope of work, women also started to change their expectations around the intractable nature of GBV. This is consistent with other findings that shifting service provider attitudes and perceptions are crucial for altering women's acceptance of GBV services [55].

Implementing this pilot GBV program using a six-step process as recommended by the WHO [29] has important strengths. Local stakeholders were involved in the process from the beginning. The design and content of the pilot program was based on formative research in communities where the services were to be instituted and built on successful models for training health workers in GBV that have been used elsewhere [33, 36]. Training of the entire staff of the health facility was important, especially for a resource-constrained setting where patients often rely on nonclinician staff for advice and assistance. Although clinicians conducted the GBV screening, nonclinicians were involved in giving information and support. The involvement of the whole clinic may also increase provider commitment and sustainability of the program [56].

However, it should be noted that the pilot was conducted in only one community/clinic, and some special features of this setting may make the strategy less generalizable. Although we built in program evaluation, using anonymous risk assessment form data, focus groups, and in-depth interviews, we were not able to collect data directly from ANC clients on their experiences with the screening and the GBV program. Although we have clinic data on screening and referrals and a wealth of stories from the research participants on the outcome of the GBV cases identified, we were not able to follow women or collect any quantitative data on the outcomes of GBV referrals. Some of these limitations were due to resource constraints, while others had to do with the highly sensitive nature of this topic and the need to avoid putting women at any additional risk due to research procedures [41]. In addition, we did not collect representative quantitative data on the community response to the intervention. Future studies should use ethical and sensitive methods to determine the effects of such GBV screening and referral programs on both community attitudes and outcomes for women. Future research can be guided by the cluster randomized trial design that is currently being used to evaluate community response to *SASA!* Program for preventing violence against women and HIV infection in Uganda [57]. Although the program was clearly of low-cost, as it used existing staff and infrastructure as well as volunteer work, we did not collect specific cost data nor conduct cost or cost-effective analyses.

5. Conclusions

We integrated a GBV program into a rural antenatal clinic that also provides HIV testing and PMTCT services with the participation of the community and primary healthcare workers. This program was found to be acceptable and feasible and has potential to contribute to primary and secondary prevention of GBV. This model may be applicable to address GBV in the multitude of rural communities in Kenya and elsewhere in sub-Saharan Africa, where the majority of the African population live [58]. If this strategy can be scaled up to other primary healthcare clinics, it has potential to impact on the intersecting epidemics of GBV and HIV.

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Review Article

Developing Multipurpose Reproductive Health Technologies: An Integrated Strategy

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Women worldwide confront two frequently concurrent reproductive health challenges: the need for contraception and for protection from sexually transmitted infections, importantly HIV/AIDS. While conception and infection share the same anatomical site and mode of transmission, there are no reproductive health technologies to date that *simultaneously* address that reality. Relevant available technologies are either contraceptive or anti-infective, are limited in number, and require different modes of administration and management. These "single-indication" technologies do not therefore fully respond to what is a substantial reproductive health need intimately linked to pivotal events in many women's lives. This paper reviews an integrated attempt to develop multipurpose prevention technologies—"MPTs"—products explicitly designed to *simultaneously* address the need for both contraception and protection from sexually transmitted infections. It describes an innovative and iterative MPT product development strategy with the following components: identifying different needs for such technologies and global variations in reproductive health priorities, defining "Target Product Profiles" as the framework for a research and development "roadmap," collating an integrated MPT pipeline and characterizing significant pipeline gaps, exploring anticipated regulatory requirements, prioritizing candidates for problem-solving and resource investments, and implementing an ancillary advocacy agenda to support this breadth of effort.

1. Introduction

The combined burden of maternal and infant mortality and morbidity produced by unintended pregnancies and sexually transmitted infections—individually and as a consequence of their multiple interactions—is compelling in its volume, extent, and complexity. For an array of behavioral, biological, physiological, and sociocultural and political reasons, most of that burden falls on women in developing countries. In those countries, of the 80 million unintended pregnancies estimated for 2012, 63 million will occur among the 222 million women defined as having an "unmet need" for modern contraception [1]. Those unintended pregnancies will, in turn, result in 30 million unplanned births; 10 million miscarriages, including stillbirths; and 40 million abortions, of which one-third to one-half will be unsafe. Women aged 15–19 are at particular risk of these events [2].

Sexually transmitted infections (STIs) further compound these burdens, with which they are relentlessly intertwined. The World Health Organization estimates that 448 million new cases of the curable STIs (trichomoniasis, chlamydia, gonorrhea, and syphilis) occur annually in adults aged 15–49 years [3]. Cases of the major incurable viral diseases—genital herpes (HSV-2), human papillomavirus (HPV), and HIV-1—account for an even greater burden of both morbidity and mortality. The estimated number of people aging 15–49 years living with HSV-2 worldwide in 2003 was 536 million, with overall prevalence higher in women than in men [4]. Each year an estimated 493,000 women are diagnosed with cervical cancer, largely attributable to HPV infection; over 273,000 die

from the disease, 234,000 of those in developing regions [5]. Lastly, there is HIV, with 2.7 million new infections in 2010, of which, in many regions and subpopulations, women account for over half.

Over 20 years ago, a seminal review described the relationship between the "classical" STIs and HIV-1 as an essentially lethal "epidemiologic synergy" [6]. The authors presented persuasive evidence that both ulcerative and nonulcerative STIs significantly promoted HIV transmission by augmenting HIV infectiousness and susceptibility, concluding that STI treatment should therefore be an essential component of HIV prevention strategies. Yet, while subsequent studies continued to document and elucidate those relationships, interest in addressing the relationship between STIs and HIV-1 waned, primarily because it has "proven nearly impossible to reduce the spread of HIV-1 through directed or empirical treatment of STDs" [7].

Addressing contraception and STI prevention in meaningfully coordinated fashion has had limited success, even given potential cost savings [8]. Typically, women must seek care for contraception and HIV prevention from separate health facilities and different providers, and examples of truly functional integration of HIV, STI, and family planning services remain rare. Such efforts can be organizationally and/or financially difficult to implement and HIV-associated stigma may act as an additional barrier.

The premise of the work reported here is that multipurpose prevention technologies—"MPTs"—addressing more than a single reproductive health indication with a single administration would offer an additional route to integrated reproductive health. Potential components for such products exist, some already commercially available; new components and formulations are also likely to be required. MPTs could comprise combinations of HIV prevention technologies with agents having contraceptive activity; available contraceptives and agents active against HIV; single drugs targeting more than one indication; totally new drug combinations or combinations of drugs and devices; and/or multi-indication vaccines.

2. Materials and Methods

This paper describes an innovative process designed to advance the development of MPTs through systematic, iterative consideration of, first, the key components of a standard product development pathway and, second, different product requirements in different user populations. The organization of the account that follows below responds to the general categories proposed for the COREQ, the checklist of consolidated criteria for reporting qualitative research [9].

2.1. Research Teams. Advancing the MPT concept was expected to be scientifically, technologically, and practically challenging. Mobilization of the scientific and financial resources required for MPT development would demand a sound evidence-based argument for the need for MPTs and their plausibility as a product category, plus an integrated mix of expertise and advocacy. To that end, the Initiative for Multipurpose Prevention Technologies for Reproductive Health (IMPT) was founded in 2009 as a global coalition of multidisciplinary and multinational stakeholders, scientists, policy-makers, advocates, donors, and product developers [57]. Housed at CAMI (Coalition Advancing Multipurpose Innovations) in California, USA, the IMPT was organized as a nonaligned convener for affiliates and as an umbrella for working groups and teams with specific research and advocacy responsibilities.

The activities of the Initiative and its colleagues focus in three areas:

(1) defining an integrated MPT product pipeline and scientific agenda, as guidance for donors, product developers, regulators, and advocates about MPT scientific priorities and needs;

(2) exploring the associated regulatory pathways and anticipated needs around delivery of and access to such products;

(3) designing and implementing a strategy for communication, advocacy, and outreach to raise global awareness around MPTs as a prospective public health product.

The emphasis in this paper is on the first two of these activities and the teams formed sequentially for their implementation: the Think Tank, Drug-Drug/Drug-Device Working Group, Multipurpose Reproductive Health Vaccine Working Group, and Scientific Agenda Working Group (SAWG). The CAMI Advisory Committee and Management Group was led by the authors of this paper and was responsible for the overall conceptual guidance and management of the entire process. Figure 1 presents the chronology of team formation and key MPT process-related activities; Table 1 in the section on study design summarizes the objectives and methodology used by each team and their contributions to the strategy process.

3. Study Design

3.1. Theoretical Framework. The novelty, breadth, and complexity of the MPT concept required a comparably broad and complex methodology. The Advisory Group opted for an iterative research and advocacy strategy comprising focused consultations, surveys, qualitative data-gathering, and pipeline analysis, all informed by input from scientists, product developers, representatives from relevant geographic regions, and donors. The strategy objectives were to assess the scientific feasibility of the MPT concept, develop an "MPT Target Product Profile," and define and prioritize a scientific agenda for MPT research and development that would inform MPT investment, policy, and advocacy.

Assessing the potential of each MPT candidate according to the desired TPP was expected to (1) identify the nature and magnitude of required resources for advancing the most promising pipeline candidates, (2) flag unproductive redundancies in the overall pipeline, and (3) avoid duplication of effort or development of products that fail to meet the minimum requirements of the TPP. The intended output

Table 1: Study design components.

Teams and associated activities*	Tasks and deliverables	Data collection approach	Participants	Process contributions (summary conclusions/material outputs)
CAMI Advisory Committee and Core Management Group	Overall design and management of strategic process	Regular telephonic and internet consultation, document preparation, and review	(i) Core strategy management group ($N = 6$) (ii) Entire CAMI Advisory Committee ($N = 24$)	Series of meeting reports, circulation of survey findings, web posting of presentations, conference convening
Think Tank*	Answer 2 questions: (i) Is MPC concept scientifically feasible? (ii) If so, what is most logical and effective way to organize and prioritize the scientific agenda for MPT R&D? (Results to be discussed at International MPT Symposium, November 2011)	Document review and consultation (May 2011) (i) Review of ideal characteristics for populations most likely to benefit from MPTs (ii) Review of pipeline of relevant technologies (iii) Preliminary definition of research needs, gaps, obstacles for each MPT component	28 representatives from businesses, foundations, universities, nonprofit organizations, US government agencies (USAID, NIH, FDA)	Conclusions: (i) MPTs deemed feasible, though scientifically challenging (ii) Recommended adoption of Target Product Profile methodology for MPTs (iii) Agreed to form two teams to develop specific TPPs for (a) combination drug and drug/device MPTs and (b) multipurpose vaccines
Drug-Drug and Drug-Device Working Group	Implement strategy to: (i) Select and refine TPP critical attributes and appropriate parameter ranges for high-impact MPTs in these product categories (ii) Expand understanding of regional needs and priorities for MPT development	"Snowball" series of surveys, ePolls, qualitative interviews, consultations, invited presentations, consultations, and reviews of successive iterations of TPP parameters and criteria (March 2011–January 2012)	Key populations: reproductive health and HIV research experts and advocates from Asia, Africa, Europe, United States, including (i) 593 US health care providers (Association for Reproductive Health Professionals (ARHP) 2011 Conference) (ii) 289 African health care providers (International Family Planning (ICFP) 2011 Conference) (iii) ~120 participants, MPT 2011 Symposium	Consensus derived from each survey analyzed to construct consensus TPP for presentation, discussion, feedback from participants in International MPT Symposium (November 2011, Washington, DC) and >60 participants at Global Forum on Multipurpose Prevention Technologies (London, UK, January 2012)* for discussion
Multipurpose Vaccine Working Group	(i) Elicit ideas for multipurpose reproductive health vaccines (ii) Develop consensus Target Product Profile (iii) Discuss timeline for MPT vaccine development	(i) "Request for MPT Concepts" formulated, reviewed, emitted (ii) Teleconference process to develop Target Product Profile for MPT reproductive health vaccines	$N = 15$ MPT vaccine researchers and potential developers	13 submissions received based on active immunization, passive immunization, adenovirus-vectored antibodies, and MPT vaccine development strategies
Scientific Agenda Working Group (SAWG)	(i) Use TPPs developed by the product-specific working groups as framework for (ii) Characterizing the MPT pipeline from discovery through regulatory approval (iii) Prioritizing promising candidates	(i) Agenda-driven conference calls to review successive iterations of TPPs and survey responses (ii) Convening of experts charged with critiquing and debating SAWG draft to formally review SAWG recommendations	(i) Respondents to MPT Product Profiles Survey (ii) 35 experts from pharmaceutical companies, academic institutions, national regulatory authorities, global drug delivery	(i) SAWG recommendations and priorities endorsed (ii) Feedback and recommendations regarding challenges, risks, and strategies to be considered

Table 1: Continued.

Teams and associated activities*	Tasks and deliverables	Data collection approach	Participants	Process contributions (summary conclusions/material outputs)
	(iv) Analyzing overall pipeline status and gaps (v) Exploring associated regulatory implications		Efforts, and countries with greatest need for MPT products (Product Prioritization Stakeholder Meeting, October 2012)	

Reports for the starred activities are available at http://www.cami-health.org [10–13].

Table 2: TPP parameters for prioritizing MPT development.

Parameter	Preferred criteria	Minimally acceptable criteria
Indications	HIV + contraception (high emphasis for sub-Saharan African markets) (high emphasis for sub-Saharan African markets)	HIV + HSV (high emphasis for non-LDC markets) contraception + STI (high emphasis for Indian and Chinese markets) BV, HPV, and TV (moderate emphasis) GC + syphilis (minimal emphasis)
Route of administration	Vaginal rings	Oral pills, injectables
Dosage form and schedule	Sustained release (1–12 months) Pericoital Fast-acting Topical (vaginal)	Daily Oral
Efficacy:		
(i) HIV	80%	40%–70%
(ii) Contraception	>Current levels per contraceptive of >90%	Current levels with recommended use
(iii) STI	>80%	40%
Storage conditions	>40°C/75% RH	15–30°C/65% RH for topical/pills Refrigeration at 4°C for injectables
Shelf life	>36 months	24 months
Yearly product cost/user	<US$ 50	<US$ 100
Disposal/waste	Concealable, biodegradable user disposal	Controlled disposal (to include all associated materials (implant, injectables))
Adherence	>80% of users follow prescribed regimen	>60% of users follow prescribed regimen
Time to licensure	5 years	8–12 years (by 2020)
Reversibility	0–24 hours for oral, topical, sustained-release methods 14 days for implants, injectables	14–30 days for oral, topical, sustained-release methods 90 days for implants, injectables

Table 3: Multipurpose RH Vaccine Working Group: active immunization concepts.

Indication and mechanism	Immunogen, adjuvant, and delivery mode
HIV-1, HPV Stimulation of humoral and cellular immune response	DNA systemic (IM); subunit mucosal (intranasal, sublingual, and vaginal), CM cellulose (mucoadhesive)
HIV-1, HSV-2, and HPV Targeted induction of broadly neutralizing antibodies (systemic)	Synthesized and chemically modified peptide; Advax adjuvant; injected liquid
HSV, HPV, and HIV Maintain protective concentrations of cervicovaginal antibodies and/or detectable pathogen specific T-cells	Intravaginal tampon delivery of a nanoemulsion vaccine containing recombinant HSV-2 glycoprotein D and recombinant HPV 16 and 18 L1 protein and HIV glycoprotein 120
HSV, HIV Sustained protective levels of antibody and cell-mediated immunity	Subunit trimeric gp140 and HSV gD; versatile adjuvant system (PLA-NPs), systemic liquid formulation, and mucoadhesive gel carrying both antigens and immunostimulatory molecules to the same dendritic cell (prevents systemic inflammatory responses)
HPV, HBV Systemic and mucosal neutralizing antibodies	Virus-like particle (VLP) subunits, MPL or aloe-derivative adjuvant, nasal prime/boost (systemic prime/nasal boost)
HSV, HIV, and HPV Systemic and mucosal immune responses	DNA or subunit prime with HPV VLPs, gD, gp120 (intramuscular); lactococcus cocktail expressing gD, HPV E6/E7, HIV gag for mucosal boost (tablet)
HPV, sperm (immunocontraceptive can be provided separately); antibodies in fallopian tubes and in cervicovaginal mucus plus systemic antibodies and cell-mediated immunity	Salmonella vectored subunits: (a) L1 capsomeres (possibly with L2 peptide), (b) cocktail of sperm antigens; oral tablet
HIV, HSV	Codelivery of immunogens (trimeric gp140 boosts following DNA prime), and microbicides (1% tenofovir or dapivirine) via an intravaginal ring. Mucosal adjuvant is R848 (a TLR 7/8 agonist) to sustain mucosal memory
Dual-purpose HPV (multiple types) vaccine plus griffithsin microbicide (HIV, HSV)	L2 epitope fusion with griffithsin (immunogen/adjuvant); intravaginal ring (or PVA film) for burst release of HPV vaccine (L2-griffithsin fusion protein) and sustained release of griffithsin as a microbicide
HSV, HIV Systemic and mucosal protective concentrations of neutralizing antibodies	gD/Fc fusion protein, gp41 anti-idiotype; nasal prime delivered with dry inhaler; cervicovaginal boost delivered as film; FcRn-mediated transport across epithelium

was a "road map" permitting researchers, policy-makers, and donors to make decisions about next research steps and investments along the entirety of the MPT research and development pathway and identify the potential for efficiencies that might be achieved by strategic collaborations among researchers and developers. Such a review process and the resulting road map was expected to support the best alignment of technologically feasible MPTs with products identified as "ideal" by women and health care providers in regions and populations that would most benefit from multipurpose prevention technologies intended to foster and support improved overall reproductive health.

3.1.1. MPT Target Product Profile. Adoption of this methodology as a major organizing concept for the MPT strategy emerged from the deliberations of the May 2011 MPT Think Tank (Table 1), against a background of increasing interest among major health and development donors in Target Product Profile (TPP) approaches. While variously defined and applied by the pharmaceutical industry and the US Food and Drug Administration, the TPP is a goal-oriented template for assessing and prioritizing candidate biomedical products in terms of their development progress and potential and, in some cases, market prospects and likely impact [56, 58]. Each MPT strategy team was asked to adapt that basic TPP concept by selecting the attributes, parameters, and associated criteria for MPT products that would offer the highest potential public health impact for their putative user populations, responsiveness to the unmet needs of those populations, and satisfaction of the major MPT objective: contraception and prevention of HIV and non-HIV STIs simultaneously delivered in a variety of modalities.

3.1.2. Product Prioritization. Construction of Target Product Profiles for MPTs involved successive prioritizations of their main elements: primary indications (HIV prevention/contraception, HIV/STI prevention, and STI prevention/contraception; routes of administration and dosage forms; product attributes and parameters (e.g., stability, infrastructure needs, reversibility); and safety, efficacy, and potential for uptake. These individual prioritizations would then contribute to a "consensus TPP" that could shape general development priorities and fundamental design targets that would, in turn, guide funder investment prioritization and

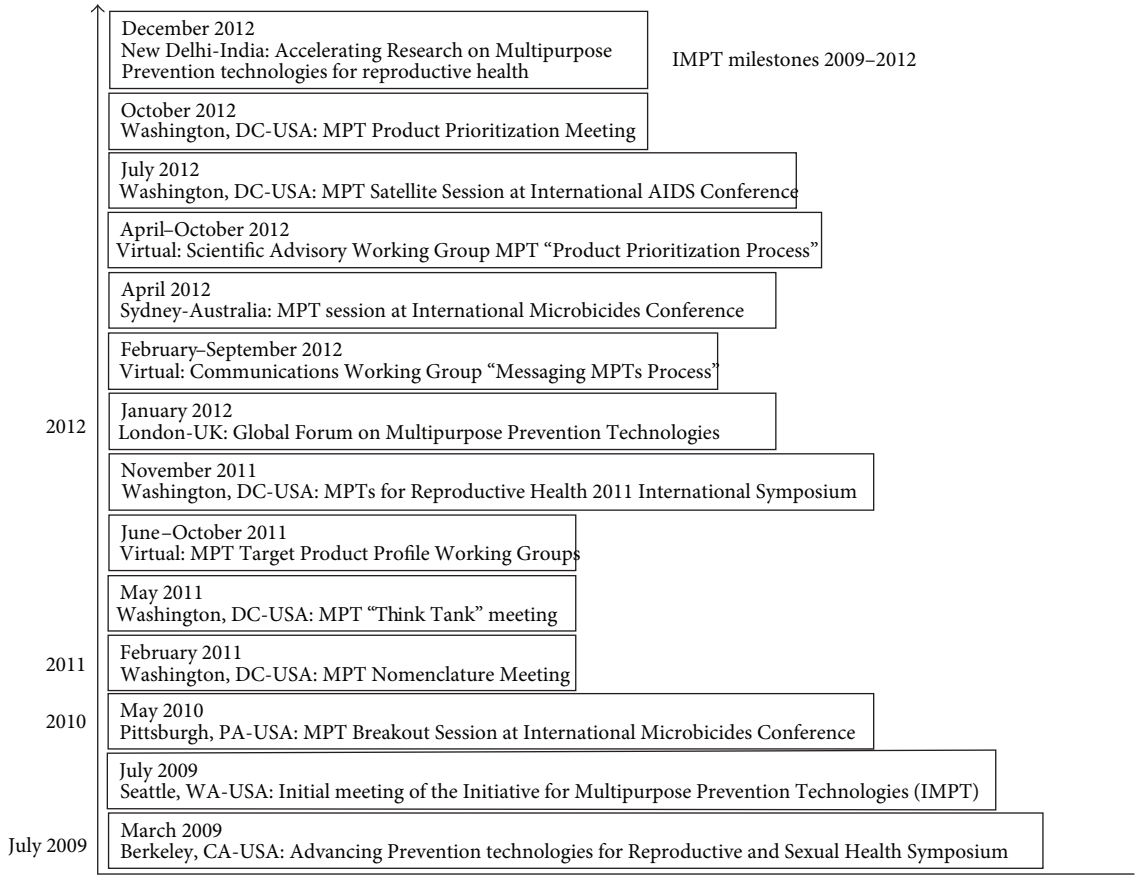

Figure 1: MPT Strategic Milestones 2009–2012.

developer R&D focus. The process would include compilation of a comprehensive list of candidate MPT-related products and product components, followed by interrelated evaluations for development feasibility, number of candidates per product type, "fit" with general TPP findings, and input from the contraceptive field. This work would be implemented by the Scientific Agenda Working Group (SAWG) and its Product Prioritization subgroup; a similar process would occur in the Multipurpose Reproductive Health Vaccine Working Group.

3.1.3. Understanding Regional Needs and Priorities for MPT Development. MPT need and demand would necessarily be affected by the fact that global unmet need and demand for modern contraception are quite variable, as are the epidemiological profiles of HIV and STI incidence, prevalence, and contribution to overall burdens on women's health. Thus the MPT prioritization process would have to take into account the types of target populations in specific geographic regions most likely to benefit from MPTs and be interested in using them.

While the MPT strategy had steadily incorporated perspectives from those regions, the principal methodological contribution to this component was the January 2012 Global Forum on MPTs, which convened 60 participants from Africa, the Caribbean, China, Europe, India, United Kingdom, and the United States to elicit international multisectoral input into draft TPPs, extend consideration of critical path for regulatory approval of MPTs beyond the US Food and Drug Administration (USFDA) to other regional regulatory authorities, encourage global perspective and international support for MPTs, and seek consensus on next steps. The results of this process component are summarized below in Table 5.

4. Results: Findings and Analysis

4.1. Primary Indications for MPT Drug-Drug and Drug-Device Combinations. Across working groups and respondents to different data-gathering approaches, consensus emerged that the most critical parameter in the construction of an MPT Target Product Profile was the *combination of indications* to be met by a given product, that is, contraception, HIV prevention, and/or prevention of non-HIV-STIs. Overall, the combination of HIV prevention and contraception was assigned the highest priority, followed closely by HIV + HSV. Non-HIV STIs were variously prioritized in terms of relevance for HIV transmission, technical feasibility, epidemiological burden, and effectiveness of available treatments.

Table 4: Reproductive Health Consensus Target Product Profile for MPT Vaccines.

Parameter	Optimally preferred
Indication and mechanism	HSV, HIV, HPV Systemic and mucosal protective concentrations of neutralizing antibodies (and cell-mediated immunity)
Target population	Women/girls: developed and developing regions
Immunogen, adjuvant, and delivery modes	Well-characterized immunogens (but range of adjuvants and delivery modes
User-action	Pharmacy or self-administered boosts
Boost schedule	Mucosal boost schedule uncertain
Typical use efficacy	HSV (70–90%); HIV (70–90%); HPV (>95%)
Side effect profile	Minimal
Additional benefits	Versatile production platform
Shelf life	Years
Storage needs	No cold chain required
Price	$1/dose
Infrastructure	Pharmacy

Variability among informant populations did produce noteworthy differences in rankings. Comparison of findings from the surveys among US and African reproductive health care providers (Table 1) found that 66 percent of African providers ranked unintended pregnancy + HIV as of highest priority, while the same percentage of US providers ranked unintended pregnancy + non-HIV STIs as the highest-priority target indication. HPV was ranked as the highest-priority non-HIV STI by both survey populations (75 percent and 68 percent of African and US providers, resp.). While response volumes from China and India were not high, the combination of contraception + non-HIV STIs appeared to command the most interest as MPT candidates for those markets.

4.2. TPP Parameters for Prioritizing MPT Development. The consensus Target Product Profile for MPTs comprised a defined set of parameters with associated "preferred" and "minimally acceptable" criteria that formed the architecture for determining what must matter most for MPT development once the highest-priority indication has been determined. Those assigned priority through the methods described in the preceding section appear above in Table 2. Several of these attributes received intense scrutiny and thus merit additional comment.

Dosage Forms. Given broad consensus that a crucial arbiter of efficacy for any MPT will be adherence to correct product use, it was not surprising that sustained-release devices, importantly intravaginal rings (IVR), were identified as the highest-priority dosage form. The rationale for IVR as a preferred delivery system was that such technologies, which could be user-inserted and designed for at least 30 days of efficacy, offered potential for greater adherence compared to other user-administered systems. IVRs are reversible, may impose less of a burden on health systems and, depending on drug activity, might also mitigate some of the side effects associated with oral administration and correspondingly greater systemic exposure. Again, however, there was variation across survey populations. US providers preferred oral dosage forms, while African providers leaned toward a "suite" of several dosage forms as offering greater potential for acceptability and use, and ranked injection and sustained-release devices slightly higher than others.

Efficacy Targets. There was consensus that MPT components for HIV prevention should meet a minimum requirement of 40–50% reduction in risk, preferably at least 80% with perfect use and 60% with typical use. Contraceptive MPT components should be no less effective than currently available products and an efficacy minimum of at least 40% was the target for prevention of non-HIV STIs.

Product Attributes. Most specific attributes were identified within the context of safety, efficacy, and other factors, with a relatively long shelf life (36 months) and storage at high temperature (40°C) as the most consistently-supported priorities.

Side Effects. The general view was that these would need to be assessed in the context of the overall safety and anticipated efficacy of the MPT under consideration, but should be "no worse than individual indication products," for example, currently available contraceptives.

Other Parameters. Another group of "non-TPP parameters" emerged in the research and review process as issues requiring further discussion with respect to their importance for different potential user populations. Those were research entity, resupply infrastructure, access to testing/monitoring, cold chain storage (if needed), time to development for compounds, potential drug interactions, mechanism of action established in other products (e.g.,Truvada, NuvaRing), novelty of mechanism of action and enhancement of pipeline diversity, pipeline redundancy, potential for drug resistance, potential for discreet use, influence on sexual experience, incidence/prevalence in target population and overall burden of disease, and few or no existing or readily available treatment options.

4.3. Multipurpose Reproductive Health (RH) Vaccine Working Group. The Multipurpose RH Vaccine Working Group's "Request for Concepts" elicited 13 submissions and/or comments, almost all based on active immunization (Table 3) and responsive to the Target Product Profile developed by this group (Table 4). Two additional concepts were based on passive immunization [59] and adenovirus vectored antibodies [60, 61] and one submission was focused on product development strategies. In general, it was recognized that advances

in mucosal vaccinology were crucial to advancement of these concepts [62].

4.4. Understanding Regional Needs and Priorities for MPT Development. The information that has accumulated with respect to regional priorities for MPTs has accelerated in volume, coverage and, with the refinement of the Target Product Profiles, its relevance to MPT development writ large. The January 2012 Global Forum on MPTs hosted by the Wellcome Trust was explicitly designed to elicit international multisectoral input into the draft TPPs, extend consideration of the critical path for regulatory approval of MPTs beyond the perspectives of the USFDA to include the views of representatives from other regulatory authorities; encourage a global perspective and international support for this Initiative and seek consensus on next steps, and identify the types of target populations in specific geographic regions most likely to benefit from MPTs. Table 5 summarizes the extensive output of that vital consultation and background material provided by its participants.

4.4.1. The MPT Pipeline. Extensive research by the Scientific Agenda Working Group (SAWG) and colleagues also recently generated the first comprehensive list of all known potential MPT candidate products and components, concepts, relevant technology platforms, and delivery systems responsive to the major MPT indications. The drug candidates in this listing were then subcategorized by mechanism of action, chemical class; product candidates were organized according to dosage form and stage of development. In addition to yielding a summary set of MPT product priorities, this review and analysis process revealed certain imbalances in the R&D efforts being invested in different MPT product and component types.

4.4.2. Pipeline Prioritization and Gap Identification. Priorities. The exercise to prioritize MPT candidate drugs and products identified specific active pharmaceutical ingredients (API) and product configurations appropriate for timely and effective development of MPT products. In light of the priority indications of HIV and pregnancy prevention, MPTs that involve small organic molecule antiretroviral (ARV) agents and hormonal contraceptives were prioritized. The lack of candidate STI prevention options did not allow for specific prioritization for this indication (see in what follows). Further, it was recognized that a suite of MPT product configurations would be necessary to achieve maximum public health impact. Specifically, vaginal rings, long acting injectables, and alternative on-demand formulations are all defined as priority configurations for MPT products.

Gaps. A range of gaps were identified in the course of the prioritization exercise. Specifically, it was noted in the following:

(i) There is a lack of alternatives to reverse transcriptase inhibitor (RTI) antiretrovirals (ARV) for the HIV indication.

(ii) Sufficient understanding of the potential relationship between specific forms of hormonal contraception (e.g., injectable DMPA) and increased risk of HIV transmission is lacking.

(iii) Viable, pathogen-specific options for the non-HIV STI indication for potential MPTs are unavailable.

(iv) There are insufficient data on acceptability, use, and uptake of intravaginal rings.

(v) Too few options for long-acting injectable delivery modalities are in development.

(vi) Insufficient knowledge about the safety of intermittent use of ARVs and other anti-infectives is a risk for on-demand product options in general.

(vii) Limited non-hormonal-contraception and STI-prevention options exist.

(viii) Definitive social-behavioral science to support all product options is limited.

Needs. The analysis also generated a short list of early-stage development candidate categories meriting pursuit for possible longer-term development:

(i) STI-specific APIs;

(ii) non-ARV-based HIV prevention;

(iii) lactobacillus-based products;

(iv) nonhormonal contraceptives;

(v) novel on-demand product configurations.

Process Priorities. The product prioritization exercise also generated a set of "process priorities," the absence of which could hinder the MPT effort in the longer term. The key process priority is the need for coordination across donor investments, sponsor development, and program management. This, in general, has been seen as desirable but often absent; however, current resource limitations and the complexities around MPTs dictate the urgency of

(i) consensus on priority products, gaps, and development strategies,

(ii) a coordinated approach to identify single-lead products for each priority MPT product type,

(iii) pooling of capacity, capability, expertise, and other resources between viable development entities interested in MPT products,

(iv) coordinated investment and collaborative/partnered development management,

(v) early and proactive engagement of regulatory authorities, supported by TPP templates specific to product types.

Table 5: Understanding Regional Needs and Priorities for MPT Development*.

Region	Epidemiology	Priorities, opportunities, challenges for MPT development
Sub-Saharan Africa (SSA)	*Contraception* (i) SSA lags behind global trends for increasing contraceptive prevalence and fertility decline, with high rates of unintended pregnancy and maternal mortality (ii) The region is not homogeneous: faster evolution in Southern and Eastern Africa. Demand for contraception now reaching 50% of married women, but only accessible to 20% [14–16] (iii) Method preferences also vary: unmarried women throughout SSA mainly rely on male-controlled condoms; pills, and injectables used predominantly by married women, rarely with additional protection against STIs [17]. Female condom is underutilized and comparatively expensive, with 50 million distributed annually by UNFPA [18] *STI protection* (i) Women on HIV antiretroviral therapy often do not use modern contraception, or forgo additional condom use [19]. In southern and eastern Africa, where a sizable proportion of HIV-positive women use injectable hormonal contraception [20] (ii) Syndromic management has reduced rates of bacterial STIs such as syphilis and chancroid [21], rates of the other dominant viral (STIs, HSV, HPV) extremely high, with prevalence rates up to 70% for HSV [4], between 20 and 33% HPV [22] in some cohorts (iii) Prevalence of bacterial vaginosis (BV), associated with increased risk of HIV-1 acquisition, reaches rates of 16–50% of women [23–25].	*Priorities* (i) STI prevention targets dictated by prevalence, that is, HIV, HSV, BV, trichomonas vaginalis (TV), and HPV. (ii) Strong regional preference for injectable products, but barrier methods and vaginal products also highly acceptable. *Opportunities* (i) Contraceptive uptake could increase by expanding method mix, moving toward low-dose hormonal products (and IUDs), addressing health concerns through expanded user education, focusing on populations with a high unmet need (ii) Increasing pressures for integration of services for HIV prevention, testing, PMTCT and care, and family planning services *Challenges* (i) Method needs differ for married and unmarried women, and preference varies across the region (ii) MPTs with and without a contraceptive component required for women at risk for STIs and wishing to become pregnant (iii) Given current popularity of injectable contraceptives, concern about impact of progestins on HIV acquisition is high [26]. (iv) Health interventions in low-resource and middle-income countries often experience slow uptake, necessitating interventions with long-term horizons
India	*Contraception* (i) Population growth main concern, but total fertility rate showed dramatic decline over last few decades, to total fertility rate of 2.6 [15, 27]. Decreasing significant rate of unintended pregnancies [28] instrumental in reaching replacement level fertility, a critical requirement to prevent doubling current population within next 50 years [15, 29] (ii) Only 7% of sexually active young women have ever used condoms for premarital sex; 25% of women are pregnant or mothers by age 18 [30] (iii) Current contraceptive prevalence just under 50% [15]; method mix consists primarily of female sterilization, IUDs, male condoms, and oral contraceptives; injectables and female condoms rarely used [31] *STI protection* (i) HIV prevalence in India estimated at 0.31% (2.39 million people), concentrated in high-risk groups (female sex workers, migrant workers, men who have sex with men, intravenous drug users) (ii) HIV acquisition is primarily through heterosexual sex and 39% of all infections occur in women [32] (iii) Bacterial STI prevalences overall below 10%; candidiasis and HSV-2 reach low double digits; bacterial vaginosis reported as high as 63% [33] (iv) Regions with low HIV prevalence (e.g., Bihar, Orissa, Uttar Pradesh) also have low rates for other STIs, but lead national statistics with the worst maternal mortality rates, highest fertility rates, and lowest rates of use of modern contraceptive methods [34]	*Priorities* (i) The Indian market for MPTs would be driven by priority for a contraceptive indication *Challenges* (i) Cultural factors such as women's often limited ability to act as decision-maker for own health, husband's support (as well as varying comfort levels with administration of vaginal products) will all influence uptake of MPTs

Table 5: Continued.

Region	Epidemiology	Priorities, opportunities, challenges for MPT development
China	*Contraception* (i) At almost 85% of married women, one of world's highest rates of contraceptive use [35] (ii) Contraceptive method mix dominated by IUDs (40%) and female sterilization (almost 30%); condom use has increased with urbanization and increased income (iii) Availability of oral contraception, implants, and injectables still limited, partly due to lack of government funding and substantial regulatory approval processes, discouraging to private enterprise *STI protection* (i) Overall HIV prevalence low, almost 80% concentrated in Guangzi, Guangdong, Henan, Sichuan, Xinjian, Yunnan provinces; overall HIV prevalence estimated at 780,000, with 48,000 new HIV infections in 2011 (ii) More than 75% of HIV transmission is heterosexual; 28.6% of all HIV infections in China are in women. In economically developed provinces, for example, Dongguan, Guangdong, many new HIV cases are among migrant workers [36, 37] (iii) Due to expanded reproductive health care in government facilities, STI prevalence in China declined over past two decades, but prevalence in underserved rural areas remains high [38] (iv) STI epidemic in China is changing: while gonorrhea and HPV were main infections in past decades, nongonorrheal urethritis (NGU) and syphilis surged over last 20 years (v) Today, syphilis is the dominant STI, mainly among young migrant workers and female sex workers in richer coastal regions; chlamydia, gonorrhea, HPV, non-gonococcal urethritis (NGU), and HPV are widely distributed [39–41]	*Priorities* (i) MPT development will be driven by the need to respond to the STI epidemic, including HIV, as well as by expansion of contraceptive method mix toward a larger proportion of short-term methods
Developed Countries	*Contraception* (i) Nearly half of all pregnancies in 29 US states are unintended [42], especially in young women age 15–19 (over 80%) [43]: more than half of American women experience an unintended pregnancy, and 30% undergo an abortion [44] (ii) While unintended pregnancy rates have improved overall, socioeconomic disparities remain. Between 1994 and 2006, rate of unintended pregnancy among US higher-income women fell by 29%, while that rate among lower-income women rose by 50% [45]. Even though national teen pregnancy rate is now the lowest in 40 years, rates among Hispanic and black teens are 2 to 3 times higher than those of non-Hispanic white teens [46] *STI protection* (i) In 2007, CDC reported 1.1 million cases of chlamydia (3-fold in women compared to men), and 356,000 cases of gonorrhea (5-fold among women age 15–24 compared to women overall) [47] (ii) CDC estimates that 20% of adolescents and adults have had a genital herpes infection [48] and about 7.4 million new cases of trichomoniasis occur each year [49] (iii) Despite regulatory approval and availability of HPV vaccines, HPV continues to infect 6.2 million Americans each year [50]. (iv) Each year about 47,000 new HIV infections occur in the US [51]. In 2010, women accounted for 23% of all diagnoses and for growing majority of all heterosexual transmissions [51]; in 2010, black women accounted for 64% of new AIDS diagnoses among women, Latinas for 17%, a rate 22 times and 5 times higher, respectively, than for white women [52]	*Priorities* (i) Developed countries were found to place highest emphasis on MPTs that would serve both as contraception and be active against selected STIs, notably HSV and HPV. (ii) HIV largely seen as issue for specific subpopulations

Table 5: Continued.

Region	Epidemiology	Priorities, opportunities, challenges for MPT development
	(v) Approximately 20% of US HIV-positive individuals unaware of their status [51, 53] (vi) HIV and high rates of other STIs burden many European countries. In 2009, almost 344,000 cases of chlamydia and almost 30,000 cases of gonorrhea reported from EU/EEA Member States [54] (vii) Chlamydia affects more women than men, and both chlamydia and gonorrhea disproportionately affect young people in this region, where 15–24 year-olds account for 75% and 40% of reported infections, respectively (viii) In 2010, close to 120,000 cases of HIV were reported by 51 European countries, 76% of those in the East [54, 55], with heterosexual contact remaining a main route of transmission, at 43% of reported HIV cases [55]	

*Table based on literature review and presentations, discussion, and analysis at January 2012 Global Forum on MPTs hosted by the Wellcome Trust [56] and Microbicides 2012 Conference.

5. Discussion and Conclusions

5.1. The State of MPT Research and Development. The purpose of the MPT Scientific Agenda Working Group activities is to inform and provide guidance for donors, product developers, and regulators about MPT priorities and investment needs. It adopted an iterative strategy of steps, feedback loops, adjustments to its own received wisdom and that of others, and an expanding circle of engagement that could inform the process but not cripple it.

The IMPT will continue its iterative process of sharing the priorities identified and associated recommendations, particularly in the area of drug/drug and drug/device combinations, with an expanded range of stakeholders, including regional experts, sociobehavioral scientists, clinicians, and manufacturers. It will also continue to monitor the MPT pipeline and support coordinated donor and developer engagement. As the MPT field advances, MPT product priorities will evolve and expand as the realization of multipurpose reproductive health vaccines, with a longer time line, also proceeds. Both MPT categories are believed to offer considerable potential for innovation, public health impact, and a sizable market in both the developed and developing worlds.

Some critical building blocks are already in place for drug-drug and drug-device MPTs. There are putative MPT components in products long approved for single indications and in contraceptive products already commercially available in multiple configurations. Drugs for treatment of HIV and STI are available, though in some cases imperfect and problematic, and infectious disease prophylaxis is established for some indications. HIV prevention of mother-to-child transmission (PMTCT) is proving effective and results from late-stage trials of Pre-Exposure Prophylaxis of vaginal and oral products suggest that HIV prevention is, with some critical questions to be asked and answered, within reach [63].

A few MPT candidates have completed discovery and are in ongoing development:

(i) an intravaginal ring that continuously releases tenofovir and levonorgestrel from separate ring segments over a period of 90 days, for contraception and HIV prevention [64];

(ii) a gel combining MIV-150, zinc acetate, and carrageenan, with combined activity against HIV and HSV [65];

(iii) a vaginal ring releasing dapivirine and a hormonal contraceptive over 60 days for contraception and HIV prevention [66, 67];

(iv) reformulated tenofovir gel is being studied in conjunction with the existing SILCS diaphragm as a combined barrier contraceptive, adding sperm immobilizing agents and antiviral chemical protection against HIV and HSV [64].

5.2. Allied Efforts. The structure of the Initiative for Multipurpose Prevention Technologies and the work of its colleagues were explicitly designed to take into account that simply having an MPT pipeline and prioritizing R&D investments would not be sufficient to getting an actual MPT on the market and into the hands of users. Thus, while the activities of the Scientific Agenda Working Group (SAWG) are the focus of this paper, that work could not have evolved nor can it continue without a range of support, importantly including financial resources.

Thus, the Initiative has, through a cross disciplinary approach, implemented a series of activities to support the emerging MPT field and the Scientific Agenda derived from the work of the SAWG. Among those activities are working groups charged with Communications, Advocacy and Outreach and with MPT Acceptability and Access. Both teams aim to increase global awareness and support for MPT development among scientists, donors, policy-makers, regulators, health care providers, and advocates. The Communications, Advocacy and Outreach Working Group has identified and convened regional experts and affiliates in a number of different countries with high unmet need for MPTs (e.g., China, India, Jamaica, Kenya, South Africa, and Tanzania) to help shape the scientific agenda, ensure that the MPTs that are developed will be socially and culturally appropriate and craft messages to raise awareness and support for product research and development. The allied MPT Acceptability and Access Working Group aims to ensure that MPT products will be accessible and affordable for those with highest unmet need, through attention to potential regulatory requirements for MPT products and exploration of the most promising delivery pathways for MPTs in different global regions.

6. Conclusions

The road to even the first MPT product will not be smooth. That became clear as the MPT Prioritization Process fulfilled its mandate to highlight key challenges, gaps, and needs if MPTs are to be realized efficiently and with reasonable speed. Different chemical compounds may require different conditions for formulation and release and the human vaginal environment is difficult to mimic accurately in *in vitro* laboratory or animal experiments. Drug interactions between concurrently released compounds could impact product efficacy and safety. The impact of hormonal contraception on HIV transmission has recently risen to a global level of concern and awaits clarification. There is much to be known about *in situ* placement of vaginal devices in terms of safety, drug uptake, and distribution, and timely efficacy with respect to prevention. Since women's needs vary in different regions of the world and throughout their lives, a single MPT will not be fully responsive and a "suite" of MPT products will be critical for these new technologies to have optimum public health impact.

Because the prospective user populations for many MPTs reside in a range of economic and epidemiologic settings, review of MPTs will require experts from different fields and collaboration among international regulatory and national health authorities. While the preferential use of already approved drugs and devices as MPT compounds may save time and resources in the navigation of regulatory requirements and although FDA approval for drugs and devices can

facilitate and accelerate drug approvals in other countries, a comprehensive drug development strategy must nonetheless include regulatory requirements for all target markets.

There are also the linked questions of cost and effectiveness. There is solid evidence for substantial cost savings to be derived from responding to unmet needs for modern contraceptives [2]. Simple modeling exercises indicate that the potential of MPTs to increase product adherence could lead to meaningful positive economic benefits [68].

Advancement of scientific research and public health technologies, particularly innovative technologies for the developing world, has traditionally confronted constraints: insufficient funding, regulatory barriers, private industry perceptions that products designed for the developing world offer scant profit, numerous impediments to product availability, and, sometimes, lack of fit between the technology involved and the population it was meant to benefit. All these constraints have surfaced repeatedly and in some ways uniquely in reproductive health, owing to deep-rooted cultural, political, and socioeconomic factors.

In sum, developing a menu of prevention technologies, indeed even the first such technology, will take years; the perseverance of scientists, donors, and advocates; and the capacity to deal with the inevitable failures inherent in drug development. However, emerging from the most recent conversations hosted by the SAWG was agreement on the requirement to "think big" and resist temptations to settling on refinements of what is already in the pipeline, since multipurpose technologies that simultaneously address two primary reproductive health needs for women worldwide justify the imagination, skills, and sheer grit that will be required for their realization.

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Research Article

Tanzanian Couples' Perspectives on Gender Equity, Relationship Power, and Intimate Partner Violence: Findings from the RESPECT Study

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Intimate partner violence (IPV) is widely prevalent in Tanzania. Inequitable gender norms manifest in men's and women's attitudes about power and decision making in intimate relationships and are likely to play an important role in determining the prevalence of IPV. We used data from the RESPECT study, a randomized controlled trial that evaluated an intervention to prevent sexually transmitted infections in a cohort of young Tanzanian men and women, to examine the relationship between couples' attitudes about IPV, relationship power, and sexual decision making, concordance on these issues, and women's reports of IPV over 12 months. Women expressed less equitable attitudes than men at baseline. Over time, participants' attitudes tended to become more equitable and women's reports of IPV declined substantially. Multivariable logistic regression analyses suggested that inequitable attitudes and couple discordance were associated with higher risk of IPV. Our findings point to the need for a better understanding of the role that perceived or actual imbalances in relationship power have in heightening IPV risk. The decline in women's reports of IPV and the trend towards gender-equitable attitudes indicate that concerted efforts to reduce IPV and promote gender equity have the potential to make a positive difference in the relatively short term.

1. Introduction

Intimate partner violence (IPV) is a major public health and human rights concern in Tanzania [1]. According to the World Health Organization's Multi-country Study on Women's Health and Domestic Violence (2000–2003), the prevalence of physical and/or sexual IPV was 41% and 56%, respectively, among a representative sample of ever-partnered women in Dar es Salaam and the southern district of Mbeya [2]. A growing number of studies have documented the association between IPV and an array of adverse reproductive and sexual health outcomes, including pregnancy loss and HIV infection among women in Tanzania [3–7]. Of particular concern is evidence on the links between IPV, sexual risk behaviors, and HIV infection among young Tanzanian women and men [6–9]. According to one study at an HIV voluntary counseling and testing center in Dar-es-Salaam, the odds of IPV were ten times higher among young HIV-positive women (<30 years of age) than among similarly aged HIV-negative women [6]. Another study involving 951 young men aged 16 to 24 years in two neighborhoods of Dar-es-Salaam found that about a third had ever perpetrated IPV and that those who reported more lifetime sexual partners were also more likely to perpetrate IPV [7]. Given the high

prevalence of IPV and its adverse health impacts, a better understanding of the risk of IPV, especially among young women, is needed.

It is widely accepted that gender inequities, perpetuated by cultural norms regarding gender roles and manifest in men's and women's ideas about power and decision making in relationships, have a profound impact on the perpetration and experience of IPV [10]. Several qualitative studies in Tanzania have documented the links between entrenched gender inequities and IPV [8, 9, 11]. In one study, 16–24-year-old men and women in Dar-es-Salaam described the ideal woman as one who is home-bound, loyal to her partner, and sexually submissive [9]. Young women who deviated from these prescribed behaviors risked being beaten. Infidelity or perceptions of infidelity were the most commonly cited triggers of violence against female partners across studies [8, 9]. Men and women often justified violence against a female partner as a response to a woman's infidelity or confrontations regarding a man's infidelities. Furthermore, it was not uncommon for women to be blamed for provoking IPV, preventing women from seeking support or medical care, and making law enforcement difficult [12].

Survey data lend support to the observation that both men and women in Tanzania condone IPV as a normal part of an intimate relationship [7, 13]. According to the Demographic and Health Survey (DHS, 2004), 60% and 42%, respectively, of women and men found spousal abuse to be acceptable under one or more scenarios (e.g., wife neglects child, goes out without permission, argues with husband, etc.) [13]. Maman et al. reported that 46% of a sample of young men condoned violence against a female partner in one or more circumstances [7]. A similar proportion of women attending an HIV voluntary counseling and testing center in Dar-es-Salaam felt that physical abuse was justified in at least one of several situations such as infidelity, disobedience, and nonperformance of domestic work [14].

Although research has explored men's and women's attitudes about IPV, few studies have empirically examined the association between these attitudes and IPV risk [15]. For example, a cross-sectional survey of men working in three municipalities in Cape Town, South Africa found that men who thought it was acceptable to hit women were more likely to also report recent or past physical violence against a partner [16]. Still fewer studies have assessed the relationships between concordant or discordant attitudes towards IPV within a couple and women's experience of IPV. A recent analysis of DHS data from six African countries (Kenya, Liberia, Malawi, Rwanda, Zambia, and Zimbabwe) examined the relationship between couple concordance on attitudes towards IPV (partner agreement that violence is justified in at least one situation) and IPV (any physical or sexual violence reported by women) [17]. The authors found that IPV was more commonly reported among couples who agreed that IPV was acceptable in at least some situations as well as those who expressed discordant attitudes towards IPV compared to couples who agreed that IPV was never acceptable. Notably, statistically significant associations between concordance on IPV acceptability and reported IPV and between discordance and IPV were observed in five and four out of six countries, respectively.

To our knowledge, the association between couples' attitudes towards IPV, couple concordance in attitudes and IPV risk has not been examined in Tanzania. Using data from the Rewarding STI Prevention and Control in Tanzania (RESPECT) study, we examined men's and women's attitudes about IPV, relationship power, and sexual decision making and couples' concordance on these issues, and whether these attitudes were associated with women's experience of IPV at baseline and over time.

2. Methods

2.1. The RESPECT Study. The year-long RESPECT study was a randomized controlled trial designed to evaluate whether conditional cash transfers (CCT) promoted safe sex and reduced the incidence of sexually transmitted infections (STIs) (see [18] for additional details regarding the study). Women and men aged 18–30 years living in 10 villages in the Kilombero/Ulanga districts in south-western Tanzania were randomly selected from the Ifakara Demographic and Health Surveillance System database. Participants who were interested in enrolling jointly with their spouse were encouraged to do so and considered to be a couple if they each reported that they were married to one another or were living together as if married. Couples were linked through a common household identification number.

About 50% of participants were randomly assigned to a no-payment control group, 25% to a low-value CCT group, and the remaining 25% to a high-value CCT group. Participants were followed for 12 months and interviewed every 4 months to gather data on a range of issues, including sociodemographic background, economic status, sexual and reproductive health knowledge, practices, and history, attitudes about IPV and relationship power, as well as experiences of IPV (women) and perpetration of IPV (men). They also underwent STI and HIV counseling and testing. Participants in the CCT arms received cash payments for every 4 monthly negative STI laboratory test result. All enrolled individuals were invited to group counseling sessions that focused on relationship and life skills training based on the Stepping Stones curriculum [19].

2.2. Theoretical Framework and Hypotheses. The analysis is guided by a social-ecological framework, which posits that IPV risk is shaped by the interplay of a host of individual, community, and societal factors, including individual beliefs and practices within an intimate relationship as well as community and societal norms regarding gender and power [20]. It is also informed by the proximate determinants framework proposed by Boerma and Weir, which enables the classification of factors into distal and proximate predictors of IPV [21]. According to the proximate determinants framework, ecological factors such as cultural norms influence a particular health outcome through a set of intermediate or proximate variables. These proximate determinants, which can include a combination of social and biological factors, directly influence the health outcome of interest.

In this analysis, we considered attitudes toward IPV as proximate determinants, and gender norms as a key underlying, distal determinant of IPV. For example, women's access to education and employment is limited in social and cultural environments that are highly patriarchal, increasing their economic dependence on male partners, which is a known risk factor for IPV (i.e., a proximate determinant) [22]. Similarly, inequitable gender norms can also create an environment that is generally tolerant of male dominance in intimate relationships and violence against women (a distal determinant) [23], and influence both men's and women's attitudes towards IPV (a proximate determinant), and in turn affect women's experience of IPV.

We outlined our hypotheses about the causal relationships between all variables in a Directed Acyclic Graph (DAG; not presented) and used the DAG to determine the minimum variables necessary to include in multivariable analyses to remove confounding of the main effects. Our primary hypothesis is that men's and women's attitudes about IPV, relationship power, and sexual decision making (including couple concordance/discordance on these attitudes) are proximate determinants of women's experience of IPV. Specifically, we proposed that women's and men's espousal of inequitable gender attitudes would be associated with greater experience of IPV at baseline and over time. We also hypothesized that couples' discordance on these issues would be associated with a heightened risk of IPV at baseline, and that this relationship would persist over time. We further hypothesized that the very fact of discordance between couples is more important than the nature of that discordance; that is, we proposed that lack of agreement between a woman and her partner (regardless of which partner held the more inequitable attitudes) would be associated with a higher risk of IPV than if she agreed with her partner. This finding would be consistent with earlier studies that have found that women themselves often exhibit highly inequitable attitudes about IPV as a way of fitting in with their communities and protecting themselves from violence [24, 25].

2.3. Ethical Considerations. Study protocols were approved by institutional review boards in Tanzania and the United States. All study participants gave written informed consent to participate in the study. Couples were interviewed separately at a study station that was set up on the outskirts of the village, and care was taken to ensure privacy and confidentiality. Study interviewers received in-depth training on interviewing techniques, gender and reproductive health, and the study protocols. A study liaison was identified in each village to help participants gain access to further information, counseling services, and study personnel. In addition, study counselors received training on how to offer psychosocial support and were equipped with information on domestic violence-related services.

2.4. Measures. The outcome of interest—women's self-report of intimate partner violence over the previous 4-month period—was measured using a dichotomous variable based on four questions from the RESPECT questionnaire: "have you been hit, kicked, or beaten by your partner and/or a family member for any reason during the last 4 months?", "Has your partner or another family member done any of the following during the last 4 months: humiliated you in front of others, insulted you, tried to scare you, threatened to hurt you or someone you care about?", "Have you been physically forced to have sexual intercourse when you did not want to during the last 4 months?", and "Did you, during the last 4 months, have sexual intercourse when you did not want to because you were afraid of what your partner might do?". Participants who responded "yes" to one or more of these questions were coded as having experienced violence, while those who responded "no" to all four questions were coded as not having experienced violence. The RESPECT questionnaire did not ask women about lifetime experience of violence; at all rounds, women were asked about their experience of violence in the previous four months.

Although the RESPECT questionnaire asked similar questions regarding male participants' perpetration of violence against their partners, couples did not always agree on violence within their relationships (data not shown). Given this disagreement and our primary interest in examining women's experience of IPV during the course of the study, we decided to focus on women's report of violence as the outcome measure.

Our analyses focused on the association between women's reports of IPV and women's and men's attitudes about IPV, relationship power, and sexual decision making and couples' concordance. Men's and women's attitudes towards IPV and opinions about power within relationships were assessed using four exposure variables. The first question ("is a husband justified in beating his wife if...") measured the acceptability of physical IPV in five hypothetical situations: if a wife goes out without telling her husband, if she neglects the children, if she argues with her husband, if she refuses to have sex with her husband, or if she burns the food. A binary variable was created to measure acceptability of IPV, coded as "1" if a participant responded in the affirmative to any of these five situations and coded as "0" if the participant did not agree that violence was justified in any of these situations. The second question assessed the acceptability of IPV as a response to a wife refusing to have sex with her husband: "if a woman refuses to have sex with her husband when he wants her to, he has the right to: get angry and reprimand her, refuse to give her money or other means of financial support, use force and have sex with her even if she doesn't want to, or go and have sex with another woman." A binary variable (yes/no) was created on the basis of whether participants thought IPV was acceptable in response to a wife's refusal to have sex. For each of these questions, couples were coded as having concordant responses if both partners shared the same binary response.

Our third and fourth exposure variables of interest assessed participants' opinions about power within their relationship. These were ascertained using the following two questions: "who usually has more say about whether you have sex?" and "in general, who do you think has more power in your relationship?" Participants were given the response options "myself", "my partner", or "both people equally."

Couples were determined to be concordant if they shared the same response about which partner had more to say about having sex or had more power in the relationship, regardless of which partner this was or whether they agreed that they shared these decisions equally.

Other covariables we considered included age (measured as a continuous variable), education status (measured as a categorical variable—no schooling, some primary school, primary school completed, some secondary school, secondary school completed, and postsecondary or university education), and socioeconomic position (measured by asking participants to rate themselves on a scale from 1 to 7 relative to others in their community). We also examined differences in reported IPV by study arm.

2.5. Statistical Analyses. Analyses were conducted using data from the subset of heterosexual couples who were enrolled in the study together. All couples were included in the baseline data analysis, and couples on whom data were available for a minimum of two out of the four rounds were included in the longitudinal analyses. For each round, couples were included in the analysis as long as there were no missing data on the variables of interest.

Preliminary analyses focused on the cross-sectional relationships between age, education, and socioeconomic position and ever having experienced IPV at baseline using contingency tables, Chi-square analyses, and Student's t-tests. Next, we looked at changes in women's reports of IPV as well as changes in participant's attitudes about IPV and relationship power during the follow-up period. We conducted tests for trend to determine whether changes were statistically significant.

To examine the independent relationship between the exposure variables (women's and men's attitudes towards IPV and relationship power and partner concordance on attitudes) and IPV, we fit separate logistic regression models for each indicator. We also ran a multivariable logistic regression model to examine the association of each main exposure variable and IPV, adjusting for socioeconomic status, age, and education.

Finally, to examine the longitudinal relationship between the exposure variables of interest and women's experience of IPV, we used multivariable random effects logistic regression models [26]. These models were used to examine the effect of changes in men's and women's attitudes about IPV and relationship power and couple concordance on odds of experiencing IPV over time. A random effects model was chosen to evaluate the change in IPV odds for a single woman when she expressed inequitable attitudes versus when she expressed equitable attitudes. This model produced an odds ratio of experiencing IPV for an individual woman when she expressed inequitable attitudes relative to when she expressed equitable attitudes. Similar interpretations apply to the set of analyses run on men's attitudes, as well as the set of analyses on couple concordance. Clustered standard errors were used to account for the nonindependence of an individual's observations over time.

Socioeconomic position, age, education, and round of data collection were included in the models as confounders. Interactions between these confounders and the exposures of interest were also considered. However because they were not statistically significant, they were not included in the final model.

We examined three "families" of hypotheses: based on women's attitudes and opinions, men's attitudes and opinions, and couple concordance. We believed that an individual hypothesis within each family would have to be considered in light of the additional tests performed on other hypotheses within the subgroup. Since each family of hypotheses included four exposure variables, we determined that an appropriate significance level (alpha) for each hypothesis test would be set at 0.05/4 or 0.0125.

3. Results

Out of a total of 2,399 individuals enrolled in RESPECT, 567 couples were identified and included in this analysis. A comparison of individuals who reported being married or living together as married and who did not enroll as a couple and those who did enroll as a couple indicated that there were no statistically significant demographic differences between the two groups. A total of 26 couples were lost to follow up: seven after the baseline round and an additional 19 between rounds 2 and 4. Additionally, at each round, between two and four couples were missing data on one or more variables and were excluded from the analysis. Couples who were lost to follow or excluded due to missing data did not differ in terms of demographic characteristics or women's reports of IPV (data not shown).

Participant characteristics at baseline including demographic background, experiences of IPV, attitudes about violence and opinions about sexual decision making and relationship power are shown in Table 1. About one in five women (20.5%) reported experiencing IPV at baseline. Women who reported experiencing IPV and those who did not were of similar age and had similar levels of education and self-reported socioeconomic status. Of note is the fact that large proportions of men and women felt that IPV was justified in some instances: at baseline, 71% of women and 48% of men reported that beating a wife was justified in one or more situations. In addition, according to both women and men, husbands had more say over sex and had more power in their relationship than wives. Overall, men espoused more gender-equitable attitudes than women.

Analyses revealed that women's reports of violence and participants' attitudes about IPV and opinions about sexual decision making and relationship power changed consistently and substantially over the 12-month follow-up period. Reported IPV (in the four months prior to the interview) decreased steadily over time from 20.5% at baseline to 11.8% at 12 months (data not shown). The decrease was statistically significant ($P < 0.0005$) and was not associated with demographic characteristics or study arm. In addition, at 12 months, fewer women and men noted that violence against a wife was acceptable, and a larger proportion of participants reported that sexual decision making was shared by both partners (Table 2). Interestingly, for both men and women, responses to questions about the acceptability of

Table 1: Baseline characteristics of couples in the RESPECT study.

Variable	Men		Women				All women	
			IPV		No IPV			
N^a	567		114		442		567	
Mean age (min, max)	32.9 (19, 60)		26.3 (18, 35)		26.6 (17, 35)		26.5 (17, 35)	
	n	%	*n*	%	*n*	%	*n*	%
Education status (%)								
None	43	7.7	18	15.8	63	14.3	82	14.5
Some primary	87	15.5	32	28.1	108	24.4	142	25.4
Primary completed	389	69.3	60	52.6	258	58.4	319	57.0
Some secondary	23	4.1	2	1.7	9	2.0	11	2.0
Secondary or higher completed	19	3.4	2	1.7	4	0.9	6	1.1
Self-reported SEP (%)								
0–2 (low)	278	49.0	61	53.5	237	53.6	303	53.5
3–7 (high)	289	51.0	53	46.5	205	46.4	263	46.5
Attitudes about IPV								
Is a husband ever justified in beating his wife?								
Yes	265	47.7	84	73.7	308	70.5	394	71.0
No	291	52.3	30	26.3	129	29.5	161	29.0
Is any kind of violence justified if a woman refuses sex?								
Yes	248	44.5	89*	78.8	269*	61.4	360	64.9
No	309	55.5	24*	21.2	169*	38.6	195	35.1
Opinions about relationship power								
Who has more say about having sex?								
Husband	304	54.6	83	72.8	290	65.6	374	67.0
Wife	74	13.3	8	7.0	24	5.4	32	5.7
Both	179	32.1	23	20.2	128	29.0	152	27.3
Who has more power in your relationship?								
Husband	361	65.2	101	88.6	384	86.9	487	87.3
Wife	85	15.3	5	4.4	12	2.7	17	3.0
Both	108	19.5	8	7.0	46	10.4	54	9.7

[a] Distributions of baseline characteristics do not always add up to total *n* because of missing responses.
* $P < 0.05$.

IPV showed more dramatic changes from baseline to 12 months than responses to questions about power within relationships, which barely changed. No changes in the level of couple discordance/concordance in attitudes about IPV were observed (data not shown).

Table 3 summarizes the results of the longitudinal and random effects of multivariable logistic regression analyses. The associations between men's attitudes about IPV and relationship power and spousal reports of IPV were in the hypothesized direction, but were not statistically significant. However, several measures of women's attitudes about IPV and relationship power were statistically associated with their reports of IPV. Women who reported that violence was ever justified if a woman refuses sex were more than twice as likely to report IPV (adjusted OR = 2.29, 95% CI: 1.65–3.17). Furthermore, women were less likely to report IPV when they said that both partners shared sexual decision making (adjusted OR = 0.70, 95% CI: 0.5–0.98), as compared to women who said that their partner controlled sexual decision making. Notably, we found that women were less likely to report IPV when they said that both partners had equal power (adjusted OR = 0.43, 95% CI: 0.21–0.89) or that they controlled more power (adjusted OR = 0.91, 95% CI: 0.28–2.94). For all four exposures of interest, women were more likely to report IPV when couples expressed discordant attitudes relative to when they shared concordant attitudes, but these effects were relatively small and not statistically significant (Table 3).

In all longitudinal analyses, a statistically significant portion of the variance of the estimates was due to the random effect of individuals, suggesting that there was a significant amount of between-subject variation (data not shown).

4. Discussion

This longitudinal analysis suggests that couples' attitudes towards violence and opinions about sexual decision making

Table 2: Attitudes about IPV and opinions about relationship power at 12 months and changes over time.

	Men's attitudes		Women's attitudes	
	Month 12	Change in percentage points from baseline	Month 12	Change in percentage points from baseline
Is a husband ever justified in beating his wife?				
Yes	144 (26.8%)	−20.9*	313 (57.5%)	−13.5*
No	394 (73.2%)	20.9*	231 (42.5%)	13.5*
Is any kind of violence justified if a woman refuses sex?				
Yes	181 (33.6%)	−10.9*	263 (48.3%)	−16.6*
No	357 (66.4%)	10.9*	281 (51.7%)	16.6*
Who has more say about having sex?				
Husband	259 (48.5%)	−6.1*	292 (53.7%)	−13.3*
Wife	9 (1.7%)	−11.6*	27 (5.0%)	−0.7
Both	266 (49.8%)	17.7*	225 (41.4%)	14.1
Who has more power in your relationship?				
Husband	424 (79.4%)	14.2	486 (90.2%)	2.9
Wife	13 (2.4%)	−12.9	6 (1.1%)	−1.9
Both	97 (18.2%)	−1.3	47 (8.7%)	−1.0

*Statistically significant trend ($P < 0.05$).

Table 3: Men's and women's attitudes as predictors of women's IPV report, multivariable logistic regression analysisa.

	Men's attitudes		Women's attitudes		Couple discordance[d]	
	OR	95% CI	OR	95% CI	OR	95% CI
Is a husband ever justified in beating his wife?						
Yes[b]	1.34	0.95, 1.88	1.31	0.93, 1.85	1.01	0.75, 1.37
Is any kind of violence justified if a woman refuses sex?						
Yes[b]	1.06	0.76, 1.47	2.29	1.65, 3.17*	1.35	0.99, 1.79
Who has more say about having sex?						
Wife[c]	1.13	0.60, 2.16	1.31	0.70, 2.45	1.06	0.78, 1.45
Both[c]	0.93	0.66, 1.30	0.70	0.50, 0.98**		
Who has more power in your relationship?						
Wife[c]	1.40	0.73, 2.66	0.91	0.28, 2.94	1.20	0.89, 1.69
Both[c]	1.33	0.84, 2.11	0.43	0.21, 0.89**		

[a]The adjusted model assesses the relationship between each independent variable and IPV, adjusting for the other independent variables in the model and confounders-age, socioeconomic position and education (see Measures).
[b]Reference group is never justified.
[c]Reference group is husband.
[d]Reference group is concordance in responses.
*$P < 0.0125$.
**$P < 0.05$.

and relationship power are proximate determinants of women's experience of IPV. The study also provides some evidence that discordance among couples on these issues may heighten women's risk of experiencing IPV.

Our observation that gender inequitable attitudes were more commonly reported by women than men is consistent with findings from other studies [13]. It is possible that due to social desirability bias, men were less likely than women to openly agree that violence against women is justified. However, researchers have suggested that women's acceptance of IPV and conformity to dominant understandings of gender roles and relationships is likely to be an expression of their experience and expectations as well as a reflection of prevailing social norms [11, 24, 25]. Studies elsewhere in the world have noted that women who transgress norms, for example, by choosing their spouse or by seeking economic independence, are more likely to experience IPV [27, 28]. Indeed, conformity to social norms and expectations may be a protective mechanism-enabling women to fit in and avoid family and community censure. Qualitative research in Tanzania suggests that pressures on women to conform are considerable. In Lary et al.'s study in Dar-es-Salaam, young female participants placed "great value on community perceptions of their character" and noted that even taking a walk may raise family and community members' suspicions [9]. Other research by Laisser et al. in an urban community

in Tanzania also highlighted women's internalization of inequitable norms. In the words of one female participant, "we annoy our husbands with our behaviours and sometimes we deserve to be beaten [11, page 5]." That said, the authors also noted that perceptions of IPV may be changing, with both men and women acknowledging the adverse impacts of violence on women's self-esteem, health, and dignity and expressing a need for governmental action, including laws against IPV and health care services for survivors [11].

It is encouraging to note that men and women tended to express more gender equitable attitudes by the end of the study. The fact that attitudes about the acceptability of IPV changed far more than opinions about sexual decision making and power within participants' relationships suggests that the changes could have been partly a result of social desirability bias. However, reported 1PV declined steadily over the course of the study from 20% at baseline to 12% at the end of one year of followup, and were not associated with demographic characteristics or intervention/control status. Since we have data on levels of IPV only from RESPECT study participants, we cannot determine whether this result reflects a declining trend in IPV in this region. However, to our knowledge, no major interventions on IPV occurred during this time period and it is unlikely that such a substantial reduction in IPV could be explained in this fashion. The reduction in women's reports of IPV—despite improved rapport between participants and study staff (which may have improved IPV disclosure)—suggests that changes in men's attitudes and behaviors may have resulted from study participation. Given that the proportion of individuals who participated in the group counseling sessions on relationship and life skills was low (data not shown), and that STI/HIV counseling did not explicitly address relationship issues, we hypothesize that repeated exposure to survey questions on relationship dynamics and the opportunity to participate in the study as a couple may have contributed to these shifts. Engaging men and women—as individuals, couples, and community members—is widely accepted as an important component of IPV prevention efforts worldwide [23, 29]. At a minimum, our study demonstrates the feasibility, safety, and potential effectiveness of engaging young Tanzanian men and women as couples in programs that address subjects considered controversial or taboo in their communities.

Results of the longitudinal regression analyses point to the potential benefits of promoting notions of equity in relationships. Women who reported that they shared sexual decision making and relationship power with their partner were consistently less likely to report IPV. In contrast, IPV was reported more frequently when men and women espoused inequitable attitudes or reported that women had more decision making control in the relationship although few of these associations were statistically significant. These findings underscore the need to better understand the delicate balance of power in intimate relationships and the role that perceived or actual imbalances in power (especially in favor of women) have in heightening women's risk of IPV. Further qualitative research may shed light on the dynamics of power, conflict, and violence within relationships in which partners hold similar or differing views.

The association between couples' concordance on attitudes about IPV and relationship power and women's experience of violence also merits further investigation. Our study had limited statistical power to investigate the relationship between different types of concordance/discordance and IPV risk. Thus, we were unable to examine whether IPV risk differed depending on who held more equitable attitudes within a relationship. For example, future research should explore whether risk is higher among women who feel IPV is unjustified and whose partners feel it is justified. Previous research has suggested that discordance within a couple arising from perceived or actual gains in power by women can result in backlash, including IPV by men [27, 29, 30]. However, researchers have also pointed out that women can also be resistant to changes in gender roles and relations and unwilling to let go of their beliefs and expectations regarding men's and women's roles and responsibilities within relationships, leading to conflict and violence [29].

Overall, much remains to be learned about how women and men perceive and engage with ideas of greater equity in intimate relationships. Gender norms and values are dynamic, and their relationship with individual behaviors and experiences is complex. Further in-depth examination of young women's and men's evolving ideas about gender, identity, and relationships is needed. Several questions merit study. For example, do young men and women perceive their relationship to be "healthy"? Do they desire greater equity and how do they define equity in a relationship? Are these views—and concordance/discordance in views within a couple—associated with how partners communicate with each other, handle conflicts, and experience or perpetrate IPV? A better understanding of these questions will further illuminate the ways in which gender norms and relationship dynamics influence women's risk of experiencing of violence and help identify entry points for IPV prevention efforts.

Our study has additional limitations. First, the decision to measure IPV as a binary variable without accounting for frequency or type of IPV, while providing us with more statistical power, may have prevented us from observing crucial differences in the associations between attitudes and IPV risk. Second, it is especially difficult to draw strong conclusions about the heightened risk of IPV among couples holding discordant attitudes without a finer understanding of how the composition of this discordance might differently impact women's experience of IPV. Third, the decision to use only partnered couples in these analyses also raises issues of potential selection bias. It is possible that partners who both chose to participate in the RESPECT study differed in important ways from participants whose partners chose not to be in the study, including on attitudes about the acceptability of IPV. Finally, it is possible that women who experience IPV are more likely to report that violence is justified.

5. Conclusions

Despite its limitations, this research provides some new insights on the role of women's and men's attitudes toward

IPV and relationship power, including the role of partner discordance, in influencing women's experience of IPV. Unlike most previous research in Tanzania, this study prospectively examined the relationship between attitudes about gender relations and IPV among young couples. The widespread acceptance of IPV and inequitable power within relationships in this population highlights the urgent need for programs that help young people acknowledge, understand and challenge gender-based hierarchies. Greater understanding of young people's perceptions of "gender equity"—by focusing on women and men who do not condone IPV and who share power within their relationship—will facilitate the development of antiviolence programs. Furthermore, couple-based programs for HIV testing and treatment have been successful in sub-Saharan Africa and offer a foundation for antiviolence efforts [29]. The decline in women's reports of IPV and the trend towards gender-equitable attitudes that we observed in the RESPECT study indicate that concerted efforts to reduce IPV and promote gender equity have the potential to make a positive difference in the relatively short term.

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Research Article

Childbearing Decision Making: A Qualitative Study of Women Living with HIV/AIDS in Southwest Nigeria

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Using the PEN-3 model, the purpose of this qualitative study was to understand the factors responsible for the childbearing decisions of women living with HIV/AIDS (WLHA) in Lagos, Nigeria. Sixty WLHA who sought care at a teaching hospital in Lagos were recruited to participate in in-depth interviews. The average age of the participants was 30 years, and 48 participants were receiving antiretroviral therapy. Healthcare and spiritual practices, healthcare provider-patient communication about childbearing, and husband/partner support emerged as factors that contribute to the childbearing decisions of WLHA. The findings reveal the importance of discussing sexual reproductive health and childbearing issues with WLHA in the healthcare context prior to pregnancy.

1. Introduction

Childbearing (CB) is a source of concern for women living with HIV/AIDS (WLHA), because of the risk of HIV transmission to children and sexual partners [1–4]. WLHA must consider many factors when making childbearing decisions, including support from partners and healthcare providers [1, 3, 5].

As the HIV/AIDS epidemic enters its third decade, the reproductive choices available to WLHA are evolving. The initial recommendations of the CDC in 1985 and the American College of Obstetrics and Gynecology in 1987 discouraged WLHA from getting pregnant [6]. In 1994, the American Society for Reproductive Medicine encouraged physicians to discuss other options such as assisted reproductive technology [6]. Unfortunately, some of the recommended assisted reproductive technologies are not widely accessible to WLHA in resource-constrained settings [4]. However, given that many women believe that a woman's identity is affirmed by her motherhood status [5, 7–9], many WLHA in these settings make plans to have children with partners whose HIV statuses are sometimes unknown. By doing so, WLHA are at an increased risk for infection with other STIs or reinfection with a different strain of HIV by engaging in unprotected sexual practices to become pregnant [1, 4].

Women in sub-Saharan Africa between the ages of 15 and 24 years constitute 76% of those at risk for contracting HIV, and the risk of infection for this group is three times that of the general population [10]. Because HIV affects mostly women in their reproductive years, decisions about childbearing among WLHA continue to be a subject of debate in resource-constrained settings. Despite advances in antiretroviral (ARV) therapy and prevention of mother-to-child transmission services, many WLHA in these settings wrestle with the decision to have children [1, 3]. Moreover, since it is perceived that many healthcare workers are unsupportive of WLHA childbearing plans, WLHA often are discouraged from having children [3].

In this paper, we examine the ways in which childbearing decisions of WLHA are influenced, especially by partners, families and healthcare workers [1, 2, 4, 11, 12]. Moreover, the power to make such decisions depends on the information available to these women and how independent or

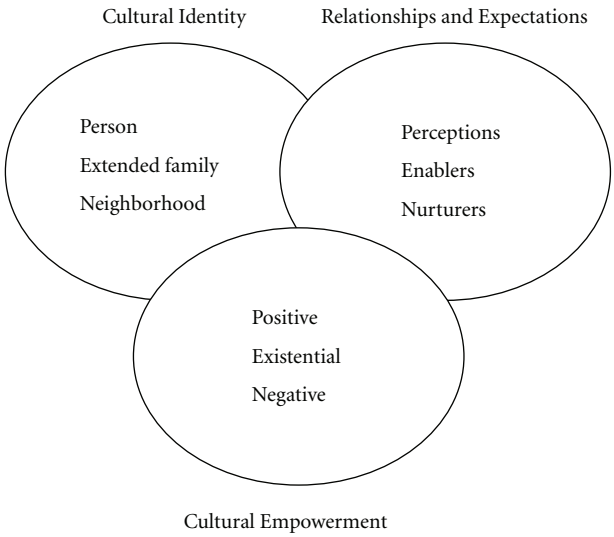

Figure 1: The PEN-3 model.

autonomous they are within their families and society at large [7]. Many WLHA in this study population in Nigeria do not have the independence or autonomy to make decisions on childbearing outside their sociocultural norms [7, 13].

Our aim was is examine the childbearing decision making process of WLHA by utilizing the culture-centered PEN-3 model. We assess the values and beliefs that underlie WHLA perceptions; reveal enablers, such as available healthcare support and resources; and identify nurturers, such as the influence of partners involved in their decision making.

2. Theoretical Framework

The PEN-3 cultural model is used to examine the role of culture in addressing beliefs and behaviors that contribute to health decisions [7, 14]. The PEN-3 model emphasizes the need to focus on the cultural factors that influence decision making [7]. In other words, the emphasis is not on the individual, but on multiple factors that collectively shape health decisions.

PEN-3 has three domains, and each domain has three dimensions (see Figure 1). The three interconnected domains are cultural empowerment (CE), relationships and expectations (RE), and cultural identity (CI). CE considers the positive, existential, and negative cultural values that are factored into health behaviors and decisions. RE considers factors such as perceptions, enablers, and nurturers that influence health behaviors and decisions. CI reveals the appropriate level of focus for health interventions—the person, the extended family, or the neighborhood—by addressing how one's identity plays a critical role in influencing health decisions [7, 14].

RE is the domain of interest in this study, which explores the perceptions, enablers, and nurturers that facilitate or hinder childbearing decisions of WLHA. Perceptions include the values and beliefs that may promote or hinder healthy behaviors when factored into childbearing decisions of WLHA. Enablers are the institutional (healthcare) support services that may influence healthy behaviors and practices among WLHA that may affect childbearing decisions. Nurturers are partners and family members who may support or discourage childbearing among WLHA.

3. Methods

3.1. Study Site. The study was conducted between July and August 2011 at the hematology clinic of the Lagos State University Teaching Hospital (LASUTH), located in Southwest Nigeria. With a population of about 9 million, a total fertility rate of 5.4%, and a mix of Nigerians from different ethnic groups, Lagos is one of the most populous states in Nigeria [15–17]. The study site was ideal because it provides HIV care and treatment free of charge, which enables WLHA from diverse backgrounds to access care. The clinic also provides free counseling and testing services, as well as HIV support groups.

3.2. Study Design. Using a qualitative research design methodology, in-depth interviews were conducted over a 2-month period with 60 WLHA who attended the hematology clinic. A semistructured interview guide adapted from Cooper et al. [1] was used to explore childbearing desires and sexual and reproductive healthcare (SRH) needs, and their influence on the childbearing decisions of WLHA. The first author interviewed participants individually in a private room at the clinic. All interviews were audio recorded and conducted in one of the three main languages spoken in Lagos (English, Pidgin English, or Yoruba). Verbal informed consent was obtained from participants prior to recording. Each interview lasted between 45 and 60 minutes. The participants were given 1000 Naira ($7) as an incentive to cover their transportation costs. Ethical approval was obtained from the Institutional Review Boards of Penn State University and LASUTH.

3.3. Recruitment. Purposive sampling was used to recruit WLHA between the ages of 18 and 43 years who were receiving care at the hospital. The first author obtained permission from the department head at the clinic after explaining the purpose of the study and eligibility criteria to the resident physicians. Initially, participants were recruited through referrals from the resident physicians. About a week into the study, however, we realized that physicians often forgot to refer potential participants to the study because the clinic was so busy. In addition, when referrals were made, potential participants were not interested in extending their time spent at the hospital by participating in interviews, as they simply wanted to complete the tasks that brought them to the hospital. So, we devised an alternate approach and recruited potential participants while they were waiting to collect a 3-month supply of ARV drugs at the pharmacy. This approach worked better, because WLHA were more relaxed during the final stage of their visits. Out of the 63 participants recruited, three refused to participate in the study, either because they did not want to be recorded or due to time constraints.

3.4. Data Analysis. The first author conducted a preliminary analysis of the transcripts from the first five interviews to determine the aspects of the interview guide that needed to be revised or removed for clarity. All interview transcripts were thoroughly read by the first author to become immersed in the data and then loaded into NVivo 9 to aid in organization and data management. Using constant comparison consistent with Glaser and Strauss' [18] approach to open coding, we generated free nodes. Based on similarities, we then organized these free nodes into related categories or themes guided by the PEN-3 model to generate tree nodes (axial codes). Finally, we organized emerging themes into categories within the relationships and expectations domain of PEN-3.

4. Results

4.1. Demographics. Participant demographic information is summarized in Table 1.

Table 1: Characteristics of the study population.

Characteristic	Number
Mean age (range)	30 y (20–43 y)
Interquartile range	6
20–25	8
26–30	23
31–35	20
36–40	6
41–45	3
Education	
None	2
Primary	4
Secondary	26
Higher	28
Employment status	
None	24
Self-employed	17
Employed	15
Volunteer	4
Ethnicity	
Yoruba	22
Ibo	14
Hausa	2
Ishan	6
Delta Ibo	3
Other	13
Relationship status	
Married	30
Widowed	5
Engaged	5
Single	20
Mean no. of years since diagnosis (range)	5 y (1 wk–10 y)
Currently on ARVs	
Yes	48
No	12
Partner status	
Negative	24
Positive	16
Unknown	20
Disclosure to partner	
Yes	38
No	22
Currently living children	
0	26
1	16
2	8
≥3	10
Future childbearing desire	
Yes	48
No	12

Using the PEN-3 model, the results from our in-depth interviews revealed three themes and two subthemes:

(1) the role of faith in perceptions about childbearing decisions;

(2) patient-healthcare provider communication as an enabler in child bearing decisions;

(3) partner support as a nurturing influence on childbearing decision making, including

(a) support informed by knowledge and awareness of HIV,

(b) support informed by denial of infected partner's HIV status.

4.2. Perceptions in Childbearing Decision Making: Role of Faith. Even though many of the participants held strong spiritual beliefs, almost all of them recognized the importance of utilizing available healthcare services instead of relying solely on spiritual practices such as faith healing. Nevertheless, some of the women felt they had to consider other spiritual alternatives in order to become mothers, since they believed that medical care alone would not result in successful childbearing. While some women believed in

a combination of healthcare and spiritual (prayer) practices, others believed in just one or the other.

One of the most revealing findings that emerged was the perception that HIV is a spiritual problem caused by "evil or wicked forces" that curse a woman, thereby preventing her from becoming a mother. Most of the women who held these beliefs had lost multiple children or had experienced difficulty getting pregnant, even after adhering to the HIV treatment regimens recommended by their physicians. One participant said:

> *I believe that somebody that has HIV does not die quickly, that's why I wanted to know why I lose baby after 25 days, because I used my drugs faithfully when I was pregnant and followed what the doctors told me to do. Next time, I will go to the church since this thing may be a spiritual problem and spiritual problems need spiritual solution (28 years old).*

Most women still utilized the services of the clinic during pregnancy, especially for delivery. Many also continued faith healing practices, which they believed would help their children to be born HIV negative. Most acknowledged that faith healing would not cure them of HIV, but they did believe that such practices would cure them of the underlying cause of childlessness, the "evil forces."

Some women thought that adhering to ARVs would prevent all medical problems associated with pregnancy. One participant said:

> *I was very angry; you know that after all my effort taking the drugs and following all the doctor's advice, I still lost another baby. So, in 2008 when I got pregnant again, I decided to just go to the church for prayers and my ANC (antenatal care). I (went to the hospital) and told the doctor to go through CS (cesarean section), I didn't breastfeed and I was not taking any drugs and my baby is negative. During this pregnancy, I was not going to a hospital. I was just going to the church for prayer because I believe that God will help me break the evil (curse) so I can keep a pregnancy (34 years old).*

When asked if she would do anything different if she were to get pregnant again, she responded:

> *If I want to get pregnant, I will be careful. I will follow what they tell me to do here (hospital) and I will also go to church for prayer. Let nurses help me on (what to) do (so) that the baby would not contract HIV again. That is the only thing that I need from them.*

4.3. Enabling Factors in Childbearing Decision Making: Patient-Provider Communication. Our interviews revealed that most women wanted healthcare workers to initiate discussions about sexual reproductive health (SRH) and CB. When healthcare workers simply ask if WLHA have any complaints or problems, it does not encourage open discussion about SRH and CB issues. One 27-year-old participant noted, "some people may not have the heart to talk about it... For some people if you don't ask they will not say anything. You ask, "is everything okay?" They say, "okay," even if it is not."

Very few WLHA who desire and intend to have children have initiated these conversations with their healthcare providers due to the perceived stigma associated with childbearing among WLHA [19]. WHLA are more likely to initiate these discussions with healthcare workers whom they perceive as supportive of their childbearing goals [1, 20]. WLHA are more likely to open up when healthcare workers ask them specific questions about their childbearing desires and intentions [21]. For many participants, healthcare workers who initiated such discussions enabled them "to open up freely." One 33-year-old participant remarked, "it is good if they start asking about it (CB) so that many of us can open up and they can advise us." Another participant added that it is beneficial when healthcare workers initiate these discussions, because

> *It will help them (healthcare workers) touch every other part of your life that has to do with this thing (HIV) that most people are shy or don't have the confidence to discuss. If they notice that you are asking them the questions and you are interested... they will open up about their childbearing plans... and use it (the information) to help themselves and things will get better (25-year-old).*

When physicians initiate SRH/CB discussions, WLHA "have the free mind to start telling them about the other (related) things," which results in better provider-patient dialogue and, potentially, better healthcare experiences.

When healthcare workers did not ask questions related to SRH, some women perceived that such topics were off limits and not to be discussed. One participant noted:

> *Well, if perchance during consultation a doctor asks leading questions, then it can prompt you to open up, but where they don't even broach such subjects at all, then there is no way you can open up, because it's like we're here for A and you're talking about B. It's a different thing where a doctor says that even though I know that we're here for A, you can talk about B. Feel free to talk about B, C, and D (34 years old).*

On the other hand, some women saw initiating such conversations as being beyond the scope of healthcare services. Others were unsure of the type of SRH/CB conversations they could have with their healthcare providers or the right time to broach certain topics, particularly given their sensitive and intimate nature. One 25-year-old participant with persistent itching and discharge in her genitals said, "I was thinking in my mind whether I can ask him or show him something like this. Can I tell the doctor something like this?" This sentiment also was expressed by a 28-year-old participant who had recently experienced a miscarriage.

When asked if she told her physician about the miscarriage, she explained that she did not, because "if they don't ask you, you will not say." When healthcare workers do not ask questions related to SRH/CB needs, it is a missed opportunity and a great disservice to WLHA.

For those WLHA who summon the courage to ask questions about SRH and CB, the advice they usually get from healthcare workers is, "when you are ready, tell us and we will let you know what to do." In this setting, being ready refers to fulfilling marital and reproductive goals, referred to as *life projects of marriage and reproduction* [8]. For WLHA, being armed with SRH and CB information prior to getting pregnant is essential, since some pregnancies are unplanned. One 27-year-old participant said, "they can also be telling those of us that are not married so that we will know what to do and how to go about it when that time comes."

For most participants, the sex of the physician was not a major issue in determining the content of their discussions. However, the physician's approach and interactions with them seemed to matter more in influencing the doctor-patient relationship. A 25-year-old participant said:

> *There are some doctors that you meet and the way they welcome you will give you more assurance to open up to him or her. When a person is approaching you like that, you will feel free to open up and your mind will be relaxed. It does not matter to me if it is a male or female doctor.*

In addition, a physician who "shows real interest" and does not see a WLHA "as an object or a figure" will encourage open discussion. Some women noted that supportive and encouraging healthcare workers can make them feel at ease and "alive" when discussing SRH/CB issues.

> *Before I open my mouth to tell the doctor that I want to get pregnant, I just read his face. Within that 2 or 3 minutes I read his face to know (that) he is not harsh, and that is what gave me the zeal to ask him questions. When I said I had questions, he said, "oh go on my ears are welcome." When I now told him, he said, "what are you waiting for (that you have not had another baby)? If na me be your husband, I for dan give you double belle (If I were to be your husband, I would have impregnated you with twins by now)." He was just saying it jokingly and that made me feel comfortable to go ahead and get pregnant. There are some doctors I cannot talk to like that, because of how harsh they are (32 years old).*

4.4. Nurturing Influences in Childbearing Decision Making: Role of Partners. Contrary to the negative message in the literature focusing on the nonsupportive role of partners of WLHA, most participants reported that their husbands and partners were supportive. Although the definition and degree of partner support varied, some forms of support were informed by knowledge and awareness of HIV, while others were informed by denial of their partner's HIV status. Support could take on different forms, from the partner "being there" to "encourage," "advise," "fight HIV together," "share each other's burden," and "console," to more tangible support, such as going along to the hospital or providing transportation money.

Most of the women who had disclosed their status to their partners reported that their partners were supportive and saw them as "normal," and "not as someone who is positive." This form of support can have potentially negative consequences for their partners. One 28-year-old participant said:

> *When I told my husband, he told me to remove my mind from it and I should not think about it (HIV). He is like second god to me. He advises me a lot. Right from the first day, I don't think about it at all and forget there is something like this in me because of his support. I live my life normal, even sleep with my husband normal (unprotected).*

Most women reported being indebted to their partners for the kind of support they received. As such, they were willing to do anything to reward their partners, even engage in unprotected sex. One participant adhered to her medications for this very reason:

> *I will allow him to have his fun (sex) with me, and that is why I don't miss my drugs. I know I am not protecting myself only; I am also protecting people around me. If that is what he wants, I will allow him because of the kind of support he has given me (30 years old).*

This sense of indebtedness is driven by the fact that HIV "has broken many homes;" in fact, "there are some women that are having problems at home because of their status."

Childbearing was central to the support provided by husbands to their wives. Many husbands stated that the reason they stood by their wives was because they wanted to have children. As a way of thanking husbands for their support, WLHA were willing to do whatever it took to have children. One participant expressed fear of losing her marriage, and discussed how she actively showed appreciation to her husband for his support:

> *This (children) is what my husband wants and this is what I will give him, because he has been patient and supportive from day one... You don't know their mind at all. All these men can be funny with your status again. And he is negative. Anything can happen to your marriage (32 years old).*

Negative past experiences influenced some women to "secure the relationship" by waiting until they got married and became pregnant before disclosing their status.

> *I only told my boyfriend who is now my husband, about my status when I got pregnant, because I had several relationships before him and after I told them, it did not work out. So I had to wait before telling my husband until after I got pregnant (28 years old).*

4.4.1. Nurturing and Support Based on Knowledge and Awareness of HIV. After learning from counselors and support groups at the clinic about HIV and ways to avoid transmission, most women reported that they went back home to educate their partners. After educating their partners, participants often received their full support.

> *I told him he doesn't have any problem because I have been using my drugs, and there is a way to have children. They lectured us then I used that lecture to teach him. After that, I brought him to the clinic... for counseling. They talked to him, even the lady counselor was positive, too. She said she got married and had kids after, so he supported me. He did the test and he was negative. Since then my husband supports me fully. We did not tell his family because we don't want family problems (28 years old).*

Another participant explained that after disclosure, her partner expressed his support by wanting to learn more about HIV/AIDS in order to continue with the relationship:

> *The only thing he asked me was that, "What do I do? What am I supposed to do as I am the opposite person? Do I run a test? Do I take drugs? Do I do this or that?" I just told him, "be yourself." He even comes to the hospital with me because he wants to know more about HIV (25 years old).*

Another way in which partners showed their support was by covering for their wives in the presence of his family (her in-laws), specifically about infant feeding practices and mode of delivery. When in-laws started to become suspicious, husbands would step in to dispel any rumors.

> *I did not breastfeed my baby at all, and my husband's family had a problem with that. They (in-laws) would call my husband and ask him why I am not breastfeeding. My husband had to lie that because of the CS (cesarean section) I did I can't breastfeed because the child will reject the breast milk, so we have to give her SMA (formula) (28 years old).*

WLHA also reported that they were able to extend the support received from their partners to encourage other WLHA who were in similar situations. A 29-year-old participant described an encounter with a devastated WLHA who had just learned of her HIV-positive status:

> *Because of my own experience, I went to her and asked why she was crying. She said she's HIV positive. I said, "is that why you are crying? If you see me on the road, will you know that I am HIV positive?" The woman said, "no. So, you are positive?" I said, "yes." I told her, "you are not falling sick, you can do things on your own; your health is okay, so why are you crying?" I asked if her husband knew about her status and she said, "yes." I told her, "if your husband is not giving you problem, and he is negative, then why are you giving yourself problem?"*

A 41-year-old participant also described how she felt when she had just discovered her status and how she is using that experience to help others: "when I discovered, it really weighed me down. I just felt that all was lost. I felt negative about life. But with the help of my husband who supported me, now I can encourage other younger ladies around."

4.4.2. Nurturing and Support Based on Denial of Infected Partner's HIV Status. Some husbands and partners refused to accept the fact that their partners were infected with HIV. This type of support has potentially negative consequences, since such partners tend to neglect necessary protective measures to prevent disease transmission.

> *He is negative and I am positive, but he still doesn't protect himself from me. Any other man that knows his wife is positive and he is negative will use every opportunity to protect himself at all times, but he doesn't do that (25 years old).*

Some women reported that their partners provided support to them, but refused to accept their HIV-positive status, especially those partners who were HIV negative. For example, a 28-year-old participant noted, "when I first knew (of my status), if my husband wants to make love with me I will give him the condom. He will say, 'No.' He will tell me, 'you don't have anything like that.'" This form of support could be problematic, because it prevents WLHA from taking necessary precautionary and preventive measures until it is almost too late, as in the case of a 41-year-old participant:

> *He was even the one that confused me. He gave me the impression that I didn't have it, because he was negative. He said I should forget about it and rule it out of my mind and that was why I did not start treatment until when I had the crisis.*

5. Discussion and Conclusion

5.1. HIV Seroconversion in Infants and Pregnant Women. Infants of HIV-positive mothers are at increased risk for HIV infection, and when infants are infected, the disease progresses rapidly [22, 23]. Due to the latency period associated with HIV seroconversion, a child is declared free from pediatric HIV at 1 year of age after repeat testing or 6 weeks after breastfeeding has ended [23]. In addition, maternal seroconversion of HIV status can occur during early pregnancy (<14 weeks), late pregnancy or even postpartum; that is why repeat testing in late pregnancy (32–34 weeks) and postpartum is often recommended for pregnant women [24]. The World Health Organization (WHO) recommends testing of HIV-exposed infants between 4 and 6 weeks of age, and repeat testing at 9 months and 18 months, as well as 6 weeks after cessation of breastfeeding [22, 24].

Our findings expand on previous work highlighting the dynamic and complex nature of childbearing decisions, which are deeply rooted in personal beliefs and support from significant others [3, 4, 25]. Our findings describe the childbearing decision making process for WLHA within a context of competing priorities among the women, their

partners, and healthcare workers. A majority of participants desired to have children despite their HIV status. This was due, in part, to *securing the relationship*. Moreover, their partners wanted them to have children as soon as there were physical improvements in their health, whereas healthcare workers recommend waiting for a high CD4 count and a low viral load before commencing childbearing [1, 3, 4].

Participants believed that combining healthcare services with faith healing practices was the best way to achieve favorable childbearing outcomes. Women sought alternate practices when they believed that medicine could not ward off "spiritual forces" or that healthcare practices had failed them. Our results on the role of faith in childbearing complement findings from Adogame [26], although his study did not focus on childbearing, but on how African Pentecostals deal with HIV/AIDS. Our results also confirm previous findings on the role of spirituality in future childbearing [27–29].

Supportive healthcare workers encouraged WLHA to discuss their childbearing plans with them when they were ready to have children [30]. However, not all women in our study discussed their childbearing plans with healthcare workers [1, 4]. Consistent with findings from previous studies, some WLHA resented the information they received from healthcare workers about planning pregnancy and timing unprotected sex [1, 3, 31]. Given that some WLHA viewed pregnancy as "something that just happens," not discussing SRH/CB issues in the healthcare setting is a cause for concern due to possible implications for access to preventive and treatment services.

Our findings indicate that most partners were supportive of WLHA, and that this support was expressed in many different ways. Partner support encouraged future childbearing and empowered participants to provide emotional support to other WLHA who were discouraged. This finding is contrary to prior findings that WLHA experience negative consequences such as domestic violence, abandonment, and infidelity after disclosing their status to their partners [1, 2].

Consistent with other findings, many participants expressed confusion about serodiscordance, leading them to engage in risky sexual behaviors with their partners or fail to access needed treatment [4]. As found bySmith and Mbakwem [32], participants expressed unprotected sex as a marker of partner support and trust. In addition, partners showed their support by becoming "coconspirators" and covering for their wives in the presence of family and friends [32].

This study has some limitations that should be considered. Participants were not randomly selected, and as such, the findings are biased towards WLHA who access healthcare in clinical settings. Therefore, the results should not be generalized, since they are not fully representative of all WLHA.

Despite these limitations, the results of this study have implications for healthcare providers. Healthcare workers should provide necessary SRH/CB information to all WLHA, whether they are planning to get pregnant or not, so that they can be prepared to make the right decisions. This is important, because not all pregnant WLHA will come to the clinic for antenatal care; some will seek alternative forms of care. If SRH/CB issues are not discussed prior to pregnancy, WLHA may engage in practices that may be harmful to both themselves and their children.

Conflict of Interests

No conflict of interests has been declared by the authors.

Ethical Approval

The study protocol was approved by the Institutional Review Boards of Penn State University and the Lagos State University Teaching Hospital. Informed consent was obtained from all participants.

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Review Article

Bolstering the Evidence Base for Integrating Abortion and HIV Care: A Literature Review

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HIV-positive women have abortions at similar rates to their HIV-negative counterparts, yet little is known about clinical outcomes of abortion for HIV-positive women or the best practices for abortion provision. To fill that gap, we conducted a literature review of clinical outcomes of surgical and medication abortion among HIV-positive women. We identified three studies on clinical outcomes of surgical abortion among HIV-positive women; none showed significant differences in infectious complications by HIV status. A review of seven articles on similar gynecological procedures found no differences in complications by HIV status. No studies evaluated medication abortion among HIV-positive women. However, we did find that previously expressed concerns regarding blood loss and vomiting related to medication abortion for HIV-positive women are unwarranted based on our review of data showing that significant blood loss and vomiting are rare and short lived among women. We conclude that although there is limited research that addresses clinical outcomes of abortion for HIV-positive women, existing data suggest that medication and surgical abortion are safe and appropriate. Sexual and reproductive health and HIV integration efforts must include both options to prevent maternal mortality and morbidity and to ensure that HIV-positive women and women at risk of HIV can make informed reproductive decisions.

1. Introduction

More than half of all people living with HIV worldwide are women, and most of them live in low- and middle-income countries [1]. Facilitating access to comprehensive sexual and reproductive health (SRH) services for women is currently the focus of many global health interventions, in part as a result of efforts to achieve Millennium Development Goal 5b (achieving universal access to SRH). However, few of these interventions focus on the specific challenges of facilitating access to SRH services for HIV-positive women. Fewer still focus on ensuring access to safe abortion for HIV-positive women.

HIV-positive women, like all women, require the right to access safe abortion services to prevent maternal mortality and morbidity and to be able to exercise their reproductive rights. Documented rates of unintended pregnancies among HIV-positive women highlight the importance of access to safe abortion for this population, for example, studies have shown that between 51% and 91% of pregnancies among HIV-positive women are unintended [2]. Furthermore, studies show that HIV-positive women have abortions at similar rates to their HIV-negative counterparts and seek abortions for many of the same reasons other women do, such as economic constraints or lack of partner support [3–9]. However, HIV-positive women face particular challenges when trying to access abortion services.

In addition to issues that affect women regardless of HIV-status, such as lack of information about abortion options, and financial barriers to abortion care, abortion is also legally restricted in many low- and middle-income countries where HIV is prevalent—limiting positive and negative women's access to information and services. For example, in Southern Africa, where HIV rates are the highest in the world, abortion is only available without legal restriction in South Africa [10]. Furthermore, the confluence of stigma surrounding HIV/AIDS and abortion may make it even more difficult for HIV-positive women to access abortion services. Several studies have documented that HIV-positive women experience discrimination by health care providers based

on their reproductive decisions, with some women facing pressure to carry a child to term and others to have an abortion [11–13]. Furthermore, unique clinical questions, such as concerns about transmitting HIV during pregnancy and fears about how a pregnancy will affect a woman's health, may impact HIV-positive women's abortion-related decision making [11]. Clinical concerns may also affect providers' or policymakers' decisions to make certain types of abortion services available to HIV-positive women. In particular, some authors have suggested that medication abortion may not be appropriate for HIV-positive women because they are at higher risk for anemia and that vomiting from medication abortion drugs may reduce the efficacy of HIV treatment drugs [12, 14].

The separation of abortion services from both SRH services and HIV services may present further obstacles to HIV-positive women's access to safe abortion care [15]. Efforts to integrate SRH and HIV services have become a priority in many health care settings, due to the potential benefits of integrating health care services, including increasing access to services and improving the quality of care [16]. However, integration research and programs have largely focused on including family planning and prevention and management of sexually transmitted diseases in HIV-focused services (or vice versa), but generally do not address safe abortion for HIV-positive or -negative women. Some models that could be used to integrate abortion and HIV services include providing abortion care in the same clinic where women receive HIV care and treatment or including referrals from one service to another. In settings where abortion is legally restricted, harm reduction counseling about safe and effective misoprostol regimens could be integrated into the HIV care setting.

Despite the documented need for abortion among HIV-positive women [3–8], there has been little research that addresses clinical outcomes of surgical and medication abortion for HIV-positive women or the best practices for abortion service provision and care. This paper reviews the existing data on clinical outcomes of surgical and medication abortion among HIV-positive women, with a focus on complication rates and adverse events. Given the limited amount of data available on this issue, we have selected a small group of gynecological procedures that are of similar or greater invasiveness when compared to abortion and review the literature for those procedures conducted among HIV-positive women. We, then, summarize data on blood loss and vomiting experienced by some women undergoing medication abortion to address concerns about the differential impact of these side effects on HIV-positive women.

2. Methods

We conducted two separate literature reviews which were supplemented with focused searches to identify additional literature. For the first review, from August to October 2011, we searched PubMed for studies that reported on clinical outcomes of surgical and medication abortion among HIV-positive women using the keywords "abortion" or "termination of pregnancy" and "HIV." Only original research studies published in English with female human subjects were eligible for inclusion. We scanned the titles, abstracts, and citations of all articles and removed any that were irrelevant, such as articles focusing on the reproductive rights of HIV-positive women or the characteristics of HIV-positive women seeking abortion care.

For the second review, focusing on gynecological procedures deemed to be similar to abortion as explained previously, from March to May 2012, we searched PubMed using the following search terms: "HIV" and "LEEP" (loop electrosurgical excision procedure), "laparoscopy," "cone biopsy," "fibroid treatment," "endometrial biopsy," "endometriosis management," "myomectomy," or "uterine cervical neoplasms diagnosis, surgery, or therapy [MESH]." (Medical Subject Headings (MeSH) is the National Library of Medicine controlled vocabulary thesaurus used for indexing articles for PubMed). We did not find any studies using the search terms "HIV" and "fibroid treatment," "endometriosis management," or "myomectomy." As in our first review, we considered original research studies published in English with female human subjects eligible for inclusion. We scanned the titles, abstracts, and citations of all articles and removed any that did not discuss complications among HIV-positive women.

For the third and fourth searches, to address concerns expressed regarding medication abortion for HIV-positive women, in October 2011, we searched PubMed for articles on (1) changes in hemoglobin levels due to blood loss from medication abortion where anemia is prevalent (discussed below) and (2) the frequency and duration of vomiting due to medication abortion drugs. Our aim was not to conduct an exhaustive review of this expansive body of the literature, but rather to identify key articles and identify the severity and frequency of blood loss and vomiting among women choosing medication abortion.

To identify articles on blood loss, we limited the search to India, because there is a high prevalence of anemia among Indian pregnant women [17, 18], and a large number of medication abortion studies have been conducted in India. Our search terms included "medical abortion" or "medication abortion" and "India;" these results were then narrowed down by searching within the text of each article for the keywords "anemia" or "hemoglobin." Only original research studies published in English with female human subjects were considered eligible for inclusion. We scanned the titles, abstracts, and citations of all articles and removed any that did not include "anemia" or "hemoglobin" as a keyword.

To identify articles on vomiting associated with medication abortion drugs, we used the search terms "medical abortion" or "medication abortion" and "side effects." The search results were then narrowed down by searching within the text of each article for the keyword "vomit." Only English studies with female human subjects were eligible for inclusion. We reviewed both original research articles and literature reviews. We scanned the titles, abstracts, and citations of all articles and removed any that did not include information on the frequency and/or duration of vomiting. We ultimately focused on the findings from a literature review that summarized data on vomiting from medication

abortion drugs. None of the searches were limited to specific dates of publication.

3. Results

Our first literature review on clinical outcomes of surgical and medication abortion identified 559 articles. No articles discussed clinical outcomes of medication abortion among HIV-positive women. Three articles that discussed clinical outcomes of surgical abortion among HIV-positive women met our criteria and were included in our review.

3.1. Surgical Abortion. Detailed information on each of the three articles that examined clinical outcomes of surgical abortion among HIV-positive women is included in Table 1. The first study, conducted in urban Uganda, explored whether HIV was a risk factor for postabortion endometritis-myometritis (PAEM) [19]. PAEM was defined as an incomplete abortion (admitted induced or spontaneous abortion) with intrauterine infection. Of women with PAEM, 32.7% were HIV-positive, and of women without PAEM, 36.5% were HIV-positive. The difference was not statistically significant.

The second study examined morbidity associated with curettage for abortion among HIV-positive and -negative women in a public hospital in Texas, USA [20]. Women with septic abortions were excluded from the study, and only a minority of subjects had AIDS. There were higher numbers of anesthesia-related complications and instances of retained placenta among HIV-positive women. However, the numbers were small (two and three, resp.), and the authors posit that instances of retained placenta were unlikely related to HIV-status as there is no known biologic susceptibility to retained placental tissue among HIV-positive women. Three percent of HIV-positive women and 1% of HIV-negative women experienced infectious complications; the difference between groups was not significant.

In the third study, the authors compared the risks of postoperative morbidity among HIV-positive and -negative women undergoing six categories of surgical procedures, including curettage [21]. Among patients experiencing major and minor complications after curettage (e.g., fever requiring antibiotics, additional surgical procedures, anemia, urinary tract infection, development of endometriosis and lochiostasis after obstetric procedures, and disseminated intravascular coagulation), 9.7% were HIV-positive and 1.4% were HIV-negative. However, the point estimates must be viewed with caution due to the small number of women in the sample who experienced relevant complications (7 HIV-positive women and 1 HIV-negative woman), the width of the confidence intervals (0.92–63.84), and the lack of statistical significance; it was also impossible to separate out minor from major complications based on the published data.

3.2. Other Gynecological Procedures. Due to the lack of data specifically addressing clinical outcomes of surgical abortion among HIV-positive women, we reviewed the literature on clinical outcomes of gynecological procedures deemed to be of similar or more invasiveness to abortion. We identified 144 articles. Seven articles, which provide clinical outcomes after LEEP and laparoscopic sterilization among HIV-positive women, met our inclusion criteria.

We summarize details of each of the seven studies in Table 2. We found one article on laparoscopic sterilization for HIV-positive women in Thailand [22]. The authors found that laparoscopic sterilization was safe. No study participants experienced immediate or subsequent surgical complications, though the authors did not provide detail regarding what complications were measured. Six studies examined complications among HIV-positive women undergoing LEEP. One study, conducted in Kenya, measured women's self reports of the presence and severity of complications, including bleeding, discharge, and pain [23]. No participants reported severe symptoms, and only 1% (n = 1) reported moderate symptoms. The other five studies, conducted in Thailand and Zambia, measured postoperative and intraoperative bleeding-related complications including hemorrhage and rates of postoperative infection among HIV-positive and -negative women undergoing LEEP [24–28]. There were no significant differences in complication rates based on HIV-status.

3.3. Medication Abortion. To address concerns raised in the literature regarding risks of blood loss and vomiting related to medication abortion for HIV-positive women, we conducted a review of the existing data on blood loss with medication abortion in India—a setting with a high prevalence of anemia. Our literature search identified 39 articles, five of which were included in our review. These are summarized in Table 3. While no studies were identified that specifically measured outcomes of medication abortion among women with anemia, all of the studies were conducted in India where the majority of pregnant women have anemia [17, 18]. Three of these articles reported findings from multicountry studies conducted in India, Cuba, and China [29–31]; findings reported in the text and Table 3 focus only on the India data.

Clinically significant changes in hemoglobin levels due to blood loss from medication abortion were rare in all studies. Mean changes in hemoglobin levels between study enrollment and the follow-up visit (12–14 days later) ranged from 0.1 to 0.29 gm/dL, and the percent of women whose hemoglobin levels dropped 2 gm/dL ranged from 1.2 to 4% [29–33]. In one study, one woman required a blood transfusion [30].

Our review of vomiting from medication abortion identified 147 articles, of which 66 were relevant. One literature review of nine studies comparing medication abortion practiced in homes and clinics using the evidence-based medication abortion regimen of 200 mg mifepristone and 400 μg misoprostol orally provided vomiting data for four studies conducted in Albania, Nepal, Turkey, and Vietnam [34]. Reported rates of vomiting ranged from 11.5 to 33.7%, and vomiting lasted an average of less than one day. Other relevant articles identified in our search reported similar rates and durations of vomiting among women undergoing

Table 1: Studies on surgical abortion among HIV-positive women.

Authors	Study type	Setting	Population	Number	Findings
Grubert et al. (2002) [21]	Retrospective	Germany, specialized outpatient clinic	HIV-positive and -negative women undergoing curettage	72	9.7% ($n = 7$) of HIV-positive women and 1.4% ($n = 1$) of HIV-negative women experienced complications; difference was not statistically significant ($P = 0.063$; OR, 7.65; 95% CI, 0.92–63.84)
Okong et al. (2002) [19]	Prospective	Uganda, gynecological ward at urban hospital	HIV-positive and -negative women with and without postabortion endometritis-myometritis (PAEM)	158	32.7% ($n = 17$) of women with PAEM were HIV-positive, and 36.5% ($n = 38$) of women without PAEM were HIV-positive; difference was not statistically significant (OR, 0.84; 95% CI 0.39–1.80)
Stuart et al. (2004) [20]	Retrospective	Texas, USA, public hospital	HIV-positive and -negative women undergoing curettage for abortion	284	3% ($n = 2$) of HIV-positive women and 1% ($n = 3$) of HIV-negative women experienced infectious complications; difference was not statistically significant ($P = 0.435$). 3% ($n = 2$) of HIV-positive women and no HIV-negative women experienced anesthetic complications; 4% ($n = 3$) of HIV-positive women and 0% ($n = 1$) of HIV-negative women experienced retained placenta.

Table 2: Studies on LEEP and laparoscopic sterilization in HIV-positive women.

Authors	Study type	Setting	Population	Number	Findings
			Laparoscopic sterilization		
Intaraprasert et al. (1996) [22]	Retrospective	Thailand, university hospital	HIV-positive women undergoing laparoscopic sterilization	18	No immediate or subsequent surgical complications
			LEEP		
Kietpeerakool et al. (2009) [26]	Prospective	Thailand, university hospital	HIV-positive and -negative women undergoing LEEP	789	HIV infection was not significantly associated with LEEP complications (OR, 0.41; 95% CI, 0.15–1.15)
Kietpeerakool et al. (2006) [25]	Prospective	Thailand, university hospital	Women with abnormal cervical cytology undergoing LEEP	206	HIV was not an independent risk factor for LEEP complications ($P = 0.49$)
Kietpeerakool et al. (2006) [24]	Retrospective	Thailand, university hospital	HIV-positive and -negative women undergoing LEEP for CIN	120	HIV was not significantly associated with LEEP complications ($P = 0.24$)
Pfaendler et al. (2008) [27]	Prospective	Zambia, primary care clinics and tertiary hospital	Women in a screen and treat cervical cancer prevention program undergoing LEEP	748	Number of women experiencing complications was not large enough to compare significant differences in complications based on HIV-status; complication rates were low in both groups
Sutthichon and Kietpeerakool (2009) [28]	Retrospective	Thailand, university hospital	Women undergoing their first LEEP	857	HIV status was not a significant predictor of perioperative complications
Woo et al. (2011) [23]	Prospective	Kenya, clinics	HIV-positive women who returned for a 4-week followup after LEEP	180	No participants reported severe symptoms; 1% ($n = 1$) reported moderate symptoms; 99% ($n = 179$) reported very mild to mild symptoms

Table 3: Studies summarizing data on blood loss due to medication abortion in India.

Authors	Study type	Setting	Population	Number	Medication abortion regimen	Findings
Coyaji et al. (2002) [33]	Prospective	India, urban and rural hospitals	Pregnant women with gestations of ≤63 days in the urban sites and ≤56 days in the rural site	900	600 mg mifepristone and 400 μg misoprostol; oral	Mean change in hemoglobin levels 0.1–0.2 gm/dL
Elul et al. (1999) [31]	Retrospective	India, urban hospital	Pregnant women with amenorrhea ≤56 days	250	600 mg mifepristone and 400 μg misoprostol; oral	Mean change in hemoglobin levels −0.29 gm/dL
Harper et al. (1998) [29]	Prospective	India, urban hospital	Pregnant women with amenorrhea ≤56 days	250	600 mg mifepristone and 400 μg misoprostol; oral	4% of women experienced drop in hemoglobin levels >2 gm/dL
Mundle et al. (2007) [32]	Prospective	India, primary health care center	Pregnant women with amenorrhea ≤56 days	149	200 mg mifepristone and 400 μg misoprostol; sublingual	Median change in hemoglobin levels 0.1 gm/dL; no serious complications
Winikoff et al. (1997) [30]	Prospective	India, urban hospital	Pregnant women with amenorrhea ≤56 days	250	600 mg mifepristone and 400 μg misoprostol; oral	Mean change in hemoglobin levels −0.29 gm/dL; 1.2% of women experienced drop >2 gm/dL

medication abortion, although there is variation based on the medication abortion drug regimen and other study variables.

4. Discussion

Our review identified no studies that assessed clinical outcomes of medication abortion and three studies that assessed clinical outcomes of surgical abortion among HIV-positive women. Despite the few studies, existing data show that adverse outcomes of surgical abortion in HIV-positive women are low and occur at similar rates to HIV-negative women. Similarly, the literature on LEEP and laparoscopic sterilization, two procedures that are of similar or more invasiveness to abortion, shows that adverse events when these procedures are performed among HIV-positive women are uncommon and not significantly different according to HIV-status. In addition to this data, clinical guidelines on the management of cervical intraepithelial neoplasia (CIN) specify that recommended treatment for HIV-positive women is the same as for women in the general population [35]. In the absence of other data, these findings can be used to make inferences about the safety of surgical abortion for HIV-positive women.

Data also suggests that medication abortion is safe for HIV-positive women. First, data reviewed on blood loss from medication abortion in India, where there is a high prevalence of anemia among pregnant women [17, 18], shows that significant changes in hemoglobin levels are infrequent. Additionally, because the majority of women do not experience vomiting associated with use of medication abortion drugs, and, for those that do, the average duration is less than one day, the impact of vomiting on HIV treatment drugs is likely short lived. It is also important to note that vomiting is common during pregnancy and would likely last much longer than one day. To avoid any potential (although unlikely) reductions in HIV treatment drug efficacy, women could repeat a dose if vomiting occurs less than one hour after taking HIV treatment drugs and/or begin the medication abortion drug regimen at least one hour after HIV treatment drugs [36]. Further documentation of the safety of medication abortion for HIV-positive women comes from medication abortion studies in HIV-prevalent countries. While there is a need for more research, clinical outcomes of medication abortion from countries with a high prevalence of HIV, like South Africa, are similar to reports from countries with a lower HIV prevalence [37].

There are several limitations of this literature review. First, the outcome of interest was not consistently defined across surgical abortion studies, making it difficult to compare findings. In addition, the varying legal contexts and surgical methods of abortion, as well as inclusion or exclusion of women with septic abortions, limit the ability to make generalizations about clinical outcomes of abortion for HIV-positive women. In the absence of specific data on surgical and medication abortion among HIV-positive women, our review on clinical outcomes of LEEP and laparoscopic sterilization as well as blood loss and vomiting from medication abortion may provide helpful insight regarding abortion care for HIV-positive women. However, we acknowledge that there are clinical differences when considering abortion and LEEP or laparoscopic sterilization, and the data presented here on blood loss and vomiting from medication abortion are not focused on HIV-positive women.

Further research is needed which evaluates the complications of safe abortion among HIV-positive and -negative women. Research documenting clinical experience and acceptability of medication and surgical abortion among HIV-positive women would be useful to inform discussions about standards of care. Furthermore, research examining HIV-positive women's choice of method and the impact of particular methods on HIV-treatment would strengthen recommendations and identify best practices for abortion care for HIV-positive women. Until such data are available, we are confident that our review provides a strong argument for offering HIV-positive women both surgical and medication abortion where available; offering women the choice of methods would be ideal.

Efforts aimed at integrating abortion services into SRH and HIV services are critical to protecting and promoting the reproductive health and rights of HIV-positive women. SRH and HIV providers not only need to have the clinical skills and equipment to perform abortions, but also the capacity to provide nonjudgmental counseling to HIV-positive women on their reproductive rights and choices to meet women's sexual and reproductive health needs. In addition, expanding access to and providing HIV-positive women who do not wish to become pregnant with the full range of contraceptive options is a critical component of SRH/HIV integration and could support women in achieving their reproductive goals.

We recognize that there are policy- and service-level challenges to integrating SRH and HIV services, such as legal and funding constraints, lack of national guidelines on integration, and staffing shortages [38, 39]. In settings where abortion is legally restricted, women could be provided with harm reduction counseling about safe and effective misoprostol regimens, which has been shown to decrease complications from unsafe abortion [40], or, in other cases, women with HIV might be eligible for legal abortion if continuing the pregnancy would jeopardize their health. Further, advocates for women's health must hold accountable programs and policies that do not address women's comprehensive SRH needs, including HIV and safe abortion care. The International HIV/AIDS Alliance names abortion as a key HIV and SRH intervention and outlines strategies for how to integrate safe abortion and postabortion care into HIV services [41]. Advocates for HIV-positive women should build on these recommendations and the momentum generated by the 2011 report from the United Nations Special Rapporteur on the Right to Health that calls for the removal of legal barriers to access to abortion for all women to improve women's health worldwide [42].

5. Conclusion

Based on the existing data on clinical outcomes of abortion and other gynecological procedures for HIV-positive women,

surgical and medication abortion appear to be both safe and appropriate options for HIV-positive women. Improving access to safe abortion services has been shown to lead to significant reductions in maternal mortality and morbidity. Efforts to integrate SRH and HIV services should be expanded to incorporate information about safe abortion and referrals, and/or provision of safe abortion services, and consider the specific needs of HIV-positive women.

Conflict of Interests

The authors declare no conflict of interests or financial interests in any product or service mentioned in this paper, including grants, employment, gifts, stock, holdings, or honoraria.

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Research Article

Differences in the Nonuse of any Contraception and Use of Specific Contraceptive Methods in HIV Positive and HIV Negative Rwandan Women

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Contraception can reduce the dual burden of high fertility and high HIV prevalence in sub-Sahara Africa, but significant barriers remain regarding access and use. We describe factors associated with nonuse of contraception and with use of specific contraceptive methods in HIV positive and HIV negative Rwandan women. Data from 395 HIV-positive and 76 HIV-negative women who desired no pregnancy in the previous 6 months were analyzed using univariate and multivariate logistic regression models to identify clinical and demographic characteristics that predict contraceptive use. Differences in contraceptive methods used were dependent on marital/partner status, partner's knowledge of a woman's HIV status, and age. Overall, condoms, abstinence, and hormonal methods were the most used, though differences existed by HIV status. Less than 10% of women both HIV+ and HIV− used no contraception. Important differences exist between HIV-positive and HIV-negative women with regard to contraceptive method use that should be addressed by interventions seeking to improve contraceptive prevalence.

1. Background

Sub-Sahara (SSA) Africa has the highest population growth rate and the greatest burden of HIV infection in the world. Barrier and hormonal contraceptive methods offer feasible means to address the dual burden of high fertility and high HIV prevalence in the region. While contraceptive use among SSA women has increased in the past decade, disparities remain between and within countries and use still remains below 20% in many countries [1]. Barriers to higher usage include poor access, cost, inadequate health infrastructure, and sociocultural values supporting high fertility [1–3].

Rwanda, the most densely populated country in Africa has an HIV prevalence rate of 2.9% [4], mostly among childbearing age women [5]. Expanded access to free antiretroviral therapy contributed to significant gains in health and quality of life of people living with HIV/AIDS (PLHA). These gains in health, coupled with a low risk of mother-to-child transmission to less than 1% [6] and the high value on fertility have altered the context of fertility decision making

for many PLHAs. This context is mediated by individual, interpersonal, medical, structural, and cultural factors [7–12] thus making fertility control a major policy and service delivery issue in the care of PLHA [13].

Rwandan women face significant obstacles to access and use of contraception. Ayad and Hong [14] reported that while contraceptive prevalence rate among Rwandan women increased substantially between 2005 and 2008 from 13% to 36%, the level of unmet need also increased within the same period. Other studies also reported low use and high levels of unmet need [3, 15–17] despite a prevalent desire to limit fertility [18–20].

Unintended pregnancy accounts for 15–58% of births in countries with high HIV burden [21] including Rwanda [22]. Unintended pregnancies, which may directly result from unmet needs underscore the importance of understanding contraceptive decision-making among HIV positive (HIV+) women who may be more interested in preventing pregnancy than in preserving their own health and eliminating the risk of transmitting the virus to their sex partners [15, 23–25]. Therefore access to and use of safe, effective contraception, as advocated in the Glion Call to Action [5] is critical for this population. Indeed, the effectiveness of voluntary contraception among HIV+ women has been well documented in literature [21, 26–28] with some estimates suggesting that current contraceptive use among HIV+ women may already be preventing as many as 220,000 HIV+ births annually in high prevalent countries.

There is a low but increasing rate of modern contraceptive use among Rwandan women, however little is known about the predictors of contraceptive practice. To aid policy and program planning in meeting the reproductive needs and rights of HIV+ Rwandan women [15], it is important to identify and understand factors that influence contraceptive choices and use and how this is similar to or different from those of HIV negative (HIV−) women. This paper explores and describes the factors associated with nonuse of any contraception and use of specific contraceptive methods between HIV+ and HIV− Rwandan women. We hypothesized that HIV status would significantly determine the type of contraceptive methods favored by Rwandan women, for instance that HIV+ women would prefer barrier methods such as condoms while HIV− women will prefer hormonal methods.

2. Methods

The Rwanda Women's Interassociation Study and Assessment (RWISA) is a prospective observational cohort study of HIV infected and uninfected Rwandan women. Details of the study methods (including participants, recruitment methods, eligibility criteria, and informed consent process) have been previously described [29, 30]. In 2005, 710 HIV+ and 226 HIV− women enrolled in RWISA, recruited through grassroots women's associations and HIV care sites in Kigali. Eligibility criteria included living in Rwanda and aged >15 years during the 1994 genocide, agreeing to be tested for HIV and willingness to travel to the study site to participate in follow-up visits. The Rwandan National Ethics Committee and the Montefiore Medical Center Institutional Review Board approved the study protocol and procedures.

By design, 50% of both HIV+ and HIV− participants reported rape during the 1994 genocide. During the enrollment visit, participants provided historical information, underwent physical and gynecological examination, and provided blood, urine and gynecological specimens. Interviews were conducted in Kinyarwanda by trained interviewers with nursing or trauma counseling backgrounds. The population for this consisted of 395 HIV+ and 76 HIV− women who reported at enrollment that they desired not to become pregnant.

2.1. Measures. Participants provided demographic, medical, psychosocial, and behavioral information regarding clinical status, disease progression, HIV-1 exposure risks, quality of life, symptoms of depression and posttraumatic stress disorder (PTSD), contraceptive practice, and trauma experience during the 1994 genocide.

The following variables were created for this analysis: HIV/CD4 Status (HIV−, HIV+ and CD4 < 200, HIV+ and CD4 200–350, and HIV+ and CD4 > 350); partner knowledge of HIV status (HIV+ participant whose partner knows her status, HIV+ participant whose partner does not know, HIV− participant whose partner knows, and HIV− participant whose partner does not know). Women were asked if they had used each of the following contraceptive methods at least once in the previous six months; oral contraceptives, implantable or depot/injected progesterone, intrauterine device, diaphragm or cervical cap, vaginal creams/jellies/foams, or the sponge, rhythm or withdrawal, emergency contraception, male or female condoms, and abstinence. The following methods were combined together to form "hormonal contraception": oral contraceptives, implantable, or depot progesterone. Respondents were not required to report frequency of contraceptive usage.

2.2. Statistical Analysis. We compared HIV+ and HIV− women by categorized characteristics using exact tests for statistical significance. Univariate and multivariate logistic regression models were fit to determine associations with the probability of (i) not practicing at least one contraceptive method and (ii) practicing contraceptive methods in the following categories: abstinence, hormonal, and condoms. Multivariate models were fit using stepwise selection among all variables in Table 2 with a P value for entry of 0.05 and a P value for removal of >0.1.

3. Results

Table 1 shows demographic and clinical characteristics for 471 participants. Among HIV+ women, nearly one-third had a CD4 cell count of less than 200 cells/μL. Forty-seven percent of all respondents were married or currently living with a partner. The majority was of low socioeconomic status; 37% of HIV− women and 27% of HIV+ women were employed and on a monthly income of less than 10,000 Rwandan Franc (~US$17.40). Sixty percent of HIV− and

Table 1: Demographic and clinical characteristics of 471 women who reported wanting to prevent pregnancy.

Characteristics	HIV-negative $n = 76$	HIV-positive $n = 395$	P value
Age			
<30	17 (22.4%)	97 (24.6%)	0.001
30–40	34 (44.8%)	245 (62.0%)	
>40	25 (32.9%)	53 (13.4%)	
Married and living with partner			
Yes	39 (51.3%)	183 (46.3%)	0.425
No	37 (38.7%)	212 (53.7%)	
Currently pregnant			
Yes	1 (1.3%)	2 (0.5%)	0.419
No	75 (98.7%)	391 (99.5%)	
Employment status			
Yes	27 (37.0%)	103 (26.6%)	0.071
No	46 (63.0%)	284 (73.4%)	
Monthly income			
<10,000	25 (34.2%)	121 (28.1%)	0.033
10–35,000	28 (38.4%)	208 (52.8%)	
>35,000	20 (27.4%)	65 (16.5%)	
Experienced genocidal rape			
Yes	46 (61.3%)	193 (49.3%)	0.055
No	29 (38.7%)	199 (50.7%)	
Number of living children			
0	13 (17.2%)	111 (28.1%)	0.001
1-2	16 (21.0%)	136 (34.4%)	
3-4	31 (40.8%)	108 (27.4%)	
5+	16 (21.0%)	40 (10.1%)	
HIV/CD4 Status			
HIV−	76 (100.0%)	0	0.001
HIV+ CD4 < 200	0	106 (26.8%)	
HIV+ CD4 200–350	0	152 (38.5%)	
HIV+ CD4 > 350	0	137 (34.7%)	
Partner knowledge of HIV status			
HIV+ Partner knows	0	222 (58.4%)	0.001
HIV+ Partner does not know	0	158 (41.6%)	
HIV− Partner knows	43 (60.6%)	0	
HIV− Partner does not know	28 (39.4%)	0	
Ever had sex for cash			
Yes	14 (18.4%)	94 (23.9%)	0.302
No	62 (81.6%)	300 (76.1%)	

58% of HIV+ women reported that partners were aware of their HIV sero-status.

Table 2 presents univariate and multivariate analyses of demographic and clinical characteristics associated with the use of abstinence as a contraceptive method in the prior 6 months. Abstinence was a commonly used method, reported by about 40% of HIV+ and HIV− women. Use of abstinence was significantly associated with partner's knowledge of respondent's HIV status, being married or living with a partner, income and ever having had sex for cash. HIV+ women whose partners were not aware of their status were more likely (OR = 3.83) than HIV+ women whose partners were aware of their status to use abstinence as a method of contraception; women who were married or living with a partner were significantly less likely to report using abstinence (OR = 0.06) than those who were not married or living with a partner. Women who had ever exchanged sex for cash were also more likely than those who had not to report abstinence as a means of contraception (OR = 1.61).

In the final stepwise multivariate model, marital status, HIV status/partner's knowledge of status, and ever exchanging sex for money were independently associated with abstinence. Women who were married or living with a partner were 20-fold less likely to report using abstinence: adjusted

Table 2: Univariate and multivariate analysis of demographic and clinical characteristics associated with abstinence.

Variable	Abstinence		
	Proportion practicing method *n* (%)	Univariate OR (95% CI)	Multivariate Adjusted OR (95% CI)[a]
HIV Status			
HIV−	32 (42.1%)	(*r*)	
HIV+	152 (38.7%)	0.87 (0.53–1.43)	
HIV/CD4 Status			
HIV−	32 (42.1%)	(*r*)	
HIV+ CD4 < 200	31 (44.8%)	0.57 (0.31–1.06)	
HIV+ CD4 on [200, 500]	60 (39.7%)	0.91 (0.52–1.59)	
HIV+ CD4 ≥ 350	61 (29.2%)	1.12 (0.63–1.97)	
Number of living children			
0	55 (44.7%)	(*r*)	
1-2	63 (41.7%)	0.89 (0.55–1.43)	
3-4	48 (34.5%)	0.65 (0.40–1.07)	
5+	18 (32.1%)	0.59 (0.30–1.14)	
HIV Status/Partner knowledge			
HIV+ Partner knows	50 (22.6%)	(*r*)	(*r*)
HIV+ Partner does not know	92 (58.6%)	**3.83 (2.50–5.87)*****	**1.89 (1.13–3.16)***
HIV− Partner knows	19 (44.2%)	**2.14 (1.10–4.17)***	**2.83 (1.22–6.56)***
HIV− Partner does not know	8 (28.6%)	1.08 (0.45–2.58)	0.68 (0.25–1.87)
Age			
>30	40 (35.1%)	0.57 (0.32–1.02)	
30–40	106 (38.3%)	0.65 (0.39–1.08)	
40+	38 (48.7%)	(*r*)	
Married or living with partner			
No	162 (65.3%)	(*r*)	(*r*)
Yes	22 (9.9%)	**0.06 (0.04–0.10)*****	0.05 (0.03–0.09)
Genocidal rape			
No	89 (39.2%)	(*r*)	
Yes	35 (39.9%)	1.03 (0.71–1.49)	
Employed			
No	128 (39.0%)	(*r*)	
Yes	60 (38.5%)	0.98 (0.64–1.48)	
Income			
0–10,000	79 (54.5%)	(*r*)	
10,001–35,000	85 (36.1%)	**0.46 (0.30–0.70)*****	
35,001+	17 (20.0%)	**0.20 (0.11–0.38)*****	
Ever had sex for cash			
No	120 (35.9%)	(*r*)	(*r*)
Yes	63 (47.4%)	**1.61 (1.07–2.41)***	**0.59 (0.35–0.98)***

[a]Models built by stepwise selection among all variables in this table with a *P* value for entry of 0.05 and a *P* value for removal of >0.1.
* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$.

odds ratio (aOR = 0.05). Compared to HIV+ women whose partners knew their HIV status, HIV+ women whose partners *did not* know their status (aOR = 1.89) and HIV− women whose partners *did* know their status (aOR = 2.83) were more likely to use abstinence. Ever exchanging sex for money which was associated with *more* abstinence in unadjusted analysis was now significantly associated with *less* abstinence in the multivariate model. This change in direction of the association occurred because one variable in the model, married/living with a partner, was strongly negatively associated with both abstinence and having exchanged sex for money.

Overall, condom use (both male and female) was the most frequently reported method of contraception. While condom use differed by HIV status (58% of HIV+ versus 18% of HIV− OR = 6.06) due to differences in male condom usage, female condom use reported by only 8 women did not differ by HIV status, although with the small number of

Table 3: Univariate and multivariate analysis of demographic and clinical characteristics associated with condom use.

Variable	Condom		
	Proportion practicing method *n* (%)	Univariate OR (95% CI)	Multivariate Adjusted OR (95% CI)[a]
HIV Status			
HIV−	14 (18.4%)	(*r*)	
HIV+	227 (57.8%)	**6.06 (3.28–11.18)*****	
HIV/CD4 Status			
HIV−			
HIV+ CD4 < 200	84 (46.1%)	(*r*)	
HIV+ CD4 on [200, 500]	93 (61.6%)	**1.87 (1.21–2.90)****	1.19 (0.67–2.14)
HIV+ CD4 ≥ 350	64 (47.1%)	**1.04 (0.66–1.62)**	0.62 (0.35–1.11)
Number of living children			
0	78 (62.9%)	(*r*)	
1-2	74 (49.0%)	0.57 (0.35–0.92)	
3-4	62 (44.9%)	**0.48 (0.29–0.79)***	
5+	27 (48.2%)	**0.55 (0.29–1.04)****	
HIV Status/Partner knowledge			
HIV+ Partner knows	160 (72.4%)	(*r*)	(*r*)
HIV+ Partner does not know	60 (38.2%)	**0.27 (0.18–0.41)*****	**0.34 (0.21–0.55)*****
HIV− Partner knows	11 (25.6%)	**0.15 (0.07–0.31)*****	**0.15 (0.06–0.35)*****
HIV− Partner does not know	2 (7.1%)	**0.03 (0.01–0.14)*****	**0.03 (0.01–0.13)*****
Age			
>30	67 (58.8%)	**3.63 (1.96–6.73)*****	3.59 (1.75–7.34)
30–40	152 (54.9%)	**3.10 (1.79–5.35)*****	2.24 (1.20–4.20)
40+	22 (28.2%)	(*r*)	(*r*)
Married or living with partner			
No	101 (40.7%)	(*r*)	(*r*)
Yes	140 (63.3%)	2.52 (1.73–3.65)	**3.05 (1.86–5.00)*****
Genocidal rape			
No	114 (50.0%)	(*r*)	
Yes	125 (52.7%)	1.12 (0.78–1.61)	
Employed			
No	165 (50.1%)	(*r*)	(*r*)
Yes	74 (57.4%)	1.34 (0.89–2.02)	**1.86 (3.05)***
Income			
0–10,000	60 (41.4%)	(*r*)	
10,001–35,000	135 (57.4%)	**2.00 (1.32–3.04)****	
35,001+	46 (54.1%)	**1.75 (1.02–3.00)***	
Ever had sex for cash			
No	160 (47.9%)	(*r*)	(*r*)
Yes	80 (60.1%)	1.64 (1.09–2.47)	2.54 (1.51–4.26)

[a]Models built by stepwise selection among all variables in this table with a P value for entry of 0.05 and a P value for removal of >0.1.
*$P < 0.05$, **$P < 0.01$, ***$P < 0.001$.

users there was no power to detect any difference. Univariate analysis in Table 3 shows significant associations between condom use in the previous six months and HIV status, number of living children, partner's knowledge of HIV status, age, and income. For example, HIV+ women were 3-fold more likely than HIV− women to report condom use; women with higher incomes were significantly more likely (OR = 2.00) to report condom use than were women with lower incomes. HIV+ women whose partners knew their sero-status were more likely to report condom use than HIV+ women whose partners did not know their status and HIV− women regardless of partners' knowledge of their status. Women who had no children were more likely to report condom use than were those with at least one child ($P < 0.001$ for all previous associations).

Clinical and demographic characteristics that were significantly associated independently with *condom use* in adjusted models included marital status (aOR = 3.13 for

Table 4: Univariate and multivariate analysis of demographic and clinical characteristics associated with hormonal contraceptive use.

Variable	Hormonal		
	Proportion practicing method *n* (%)	Univariate OR (95% CI)	Multivariate adjusted OR (95% CI)[a]
HIV Status			
HIV−	16 (21.6%)	(*r*)	
HIV+	40 (10.2%)	**0.41 (0.22–0.79)****	
HIV/CD4 Status			
HIV−	16 (21.6%)	(*r*)	
HIV+ CD4 < 200	15 (14.1%)	0.60 (0.27–1.30)	
HIV+ CD4 on [200, 500]	13 (8.7%)	**0.34 (0.16–0.76)****	
HIV+ CD4 ≥ 350	12 (8.9%)	**0.35 (0.16–0.80)***	
Number of living children			
0	10 (8.1%)	(*r*)	
1-2	19 (5.7%)	1.63 (0.73–3.64)	
3-4	7 (16.7%)	1.97 (0.88–4.38)	
5+	7 (12.5%)	1.61 (0.58–4.49)	
HIV Status/Partner knowledge			
HIV+ Partner knows	30 (13.6%)	(*r*)	(*r*)
HIV+ Partner does not know	9 (5.8%)	**0.41 (0.19–0.89)***	0.60 (0.27–1.34)
HIV− Partner knows	7 (16.7%)	1.35 (0.55–3.30)	1.40 (0.57–3.48)
HIV− Partner does not know	9 (33.3%)	**3.37 (1.39–8.17)****	**4.13 (1.65–10.37)****
Age			
>30	15 (13.2%)	1.31 (0.53–3.25)	
30–40	33 (12.0%)	1.18 (0.52–2.67)	
40+	8 (10.4%)	(*r*)	
Married or living with partner			
No	17 (6.9%)	(*r*)	(*r*)
Yes	39 (17.9%)	**2.95 (1.61–5.38)*****	2.67 (1.40–5.08)****
Genocidal rape			
No	27 (11.9%)	(*r*)	
Yes	27 (11.5%)	0.96 (0.54–1.69)	
Employed			
No	36 (11.0%)	(*r*)	
Yes	19 (14.5%)	1.40 (0.77–2.55)	
Income			
0–10,000	12 (8.3%)	(*r*)	
10,001–35,000	25 (10.8%)	1.26 (0.62–2.56)	
35,001+	18 (21.4%)	**2.85 (1.32–6.17)****	
Ever had sex for cash			
No	41 (12.4%)	(*r*)	
Yes	15 (11.4%)	0.91 (0.48–1.70)	

[a]Models built by stepwise selection among all variables in this table with a *P* value for entry of 0.05 and a *P* value for removal of >0.1.
$^{*}P < 0.05$, $^{**}P < 0.01$, $^{***}P < 0.001$.

those married or living with a partner compared to those not) and age (aOR = 3.35 for those less than 30 and aOR = 2.15 for those between 30 and 40 years, resp., compared to women >40 years). Similarly, current employment (aOR = 1.88 compared to women not employed) and history of trading sex for cash (aOR = 2.53 compared to no history) were independently associated with increased likelihood of condom use. Compared to HIV+ women whose partners knew their status, all other groups were independently less likely to report condom use for contraceptive purposes: (aOR = 0.35 for HIV+ women whose partners did not know their HIV status; aOR = 0.16 for HIV− women whose partners knew their status and aOR = 0.03 for HIV− women whose partners did not know their status), respectively.

About 10% of HIV+ and 20% of HIV− women reported use of hormonal methods. In Table 4, univariate analysis shows that use of hormonal contraception was significantly associated with a woman's HIV/CD4 status category, her HIV status/partner's knowledge of that status, being married or living with a partner, and having an income of at least

Table 5: Univariate and multivariate analysis of demographic and clinical characteristics of nonuse of contraception[1].

Variable	No contraception		
	Proportion practicing method *n* (%)	Univariate OR (95% CI)	Multivariate adjusted OR (95% CI)[a]
HIV Status			
HIV−	4 (5.6%)	(*r*)	
HIV+	28 (7.2%)	1.30 (0.44–3.81)	
HIV/CD4 Status			
HIV−	4 (5.6%)	(*r*)	(*r*)[b]
HIV+ CD4 < 200	9 (8.5%)	1.55 (0.46–5.25)	2.06 (0.58–7.34)
HIV+ CD4 on [200, 500]	4 (2.7%)	0.46 (0.11–1.89)	0.57 (0.13–2.40)
HIV+ CD4 ≥ 350	15 (11.2%)	2.11 (0.57–6.62)	3.13 (0.94–10.43)
Number of living children			
0	6 (4.9%)	(*r*)	
1-2	9 (6.1%)	1.26 (0.44–3.65)	
3-4	12 (8.8%)	1.87 (0.68–5.15)	
5+	5 (8.9%)	1.90 (0.55–6.50)	
HIV Status/Partner knowledge			
HIV+ Partner knows	15 (6.8%)	(*r*)	
HIV+ Partner does not know	13 (8.4%)	1.39 (0.64–3.01)	
HIV− Partner knows	1 (2.3%)	0.36 (0.05–2.79)	
HIV− Partner does not know	3 (13.0%)	2.26 (0.60–8.47)	
Age			
>30	5 (4.5%)	0.35 (0.11–1.08)	0.27 (0.08–0.87)*
30–40	18 (6.6%)	0.53 (0.23–1.22)	0.37 (0.15–0.92)*
40+	9 (11.8%)	(*r*)	(*r*)
Married or living with partner			
No	14 (6.2%)	(*r*)	(*r*)
Yes	17 (7.3%)	**2.25 (1.06–4.78)***	2.55 (1.17–5.58)*
Genocidal rape			
No	14 (6.2%)	(*r*)	
Yes	17 (7.3%)	1.18 (0.57–2.46)	
Employed			
No	23 (7.1%)	(*r*)	
Yes	7 (5.5%)	0.75 (0.31–1.80)	
Income			
0–10,000	11 (7.7%)	(*r*)	
10,001–35,000	14 (6.0%)	0.80 (0.35–1.81)	
35,001+	7 (8.4%)	1.14 (0.42–3.06)	
Ever had sex for cash			
No	27 (8.3%)	(*r*)	
Yes	5 (3.8%)	0.44 (0.16–1.16)	

[a]Models built by stepwise selection among all variables in this table with a *P* value for entry of 0.05 and a *P* value for removal of >0.1.
[b]Even though all 95% CIs contain 1, the overall *P* value for significance of HIV CD4 status considering all categories simultaneously is <0.1 by Wald test.
$^{*}P < 0.05$, $^{**}P < 0.01$, $^{***}P < 0.001$.
[1]Thus category excludes women who use surgical methods in addition to the other methods in the previous tables; condoms, hormones, and abstinence.

35,000 FRW. Women who were HIV+ and whose CD4 was greater than 200 cells/μL were less likely than HIV− women to report using hormonal contraceptive methods (OR = 0.34 and 0.35 for women with 200–350 and >350 cells/μL, resp.). In multivariate analysis, hormonal contraceptive use was independently more common in women who were married or living with a partner (aOR = 2.67) and in HIV− women whose partners knew their status (aOR = 4.13 compared to HIV+ women whose partners know their status, resp.).

Table 5 shows few women (5.6% of HIV− and 7.2% of HIV+) reported using no contraceptive method during the previous 6 months. Being married or living with a partner was significantly associated with *no contraceptive use* in the past 6 months (OR = 2.25) compared to women not married

or living with a partner. Age and marital status had significant independent associations with *no contraceptive use* in the multivariate analysis. Women reporting *no contraceptive use* were independently more likely to be married or living with a partner (aOR = 2.55) compared with those who were not. Women younger than 30 years were more likely to report *no contraceptive use* compared to women 30–40 (aOR = 0.27) and >40 (aOR = 0.37), respectively. It should be noted that 11 women (4 HIV+, 7 HIV−) had a surgical method (hysterectomy, tubal ligation, and ovary removal). While this usage was higher for HIV− women ($P = 0.0003$), the numbers were too small to allow further analysis.

A little over 10% of participants reported using multiple methods but these did not statistically differ by HIV status; 9.2% of HIV− compared with 14.7% of HIV+ women ($P = 0.21$ exact test). Condoms were almost always one of the multiple methods reported; 47 women reported using condoms and abstinence while 21 women reported using condoms and hormonal methods. This perhaps reflects that abstinence was used if condoms were not available and that condoms were most likely used as a backup to hormonal methods as well as to prevent STD transmission.

4. Discussion

In this study of Rwandan women desiring not to become pregnant we found that over 90% of both HIV infected and uninfected women described using some form of contraception, with condoms being the most prevalent method used. We also found that HIV status combined with partner knowledge of status was more strongly associated with the type of contraceptive method used than HIV status alone or CD4 count. Specifically, HIV+ women whose partners knew their status were two to ten times more likely to report condom use when compared to other groups. This suggests that disclosure of a positive HIV status to a partner may be an important contributor to pregnancy prevention through condom use in addition to partner protection from HIV. Marital status and age were also significantly associated with contraceptive method used.

We also found that older women were less likely to use condoms, suggesting perhaps a need to educate older women on condom use to prevent HIV transmission as well as pregnancy, in addition to or instead of using other methods. Apart from providing effective contraception, condoms also reduce the risk of HIV transmission and can be used concurrently with other contraceptive methods. The effectiveness of condoms, however, depends on correct and consistent use as well as acceptance by male partners. Previous studies have highlighted several socioeconomic, cultural and behavioral factors that inhibit condom use. For instance, in the case of male condoms, many men in SSA may interpret a request to use condoms as an insult, a sign of mistrust, and a hindrance to sexual fulfillment [31–35]. Additional determinants of condom use are female decision-making power [36, 37], socioeconomic factors, access to and availability of condoms [38, 39] technical issues with substandard condoms [40–43], and myths and misconceptions about condoms and fertility aspirations. It is important therefore that efforts to increase condom use address the barriers that have been highlighted in the literature.

Studies of HIV discordant couples have shown a marked increase in the proportion using condoms, following behavioral interventions, to prevent transmitting the virus between partners [3, 44–46], and not to prevent pregnancy. These studies also show that condom use was more consistent when the man was HIV− compared to when the woman was HIV−. In the current study, the strong association observed between condom use and HIV status, number of living children, partners' knowledge of HIV status, and socioeconomic status also suggests that disease prevention not pregnancy prevention may be the primary reason for condom use. For example, condom use was significantly higher among HIV+ women whereas it was lower among women who already had one or more children. Women with a history of sex in exchange for cash were also more likely to use condoms, which may indicate a desire to prevent disease and perhaps pregnancy to limit the number of dependents. Furthermore, that income status was associated with condom use could point to issues of access and affordability among those with low or no income.

Hormonal contraceptive methods are among the most effective contraception available to women who desire to control when and how to have children. Despite their effectiveness, only 21% of HIV− women and 10% of HIV+ women reported using hormonal methods. Some studies [47] have suggested that among Rwandan women, low use of hormonal contraceptive methods may be due to lack of access and availability, low knowledge, and cost. In the case of HIV+ women, studies [48–52] suggest that the low use of hormonal methods may be due to misconceptions leading to inconsistent use, concerns regarding hormonal methods' possible contribution to HIV transmission to sex partners or accelerated HIV disease progression and possible interaction with antiretroviral agents. The concerns on the interaction between hormonal methods with HIV acquisition and HIV-associated disease progression are areas of active research [53, 54]. Prior literature has been contradictory with some studies finding higher rates of HIV-acquisition [55, 56] and more rapid disease progression [57, 58] in users of hormonal contraception, and some finding no effect [59, 60]. However, since the efficacy of estrogen-containing contraception can be compromised by many of the antiretrovirals [59], it is understandable that HIV+ women are less likely to use hormonal methods.

Respondents were not asked about the frequency of contraceptive use, especially of self-reported condom use and abstinence, therefore this is one limitation of the study. It is also not possible to separate use of abstinence and condoms to prevent pregnancy from the use of these methods to prevent STD, although all of the study participants stated that they did not want to become pregnant. While generalizability of this population to other women is not certain, this group represents an important group of HIV infected and uninfected women.

Of note, about 10% of the HIV+ and HIV− women in this analysis did not use any method of contraception despite expressing a desire to not get pregnant. Younger age and

being married or living with a partner were predictors of nonuse of any contraceptive method in univariate and/or multivariate models. Although there is evidence, which suggests that an increasing number of Rwandan women now have access to and use modern contraceptive methods [1, 61] a considerable proportion of women may still experience barriers to access and use. Further studies should explore the characteristics and reasons why women in this population are not using contraception.

5. Conclusion

There is abundant literature [62–70] describing the pathways through which the HIV epidemic has contributed to population declines or indeed, a demographic transition in SSA, resulting in a fall in demand for children, significantly lowered fertility desires and increased contraceptive use. The Rwanda Demographic and Health Surveys [61] show that the proportion of women reporting contraceptive use rose from 17% in 2005 to 36% in 2008. About 90% of women in this study reported using contraception although the population is by no means representative since they were recruited from grass roots organizations and HIV clinics.

Condoms and abstinence were the most commonly used methods of contraception among the women in this study. Women who were married or living with their partners were far less likely to abstain and far more likely to use condoms. Older women were far less likely to use condoms. Women who were HIV+ and whose partners were aware of this were far more likely to use condoms. Despite their effectiveness, use of hormonal methods is still low, highlighting issues of availability, access or cost and possibly concerns about the side effects of hormonal methods, especially among HIV+ women. Moreover, the different contraceptive needs of HIV+ and HIV− women including preventing transmission of HIV and sexually transmitted diseases should be recognized when planning interventions to improve contraceptive use.

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Research Article

Women's Health Care Utilization among Harder-to-Reach HIV-Infected Women ever on Antiretroviral Therapy in British Columbia

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Background. HIV-infected women are disproportionately burdened by gynaecological complications, psychological disorders, and certain sexually transmitted infections that may not be adequately addressed by HIV-specific care. We estimate the prevalence and covariates of women's health care (WHC) utilization among harder-to-reach, treatment-experienced HIV-infected women in British Columbia (BC), Canada. *Methods*. We used survey data from 231 HIV-infected, treatment-experienced women enrolled in the Longitudinal Investigations into Supportive and Ancillary Health Services (LISA) study, which recruited harder-to-reach populations, including aboriginal people and individuals using injection drugs. Independent covariates of interest included sociodemographic, psychosocial, behavioural, individual health status, structural factors, and HIV clinical variables. Logistic regression was used to generate adjusted estimates of associations between use of WHC and covariates of interest. *Results*. Overall, 77% of women reported regularly utilizing WHC. WHC utilization varied significantly by region of residence (P value < 0.01). In addition, women with lower annual income (AOR (95% CI) = 0.14 (0.04–0.54)), who used illicit drugs (AOR (95% CI) = 0.42 (0.19–0.92)) and who had lower provider trust (AOR (95% CI) = 0.97 (0.95–0.99)), were significantly less likely to report using WHC. *Conclusion*. A health service gap exists along geographical and social axes for harder-to-reach HIV-infected women in BC. Women-centered WHC and HIV-specific care should be streamlined and integrated to better address women's holistic health.

1. Introduction

More than 30 years into the global HIV/AIDS epidemic, 33.3 million people worldwide are currently living with HIV, of whom more than 50% are women and girls [1]. In Canada, the proportion of women among newly reported HIV cases has increased from less than 5% in 1985 to 26% in 2009 [2]. In the same year, the number of women living with HIV in Canada was estimated to be 12,000, of whom approximately 2860 resided in the province of British Columbia (BC) [2]. The proportion of HIV in younger age groups is also higher for women than for men [2, 3], suggesting that women are contracting HIV at a younger age than men. The growing feminization of the HIV epidemic means that more young women of reproductive age will be living with HIV in Canada.

HIV infection is associated with many women's health issues that may not be adequately addressed in HIV-specific care [4, 5]. HIV-infected women are more likely than their HIV-negative counterparts to have abnormal gynaecological conditions, such as squamous intraepithelial lesions, cervical cancer, and both bacterial and viral sexually transmitted infections [6–11]. Psychological disorders such as depression are also more prevalent among HIV-infected women than

HIV-negative women, likely due to HIV-related stigma and lack of social support [12, 13]. In addition, HIV-infected women's health focus changes as they go through different stages of life. Women of younger age may focus on menstrual cycle disorders and family planning, while women aging with HIV might need support managing menopause symptoms and their heightened risk of osteoporosis [6]. The introduction of highly active antiretroviral therapy (HAART) has markedly prolonged the life expectancy and greatly increased the reproductive expectations of HIV-infected women [6], but HAART alone cannot address the multiple realms of health impacted by one's HIV status.

Women's health care (WHC), including regular gynaecological care and counselling, has been shown to improve women's multiple health outcomes and should be provided along with HIV-specific care to ensure a more integrated and holistic care model centered on patients' need [14–16]. The World Health Organization (WHO) has proposed a framework to strengthen the linkage between WHC and HIV care at both policy and program levels [17]. However, studies have shown an underutilization of women's health and gynaecological services among HIV-infected women in the US and eastern Canada [18–20].

This study investigates the uptake of WHC among a sample of harder-to-reach and treatment-experienced HIV-infected women in BC, Canada and the factors associated with utilization. Studies on the intersection between HIV and WHC may provide suggestions for mitigating the wide range of women's health issues associated with HIV infection by generating relevant program and policy recommendations.

2. Methods

2.1. Participants and Recruitment. We conducted our analyses using data from the Longitudinal Investigations into Supportive and Ancillary Health Services (LISA) study which was specifically designed to recruit harder-to-reach populations living with HIV who have ever accessed antiretroviral therapy (ART) in BC.

In BC, ART is distributed free of charge to all eligible people living with HIV/AIDS through the Drug Treatment Program (DTP) at the British Columbia Centre for Excellence in HIV/AIDS (BC-CfE) [21]. Medications are distributed in accordance with the guidelines set by the BC Therapeutic Guideline Committee, which have remained consistent with those from the International AIDS Society, USA between 1996 and at last revision in 2010 [22, 23]. Individuals are enrolled in DTP when they are first prescribed ART by their physicians. The physician must complete a drug request form detailing baseline information, such as CD4 cell counts, plasma HIV RNA levels, and past HIV-specific drug history [21]. Patients on ART are then typically monitored by the prescribing physicians at intervals no longer than three months [24]. As of June 2012, approximately 5500 patients are currently enrolled in the DTP [25].

In order to evaluate the impact of the social determinants of health on the health care utilization and clinical outcomes of harder-to-reach HIV-infected individuals who have accessed ART in BC, the LISA study was established. The LISA study consists of a comprehensive cross-sectional survey, which collected data on participants' sociodemographic information, service utilization, and quality of life. Individuals who have ever enrolled in the DTP (or who had initiated ART any time prior to the interview) and who were at least 19 years of age at the time of interview were eligible to participate in the LISA study. Between July 2007 and January 2010, all 9514 eligible participants enrolled in the DTP were targeted through study information letters distributed by physicians providing HIV care and at pharmacies when patients refilled ART prescriptions. In addition to these targeted recruitment strategies, participants were recruited to participate in LISA through notices posted at HIV/AIDS clinics and service organizations across the province and via word-of-mouth advertising. A result of this convenience sampling was an overrepresentation of individuals who were already accessing HIV-related services. The study sought to enroll 1000 individuals and to oversample particular subpopulations (including women, people who inject drugs, and people who identified themselves as aboriginal) to provide sufficient power for subanalyses. Therefore, the LISA cohort enrolled a nonprobability sample of DTP patients and represented more marginalized populations with some level of access to HIV-related services.

The LISA questionnaire, which was developed, reviewed, and piloted with a team of researchers and a community advisory board, was administered throughout BC by trained interviewers at various clinics, HIV/AIDS service organizations, or by telephone. The questionnaire took approximately 60 minutes to complete, and a $20 honorarium was offered to each participant. The financial incentive resulted in an oversampling of harder-to-reach populations.

For this analysis, inclusion was restricted to LISA participants who identified themselves as females (versus male or transgender) and who had HIV clinical data available through the DTP.

Ethical approval for the LISA study was obtained from the University of British Columbia/Providence Health Care, Simon Fraser University, the University of Victoria, and the Vancouver Coastal Health Research Ethics Boards.

2.2. Measures

2.2.1. Outcome Variable. The primary outcome variable "WHC utilization" was assessed via self-report based on responses to the statement "*I have a physician who I see regularly for women's health care [e.g., pap smear, gynaecology].*" Responses were dichotomized into "Yes, utilizes WHC" (based on those who responded "definitely true" or "somewhat true") or "No, does not utilize WHC" (based on those who responded "definitely false" or "somewhat false"). A small number of women who responded "neither true nor false" ($n = 5$) or who did not respond ($n = 15$) were excluded from this analysis.

2.2.2. Explanatory Variables of Interest. The demographic variables included age at interview, aboriginal ancestry (yes

versus no), health authority (HA) (based on patient address), rural residency (rural versus urban), and marital status (yes versus no; yes defined as being legally married or common-law).

Sociodemographic variables included education (high school or greater versus others), current employment (yes versus no), personal annual income (<$15,000 versus ≥$15,000; including wages, salaries, net self-employment, and any other income such as welfare), housing stability (yes versus no; stable housing defined as living in a house or apartment), and food security (yes versus no). Food security was measured based on a modified version of the Radimer/Cornell Questionnaire, and food insecurity was defined as having at least one positive answer to any of the 13 questions [26, 27].

Psycho-social variables included HIV-related stigma, perceived neighbourhood problems, perceived neighbourhood cohesion, and quality of life (QoL). HIV-related stigma was measured using the validated HIV stigma scale ranging from 0 to 100, with higher values corresponding to higher HIV-related stigma [28]. Perceived neighbourhood problems and perceived neighbourhood cohesion were assessed using the scales developed by Ellaway et al., and the original scales were transformed to range from 0 to 100, with higher values indicating higher perceptions of more neighbourhood problems or more neighbourhood cohesion [29]. The QoL of participants was assessed using the validated HIV/AIDS-targeted quality of life (HAT-QoL) instrument [30]. The HAT-QoL scale has 9 dimensions: overall function, sexual function, disclosure worries, health worries, financial worries, HIV mastery, life satisfaction, medical worries, and provider trust. Each measure has a scale from 0 to 100, with higher scores corresponding to better QoL.

Behavioural variables included alcohol use at time of interview, illicit drug use at time of interview (illicit drugs including cocaine, crack, heroin, speedball, crystal meth, steroids, ecstasy, hallucinogens, GHB, and special K), injection of drugs at time of interview (drugs for injection including cocaine, crack, heroin, speedball, and crystal meth), sexual activity (active versus inactive; active defined as having >0 sexual activities in last 6 months), condom use of sexually active participants (yes versus no; yes being defined as using condom 100% of the time during vaginal sex in the last 6 months), sex trade history (yes versus no), pregnancy intention (yes versus no), and number of births in life time.

Individual health status variables included history of sexually transmitted infections (HPV, Chlamydia, gonorrhoea, syphilis), abnormal Pap smear in the last 6 months (yes versus no), and symptoms of depression (yes versus no). The validated 10-item Center for Epidemiological Studies-Depression (CES-D10) scale was used to assess symptoms of depression, with scores of 10 or higher being defined as having symptoms of depression [31].

HIV clinical variables were obtained from DTP and included ART status at time of interview (yes versus no), CD4 count at time of interview (obtained from the most recent test result prior to interview), plasma viral load (pVL, log 10/mL) at time of interview (obtained from the most recent test result prior to interview), and VL suppression (defined as having two consecutive tests of VL < 250 copies/mL 12 months prior to interview).

2.3. Statistical Analyses. The prevalence of WHC utilization among LISA participants was estimated. Bivariate analyses were then performed to examine associations between each explanatory variable of interest and utilization of WHC. Chi-squared tests were used to compare categorical variables; Wilcoxon's rank sum test was used to compare continuous variables. Marginally associated variables ($P < 0.2$) based on the bivariate analyses were included in an exploratory multivariable logistic regression model to identify independent factors associated with WHC utilization. A backward selection procedure using the Akaike Information Criterion (AIC) was performed to select variables ($P < 0.05$) to be included in the final model [32]. All analyses were conducted using SAS 9.2 (SAS Inc., Cary, NC).

3. Results

A total of 1000 participants were recruited and interviewed for the LISA study from July 2007 to January 2010; however, only 917 were successfully linked to clinical data in the DTP, as shown in Figure 1. Out of the 917 participants with clinical data available, there were 231 women who were included in this analysis. Overall, 179 (77%) of the HIV-infected, treatment-experienced women reported utilizing WHC.

Table 1 describes the baseline characteristics of the women included in this study. The median age was 41 years (interquartile range (IQR): 34–46). Half (49%) of the participants reported being of aboriginal ancestry. The geographical distribution of the participants was 60% in Vancouver coastal HA, the more populated Pacific coast of southwestern BC, 5% in Interior HA, BC's southern interior region including many rural communities, 4% in Northern HA, northern BC consisting of a multitude of rural and First Nations communities, 10% in Vancouver island HA, mainly the islands to the west of Vancouver, and 21% in Fraser HA, a populated region to the east of Vancouver. About half (47%) of the participants had an education level of high school or greater, 15% were currently employed and 72% reported an annual income below $15,000. Housing was stable for 62% of the women and 23% were food secure.

Table 1 also compares the characteristics of women who utilized WHC and those who did not. The geographical distribution was significantly different ($P < 0.01$), with a higher proportion living in Vancouver coastal HA (63% versus 49%) and a lower proportion in Vancouver island HA (6% versus 24%) for women who utilized WHC compared with women who did not. Women who utilized WHC were less likely to use illicit drugs ($P < 0.01$), more likely to be employed ($P = 0.04$), less likely to have an annual income <$15,000 ($P < 0.01$), more likely to have stable housing ($P = 0.02$), and more likely to have a higher score for perceived neighbourhood cohesion ($P = 0.02$) and provider trust ($P < 0.01$). Although women who utilized WHC had higher percentage of ART use at the time of interview and higher rate of VL suppression, none of the HIV-related

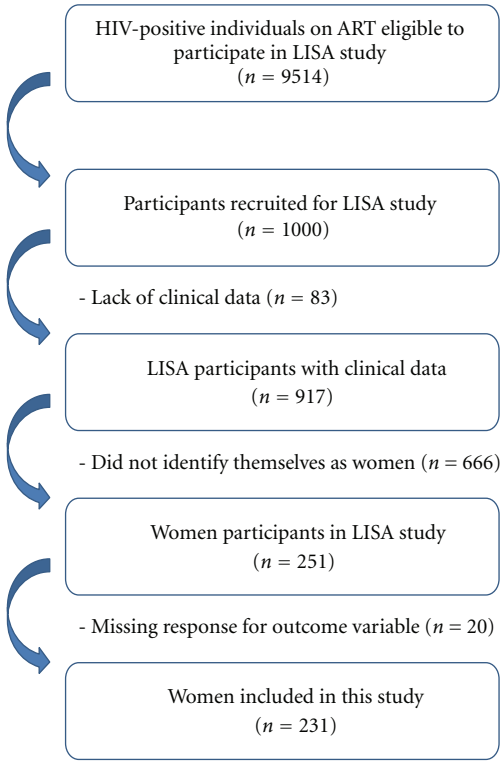

Figure 1: Selection of study subjects from the original LISA cohort.

clinical variables showed significant differences between the two comparison groups.

Table 2 displays the results of the multivariable logistic regression model and shows that the adjusted odds ratios were consistent with the unadjusted odds ratios. The adjusted odds of WHC utilization among participants were 88% lower in Vancouver island HA compared with Vancouver coastal HA (AOR = 0.12, 95 CI (0.04–0.37)), 58% lower among illicit drug users compared with nondrug users (AOR = 0.42, 95 CI (0.19, 0.92)), and 86% lower for those with income <$15,000 compared with those with income ≥ $15,000 (AOR = 0.14, 95 CI (0.04, 0.54)). A one-unit decrease in the provider trust scale was associated with a 3% decrease in the adjusted odds of WHC utilization (AOR = 0.97, 95 CI (0.95, 0.99)).

4. Discussion

Our results demonstrate the existence of a health service gap along geographical and social axes for harder-to-reach HIV-infected women who have accessed ART in BC. We found that 77% of the women in the LISA cohort used WHC. This study is among the first to assess the prevalence of WHC utilization among HIV-infected women as the previous literature documented utilization of gynaecological service only.

This study shows that poorer socioeconomic status is associated with women's ability to access WHC, despite a context that theoretically provides universal health care. Income-related inequalities in health care utilization have been well documented in countries with universal health care systems [33]. In Canada, lower income has been shown to be associated with less contact with general practitioners and specialists and decreased use of surgical day care [34, 35]. Several qualitative studies have examined the barriers to health care experienced by low-income Canadians and found some of the major barriers to be transportation cost, lack of childcare, and a lack of integration of health services [36, 37]. The socioeconomic inequality in WHC utilization demonstrated in this study points to the necessity of providing health services tailored to the needs of low-income women, which may include outreach and providing transportation reimbursement, food, and free childcare during clinic visits. Furthermore, while struggling to meet their basic needs, low-income women might have other competing demands in life such as food and housing. The fact that stable housing and employment were marginally associated with WHC utilization in this study speaks to the need for socio-economic policy reform in BC that addresses structural determinants of health such as housing affordability and unemployment.

Utilization of WHC was negatively associated with illicit drug use. This is consistent with findings from previous studies investigating the relationship between illicit drug use and gynaecological service utilization [38, 39]. It is worth noting that drug injection was not associated with the outcome in this study. This may indicate that the method of drug use does not innately influence access to WHC, but rather, that stigma and social barriers exist for all illicit drug users [37, 40, 41]. The exact pathways linking illicit drug use and WHC utilization are not clear and require further qualitative studies.

Lower provider trust was associated with a lack of WHC utilization in this study. Trust in physicians has long been identified as a determining factor for patient's utilization of health care services [42, 43], but this study has revealed a more specific relationship, namely, between trust in the physician who provides regular HIV care and women's utilization of WHC. This indicates the pivotal role of HIV care physicians in influencing HIV-infected women's health seeking behaviour. This cohort had a high score of provider trust, with a median of 92 for women who utilized WHC and 83 for women who did not. Therefore, women in the cohort were generally satisfied with the HIV care they received. In order to further improve physician trust, evidence suggests that women should be provided with a safe, nonjudgemental clinical environment and an option of seeing a female care provider who could improve patient-physician relationship by making women feel safer and more understood, especially when gynaecological care is involved [37].

The geographical variation in WHC utilization may reflect the inequity of health service provision in rural versus urban areas of BC, where larger communities in Vancouver coastal HA generally have more comprehensive and easily accessible health services than smaller communities in Vancouver island HA [44]. However, due to the large proportion of missing data for participants' rural residency status, the exact reasons behind this geographical variation could not be determined, and further studies are warranted.

Table 1: Baseline characteristics of the HIV-infected women in the LISA cohort ($n = 231$) by women's health care (WHC) utilization (yes versus no).

	WHC utilization			P value
	All ($n = 231$)	Yes ($n = 179$)	No ($n = 52$)	
Demographic variables				
Age at interview (years) (median (IQR))	41 (34–46)	41 (34–46)	41 (36–46)	0.70
Aboriginal ancestry (% Y)	114 (49%)	87 (49%)	27 (52%)	0.67
Health authority (HA)				<0.01
(i) Vancouver coastal HA	136 (60%)	111 (63%)	25 (49%)	
(ii) Interior HA	11 (5%)	10 (6%)	1 (2%)	
(iii) Northern HA	10 (4%)	7 (4%)	3 (6%)	
(iv) Vancouver island HA	22 (10%)	10 (6%)	12 (24%)	
(v) Fraser HA	48 (21%)	38 (22%)	10 (20%)	
Rural residency (% rural)*	3 (2%)	3 (2%)	0 (0%)	0.99
Marital status (% Y)	42 (18%)	29 (16%)	13 (25%)	0.15
Sociodemographic variables				
High school or greater (% Y)	108 (47%)	87 (49%)	21 (40%)	0.30
Employment (% Y)	34 (15%)	31 (17%)	3 (6%)	0.04
Annual income < $15,000 (% Y)	166 (72%)	119 (66%)	47 (92%)	<0.01
Housing stability (% Y)	143 (62%)	118 (66%)	25 (48%)	0.02
Food security (% Y)	54 (23%)	44 (25%)	10 (19%)	0.41
Psychosocial variables				
HIV-related stigma (scale, median (IQR))	53 (38–65)	53 (38–68)	50 (38–65)	0.63
Perceived neighbourhood problems (scale, median (IQR))	35 (15–62)	35 (15–62)	35 (19–62)	0.98
Perceived neighbourhood cohesion (scale, median (IQR))	56 (43–66)	56 (44–69)	51 (35–62)	0.02
Quality of life (scale, median (IQR))				
(i) Overall function	43 (29–64)	43 (25–64)	43 (32–64)	0.88
(ii) Life satisfaction	69 (50–75)	69 (53–78)	63 (47–75)	0.07
(iii) Health worry	45 (30–65)	45 (30–65)	45 (25–65)	0.79
(iv) Financial worry	38 (19–63)	38 (19–63)	38 (25–56)	0.50
(v) Medical worry	69 (56–75)	69 (56–75)	63 (56–75)	0.10
(vi) Disclosure worry	50 (35–65)	50 (35–65)	55 (35–65)	0.67
(vii) HIV Mastery	50 (42–75)	58 (42–75)	50 (42–75)	0.79
(viii) Provider trust	92 (75–100)	92 (75–100)	83 (75–100)	<0.01
(ix) Sexual function	50 (42–67)	50 (42–67)	50 (42–58)	0.58
Behavioural variables				
Alcohol use at time of interview (% Y)	105 (48%)	79 (47%)	26 (52%)	0.54
Illicit drug use at time of interview (% Y)	123 (53%)	85 (48%)	38 (73%)	<0.01
Injection of drugs at time of interview (% Y)	53 (23%)	37 (21%)	16 (31%)	0.13
Sexually active in last 6 months (% Y)	125 (54%)	100 (56%)	25 (48%)	0.32
Condom use of sexually active participants** (% Y)	46 (40%)	36 (40%)	10 (42%)	0.85
Sex trade history*** (% Y)	71 (57%)	52 (55%)	19 (66%)	0.30
Pregnancy intention (% Y)	32 (14%)	26 (15%)	6 (12%)	0.58
Number of births in life time (median (IQR))	2 (1–3)	2 (1–4)	2 (1–3)	0.43
Individual health status variables				
Ever diagnosed with HPV (% Y)	18 (8%)	15 (8%)	3 (6%)	0.53
Ever diagnosed with chlamydia (% Y)	48 (21%)	33 (18%)	15 (29%)	0.10
Ever diagnosed with gonorrhea (% Y)	38 (16%)	28 (16%)	10 (19%)	0.54
Ever diagnosed with syphilis (% Y)	22 (10%)	15 (8%)	7 (13%)	0.27
Abnormal Pap smear in last 6 months (% Y)****	34 (17%)	28 (17%)	6 (15%)	0.75
Symptoms of depression (% Y)	156 (68%)	121 (68%)	35 (67%)	0.97

Table 1: Continued.

	WHC utilization			*P* value
	All (n = 231)	Yes (n = 179)	No (n = 52)	
HIV clinical variables				
ART status at time of interview (% Y)	177 (77%)	141 (79%)	36 (69%)	0.15
CD4 count at time of interview (median (IQR))	300 (170–470)	290 (170–470)	310 (175–475)	0.85
pVL (log 10) at time of interview (median (IQR))	1.7 (1.5–3.1)	1.7 (1.5–3.1)	1.7 (1.5–3.0)	0.46
VL suppression (% Y)	140 (61%)	111 (62%)	29 (56%)	0.42

*30% of the data are missing (n = 162).
**50% of the data are missing (n = 116).
***46% of the data are missing (n = 125).
****only participants who answered "yes" or "no" were included in the denominator.

Table 2: Multivariate analysis of factors associated with women's health care (WHC) utilization among HIV-infected women in the LISA cohort.

Variable	Unadjusted odds ratio (OR) (95% CI)	*P* value	Adjusted odds ratio (AOR) (95% CI)	*P* value
Health authority (HA)		<0.01		<0.01
Vancouver coastal HA	1.00 (—)		1.00 (—)	
Fraser HA	0.86 (0.38–1.95)		0.52 (0.21–1.29)	
Interior HA	2.25 (0.28–18.40)		1.78 (0.19–16.79)	
Northern HA	0.53 (0.13–2.18)		0.43 (0.09–2.07)	
Vancouver island HA	0.19 (0.07–0.48)		0.12 (0.04–0.37)	
Annual income		<0.01		<0.01
≥C$15,000	1.00 (—)		1.00 (—)	
<C$15,000	0.17 (0.06–0.49)		0.14 (0.04–0.54)	
Illicit drug use		<0.01		0.03
No	1.00 (—)		1.00 (—)	
Yes	0.34 (0.17–0.66)		0.42 (0.19–0.92)	
Provider trust (QoL scale)	0.96 (0.94–0.98)	0.03	0.97 (0.95–0.99)	0.03

HIV-related clinical variables did not vary by WHC utilization status, suggesting that all women in this study responded similarly to HIV-specific treatment. The lack of association between WHC and HIV clinical variables reflects a lack of integration between WHC and HIV care and a deficiency in women's holistic care in BC. Centralizing and streamlining WHC with HIV-specific care should be emphasized to avoid unnecessary shuffling of patients within the health care system. WHC could be tailored to low-income women's financial need by providing transportation reimbursement and free childcare and could increase patient's provider trust by offering a safe, nonjudgemental multidisciplinary environment and the option of seeing a female care provider. These suggestions echo the best practices in promoting HIV-infected women's health [45–47]. Oak Tree Clinic (OTC) located in Vancouver has been a pioneer in implementing women-centered care for HIV-infected women in BC. The clinic is a provincial resource for HIV-infected women and children, with HIV care, obstetrical and gynaecological care, dietary care, and social support all amalgamated within one facility [48]. The fact that a quarter of the women in this study were recruited from the OTC could explain the relatively high prevalence of WHC utilization among study participants.

An ad hoc analysis was done comparing WHC utilization between women who accessed care at OTC and women who did not. As shown in Supplemental Table 1 available online at doi:10.1155/2012/560361, WHC utilization and access to OTC was highly associated ($P < 0.01$), and women who accessed OTC were significantly more likely to report WHC utilization than women who did not access OTC. This may be related to the fact that health care providers at the OTC are highly sensitized to the importance of WHC and incorporate WHC to routine HIV care. The outreach social workers and nurses, as well as free food and child care at the OTC, also help bring in harder-to-reach women, such as women who inject drugs and who have low income. Furthermore, OTC provides a safe women's majority (75%) environment to help build trust, and the clinicians have developed long-term relationship with the patients. The multidisciplinary team works to increase women's engagement and ability to deal with the HIV challenges. This ad hoc analysis provided strong evidence that women-centered multidisciplinary service integration could effectively encourage WHC utilization

and promote health among HIV-infected women, especially the harder-to-reach women. As the next step, studies could be designed to more thoroughly evaluate OTC's model of care.

Readers should be cautious when interpreting our findings to the general population of women infected with HIV in the province. Oversampling of injection drug users and aboriginal people means that women in this cohort may encounter more social vulnerability. The financial incentives provided to all LISA study participants might have introduced volunteer bias, where women in need of financial gain, particularly those who reside in the impoverished downtown east side of Vancouver, were overrepresented. As LISA study participants have accessed HIV treatment and were recruited through physicians, clinics, and AIDS service organizations, those interviewed were already connected to care in some degree. Therefore, our sample does not include those individuals who are not able to access care and may face several structural barriers to care and thus may not represent the most marginalized people living with HIV in BC. Second, the variables used in this study were self-reported and, therefore, subject to recall bias and social desirability bias. Future studies could use physician or hospital records to objectively assess WHC utilization among HIV-infected women who have accessed ART. Third, the definition of WHC might vary among study participants. Some might interpret it as services including a Pap smear, while others might consider it a full range of services tailored towards women. Future studies could divide this broader measure of WHC into more specific type of services. Fourth, automated backward selection procedure ran the risk of eliminating variables that are meaningfully associated with the outcome solely based on statistical significance, but it provided an objective way of model selection. Lastly, the cross-sectional design of this study means that causality cannot be inferred in the relationship between WHC utilization and the covariates. However, previous qualitative studies have revealed some of the social pathways linking WHC utilization with income and provider trust, rendering policy recommendations more relevant and persuasive.

In conclusion, our findings suggest that there is a health service gap for harder-to-reach HIV-infected women who have accessed ART in BC. Improvements could be made by enhancing the integration between HIV-specific care and WHC and providing women-centered health services. Socioeconomic policy reforms are also needed to address the structural inequalities in health.

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Review Article

Living with Uncertainty: Acting in the Best Interests of Women

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A recent multi-country study on hormonal contraceptives (HC) and HIV acquisition and transmission among African HIV-serodiscordant couples reported a statistically significant doubling of risk for HIV acquisition among women as well as transmission from women to men for injectable contraceptives. Together with a prior cohort study on African women seeking health services, these data are the strongest yet to appear on the HC-HIV risk. This paper will briefly review the Heffron study strengths and relevant biological and epidemiologic evidence; address the futility of further trials; and propose instead an alternative framework for next steps. The weight of the evidence calls for a discontinuation of progestin-dominant methods. We propose here five types of productive activities: (1) scaling injectable hormones down and out of the contraceptive mix; (2) strengthening and introducing public health strategies with proven potential to reduce HIV spread; (3) providing maximal choice to reduce unplanned pregnancy, starting with quality sexuality education through to safe abortion access; (4) expanding provider training, end-user counseling and access to male and female barriers, with a special renewed focus on female condom; (5) initiating a serious research agenda to determine anti-STI/HIV potential of the contraceptive cervical cap. Trusting women to make informed choices is critical to achieve real progress in dual protection.

1. Introduction

The recent Heffron et al. [1] multi-country study on hormonal contraceptives (HC) and HIV acquisition and transmission among African HIV-serodiscordant couples reported a statistically significant doubling of risk for HIV acquisition among women as well as transmission from women to men for injectable contraceptives. A more modest effect in the same direction was was also reported for combination oral contraceptives (COCs), although not attaining statistical significance. This study, together with Morrison et al.'s analyses [2, 3] on a cohort of African women seeking health services, represents the strongest data yet to appear on the association. It is unlikely that other study designs, including a randomized controlled trial (RCT), could provide stronger evidence for causal inference. Therefore goes our argument: these studies provide the weight of the evidence and the best we can get for the next decade.

Of course, one study, however good, cannot make for certainty. But by now there have been over 50 published papers and several comprehensive reviews, emphasizing the different study populations and analytic strategies and designs, all mainly emanating from high prevalence sites. Overall, the results for DMPA have shown at least a modest risk for HIV, not necessarily statistically significant depending mainly on sample size. Studies not indicating risk often have serious methodologic shortcomings, such as infrequent timing of exposure and outcome ascertainment [4], poor statistical power [5], or aberrant comparison groups [6].

However, Morrison et al., the author of the editorial accompanying the Lancet issue that published Heffron et al., and who has published other major works in this field, particularly emphasized the additional risks among young women. A recent study from South Africa demonstrated a raised risk of DMPA that only marginally failed to reach statistical significance and suggested that NET-EN,

the alternative injectable contraceptive used especially by young women in South Africa, might also be a risk factor though of lesser magnitude [7]; a second South African study also found a significant association of DMPA with chlamydia infection [8]. Neither the recent CROI nor microbicide meetings, in which these relationships were intensively discussed, showed any data to challenge seriously the relationships outlined here. The immunosuppressive effects of DMPA may bring other health risks that are particularly pronounced among young women. For example, recent data have indicated a doubling of risk for breast cancer in women aged 20–44 years associated with recent or longer term (>1 yr) use of this method [9].

This article will cover four issues: first, review the strengths of the Heffron study; second, reexamine and update biological and epidemiologic evidence to support the HC-HIV association; third, address the likely futility of further trials on this association; and finally propose an alternative framework for next steps.

2. Epidemiological Strengths of Heffron

Heffron et al. addressed a large and vulnerable high-risk population. The study followed close to 4000 HIV-serodiscordant couples across seven African countries for which HSV-2 infection status was known for each partner. Importantly, timing of the acquired HIV infections was tightly linked to the exposure period, a problem in numerous prior studies. The analysis excluded infections among men from an outside partner, via genetic testing of the HIV-1 virus, thus assuring the firmest possible control over HIV exposure source. Contraceptive exposure information was updated quarterly; self-report was validated and study sites often were the providers of the contraceptive methods (personal communication, Helen Rees). Finally, participant retention was high (over 90% at 12 months; over 84% at 24 months), minimizing threat of selective loss-to-follow-up. These four study aspects lent great strength of inference to the observed association. Study aspects leading to weaker causal inference included self-report as the source of information on condom use and sexual frequency. Nevertheless, superior methods for collecting or validating information on these exposures in such a study setting are not possible. The sexual behavior variables were controlled in numerous analytical approaches. Adjustment in Heffron strengthened the observed effect estimate and narrowed the confidence intervals. In Heffron, as in the Morrison analyses preceding, multiple statistical approaches undertaken to control effects of these confounders, moving from less rigorous to more rigorous approaches, did not undermine the observed effect and, as also in Morrison et al., demonstrated a strengthening of the effect estimate. Heffron and coauthors recently presented sensitivity analyses [10] demonstrating a persistence of the effect on HIV risk found in their original analysis. Of note, when restricting the analysis to consistent DMPA-users only (i.e. excluding South African women who also use Net-En), the risk (hazard ratio) climbed substantially, to 3.39 (CI 1.38–11.22). Also of interest, and found in other data sets, COCs, containing a lower dose of progestin, showed weaker effects on HIV risk (see also biology, below). Alternate explanations for this result, that entirely exclude an actual biological effect, are difficult to formulate.

Finally, that Heffron et al. represented a secondary analysis has been repeatedly emphasized as an important shortcoming; yet this would not appear to detract significantly from epidemiologic inference. Certainly, the number of hormonal contraceptive users was smaller than in a study explicitly designed to assess this association, resulting in relatively wide confidence intervals. Nevertheless, concern that the Heffron analysis, due to its secondary nature, demonstrated "chance findings" is unwarranted. The likelihood that there is *no* underlying effect of HC on HIV risk, when posed against the substantial body of biologically coherent data and epidemiologic evidence in favor of this association generated over 2 decades [11], is vanishingly small.

3. Supportive Biological Evidence and Coherence

There is no dearth of accrued biological evidence supportive of an increased risk of HIV infection due to endogenous or synthetic progesterone exposure; indeed, numerous biological mechanisms might act synergistically. Marx and colleagues in 1986 in macaques [12] demonstrated increased dramatic thinning of vaginal lining as well as susceptibility to SHIV with progestin treatment. Indeed, progesterone treatment is routinely used in experimental animal protocols to achieve infection. Effects of progesterone to explain the observed role in infection of monkeys include vaginal thinning and loss of keratinization of the epithelial layer, but remain less clear. In humans, Mauck and colleagues [13] found only a modest amount of epithelial thinning in a small series of American women administered DMPA, inconsistent with the degree of thinning seen in Marx et al., thereby weakening a biological plausibility argument through analogy with the monkey data. But recent data from Vishwanathan and colleagues [14] demonstrate SHIV infection risk is increased with only a modestly higher level of progestin, and a small degree of thinning that accompanies the progesterone-dominant phases of the menstrual cycle of pigtail macaques. This study has challenged the argument for vaginal thinning as one mediator of HIV infection.

Other potential mechanisms to explain an increase in infection risk for women using HC include, on a clinical level, cervical ectopy (ectopy is typically associated with immaturity; Morrison et al. [2, 3] found HIV risk with use of DMPA more marked among young women but a recent study did not support the association [15]), or mediating effects of genital tract infection, and related impact and role of *Lactobacillus* colonization of the vagina; and on a cellular level, cervicovaginal inflammation and viral replication [16]. One study of high-risk women demonstrated that HC users were more likely than non-users to become simultaneously infected with more than one variant of HIV-1 [17, 18]. Kumwenda and colleagues [19] who measured HIV viral

load quarterly among women attending general reproductive health services in Malawi, demonstrated both a strong association of DMPA with seroconversion, as well as an interaction of DMPA use with increased viral load around the time of acute infection. No association of DMPA was seen for disease progression. The findings accented the critical nature of the timing of ascertainment of exposure to detection of any underlying HC-HIV association.

Hel and colleagues [20] have extensively reviewed the multiple immunoregulatory effects of progesterone. Estrogen treatment is noted to protect macaques against infection; thus providing some biological coherence to the observation in numerous epidemiologic studies, that COCs are associated with a lower risk of HIV acquisition in women, as compared with DMPA, even when controlling for sexual behavior [3, 7, 16, 21]. Progesterone treatment in some studies increases frequency of Langerhans cells in the vaginal epithelium, an important target cell in HIV early infection events. Chandra et al. [22] recently reported significant increases in vaginal T cells, activation markers, and HIV-1 receptors among healthy women measured at 12 weeks following DMPA administration. Estrogen treatment is associated with a decreased frequency of these cells [20]. Other data converge to strongly support the contention that physiological changes in progesterone exposure during the menstrual cycle account for large differences in infection risk [23].

4. Is a Randomized Controlled Trial (RCT) Called for and Feasible?

There have been calls for an RCT to strengthen epidemiological inference on HC-HIV risk [24]. It is unlikely that an RCT, however well-designed, would answer the shortcomings of the present, large, observational data set. The main gaps in Heffron et al., confirmation of condom use and coital frequency, are difficult to fill.

First, it is unlikely that any single RCT could replicate or improve on the population diversity represented in the observational data. Exposure interactions with variables such as high-risk sexual behavior, concurrent STI, vaginal ecology variables, and other covariates, all of which may be important in the risk equation, could be entirely missed in the narrow select population of any RCT. Women who agree to be randomized to a contraceptive method (e.g., Depo Provera injection versus IUD) may be different in some important ways among women who would and would not be recruited, limiting the chances to detect an underlying association. Clinical inclusion/exclusion criteria will lead to further homogeneity of the population. Second, it is unlikely that the study could blind women to their assigned method, thereby raising the risk of differential condom use and other sexual behaviors (e.g., sexual frequency) in response to the method's secondary effects or perceived method attributes or efficacy. This undermines a primary rationale for trial design. Such behaviors will need to be captured by self-report, as with observational design; self-report of behaviors may thereby be differential by trial arm. Third, method side effects (such as nausea, breast tenderness, and intermittent bleeding for DMPA), historically a primary cause of discontinuation, would not be altered by trial design. Discontinuation, method switching, and/or poor adherence would reduce the statistical power of the trial to identify and quantify risks with HC, and is a serious threat to trial success. These considerations imply that a trial carries a substantial likelihood of missing an actual, underlying difference in HIV risk with hormonal methods, with the attendant false reassurance of safety. Adherence has been a serious challenge in other large trials of FP methods. Fourth, the assignment of trial arms will certainly be a conundrum. IUDs may pose their own risks of increased STI/HIV; concerns regarding PID are still current (see below). Comparing different hormonal products with each other will require a sample size that may be unattainable and certainly an outstanding resource commitment. Absence of a condom arm would hinder inference considerably; if hormonal and IUD arms are equivalent in HIV risk, what shall we conclude about the relative risk for women using condoms? Yet, randomizing women to nonhormonal/non-IUD contraception reproduces the potential for unequal use of condoms across arms, as mentioned above. Also, ethical arguments have been expressed in relation to randomizing women to a male condom-only condition where partner cooperation is required and often not realized [25].

In short, a RCT would be unlikely to yield greater insights into this issue, but would cost us another better part of a decade to design, conduct, and analyze, during which time HIV incidence would continue to climb, and FP program adaptation would be delayed. The reflexive move toward an RCT must be resisted; theoretical gains of randomized design would not be achieved in practice, as outlined above. The momentum of the scale-up of DMPA in FP programs over the past decade must also be considered in the risk equation and timeline to response—the yearly cost in HIV infections secondary to use of injectables has not yet reached its apex, placing an even greater urgency on decisions to change policy and discontinue use of this contraceptive method. Further, the data in Heffron pointed to a doubling of the risk of HIV transmission to the male partner with use of DMPA. This is the first such report and although not confirmed elsewhere, provides additional arguments for moving this method out of the contraceptive mix as quickly as possible.

A change in paradigm favoring the scale-up of safer, health-preserving contraceptives to men and women in low-resource, high-HIV risk settings brings clear benefits for generations to come. By contrast the marginal gains to be had in squandering precious resources on a further trial of DMPA, even with the highly optimistic and unlikely assumption that such a trial will be "perfect" and unimpeachable, are small. The move to safer contraceptives is inevitable, as is the need to decide policy in a state of scientific uncertainty.

5. Next Steps: Living with Uncertainty, Acting in Best Interests of Women

Taken together, the biological evidence and epidemiologic evidence from Heffron et al., and Morrison et al. while

not definitively ending the debate on whether HCs raise risk of HIV, have nevertheless tipped the scale considerably in favor of a presumption of risk, especially for progestin-dominant injectables. It is no longer ethically justifiable to "stay the course" with current FP programming; the weight of the evidence supports a move away from promotion of progestin-dependent methods.

This altered course, then, calls for at least five different types of activities, of which our main focus for this article shall be on the last two.

Scaling injectable hormones down and out of the contraceptive mix and bolstering provider training as well as counseling activities to support full disclosure policies for users on risks with these methods. Greatly increased emphasis of educational approaches, and their evaluation at a range of sites will be needed. It must be explained to all concerned—health workers, women at risk, and their partners—that use of hormonal methods, especially DMPA, likely increases women's risk of HIV acquisition. Women cannot be denied this information and the autonomy to act in their best interests as they see it. Protecting women "from themselves" will not advance a women's health agenda. In our view, the recent WHO Technical Statement [26] downplays risks with these products by urging no effective change in policy while at the same time vigorously promoting use of added protection against HIV; it is an unclear message that is hard to decipher for women users. Women should be dissuaded from initiating use of injectables and informed about the reasons and concerns; whether in low or high HIV-prevalence areas, women's right to the information on risk and their ability to exercise choice must be paramount. Counseling should also cite a possible elevated HIV risk for men though stressing this is unconfirmed and carefully refocusing responsibility on the male partner to use condoms for couple protection.

Strengthening and introducing public health strategies with proven potential to disrupt HIV transmission, including universal test-and-treat, treatment upon first diagnosis, circumcision programs, pre- and post-exposure prophylaxis, whether pills or microbicides, and treatment as prevention (Truvada). Addressing implementation strategies for combination prevention is likely to yield large gains in reducing HIV spread [27]. These will lower community/network infection prevalence and thus reduce the impact of contraceptive method interactions with HIV exposure.

Providing maximal choice to reduce unplanned pregnancy to a minimum, from quality sexuality education to diverse contraceptive methods to emergency contraception and safe abortion access. Scale-up and promotion of the widest range of contraceptive methods to address different age groups and diverse partnership contexts should include permanent methods (male and female sterilization) lowest dose non-progestogen-based hormonals, IUDs (with screening and triaging of users), and male and female condoms—all with careful counseling regarding risks and benefits and need for consistent use for coitally dependent methods. Current contraceptive choice in high-HIV prevalence areas is limited and must now urgently diversify towards methods that do not increase STI/HIV risk. Women must be informed that all nonbarrier contraceptives involve some level of risk (besides contraceptive failure); and that male and female condoms do not pose these safety risks. Consistent use is key for coitally-dependent methods and pills. Women should be full partners in this choice.

IUDs are highly effective and do not involve systemic exposure to progestogens, with their immunosuppressive effects [28]. Nevertheless, data remain scarce on possible effects on risk of HIV acquisition. The evidence on PID risk is still worrisome for high-STI prevalence areas [29]. Several authors have offered careful approaches to be used even in such settings, including, first and foremost, commitment to quality of care [30], as well as the use of conservative algorithms to determine candidacy for this method and presumptive antibiotic treatment for women at highest risk [30, 31]. Women users should be educated about PID—the risks and signs and symptoms.

Expand provider training, end-user counseling and access to male and female barriers—female condoms, diaphragms, and cervical caps—for sole use, dual use, or multipurpose use, with renewed focus on hierarchical counseling and use of proven interventions to ensure optimal uptake. Male condom use is certainly efficacious, and must continue to be urged; yet, the enormous obstacles many women face in negotiating their use with partners remain as valid today as they were at the start of the HIV epidemic [32]. Though progress has been made in male condom use rates, a majority of high-prevalence countries report lack of protection at last encounter [33]. Indeed, promoting the male condom now as a satisfactory solution to women's increased risk of HIV with injectable hormones only invites a cynical reception and the planting of the seeds of mistrust in women due to its seeming head-in-the-sand nature, and limited usefulness "on the ground". Cates and Steiner [34], in an early paper have argued that promoting condoms only for disease prevention may stigmatize the method. Indeed, from a woman's perspective, removing the "contraceptive justification" for male condom use from the argument repertoire—for example, where male partners are aware of hormonal contraceptive use—clearly impacts on likelihood of partner agreement. Thus, male condoms as the second (dual) method is likely to appeal only to highly select population groups such as HIV sero-discordant couples—those keenly aware of their status and mutually committed to protection. For others, recourse to female protection methods is probably still the most promising route. These arguments together point to the need to expand—in name and in deed—access to female methods as dual methods. Proactive promotion of female barriers alongside hormonal methods must start with specific mention of such methods in policy or counseling texts. These safe methods could be promoted both as alternatives to hormonal methods, or to be used in tandem with them—"offset options"—to mitigate against risk of infection while bolstering protection against unplanned pregnancy. Using "hierarchical" strategies [35], the female condom *and* male condom should be uniformly counseled on as equally protective against STI/HIV [36], with cervical barriers (diaphragms, cervical caps, cups, etc.) promoted as "next best"; some of these latter should provide some protection against disease (those infecting the cervix

mainly or solely) but less than either of the two condoms. Any serious program of scale-up of female barriers would also require provider training (across FP-HIV-reproductive health (RH) facilities) and positive re-orientation of FP personnel, at all levels, as this has been a serious hindrance to use historically [37–40]. Recent evidence from a South African female condom trial quantifies the substantial reduction in method problems experienced by the user when adequate user support is provided in the initial adoption period [41]. There has been a tendency to discount female barrier methods as impractical and unacceptable though no wide-scale evidence in developing countries supports this contention and indeed there is evidence to the contrary [42–48]. Certainly the existing evidence is wholly insufficient to glean women's actual preferences when given real choice, in an appropriately-designed research study or demonstration program. Involvement of communities of women users of contraceptive services, and their partners, will help inform the most culturally appropriate approaches [40]. Women have potentially more control over female condom use but its impact will be realized only with strong promotional programs and quality counseling including outreach activities to men wherever possible [49], as well as easy access to continuing supplies, to ensure adoption and maintenance of the behavior [36].

Initiation of a serious research agenda to determine anti-STI/HIV efficacy and effectiveness of an important yet overlooked contraceptive method: the cervical cap. Covering the cervix may help reduce HIV risk via: (a) reducing coincidence of cervical inflammation-HIV contact, (b) blocking sperm-mediated HIV infection, and (c) among young women (with immature cervices) for which injectables may carry a very high increased risk of HIV infection. Advocacy for women-controlled protection has spawned numerous, exciting directions aimed at expanding chemical and physical protection methods for women. Among these, the movement for multipurpose prevention technologies (MPTs) has as its goal to develop products with at least two indications (contraception, STI prevention, HIV prevention, reproductive health enhancement) [50]. New cervical barriers under this rubric include the Silcs diaphragm and tenofovir-releasing rings [51]. Concurrently with development of new methods, however, research on conventional, time-tested and approved female barriers must also proceed with urgency. As one example, there is a clear need for a RCT to address anti-HIV efficacy and effectiveness of the cervical cap, and specify optimal conditions of use as a contraceptive. Although the contraceptive diaphragm has been the subject of a large-scale trial for efficacy in HIV/STI prevention [52] (failing to produce evidence of effectiveness), the cervical cap has so far been passed over, despite the fact that the device may offer distinct advantages over other devices now under study and in development.

5.1. Biological Justification for Cervical Barrier Methods in Women's HIV Prevention. HIV infection across the vaginal wall, as compared to ecto or endocervical transmission—is thought by many to account for most sexually transmitted infections in women due to the large difference in surface area [23]. Nevertheless, considerable questions remain. In particular, due to the possibility of sperm-mediated transport of HIV, uterine peristalsis aiding infection of the upper reproductive tract, and the high prevalence of cervicitis in the developing world, a clear role for cervical barriers in reducing risk of HIV infection certainly exists [53]. Hormonal mediation of HIV receptor cells differs considerably when comparing upper and lower reproductive tracts [23, 54]. Protecting the cervix from inflammation due to infection or trauma, or reduced innate immunity with exogenous hormonal exposure or menstrual cycle stage should still be of high interest for reducing risk of HIV.

5.2. Cervical Caps—Efficacy: Mode of Action. Cervical caps have a distinctly different mechanism of protection than the diaphragm and other "loose" cervical barriers. Like the contraceptive diaphragm, the cap covers the cervix, but the shape of the cap is conical, like the cervix, and the device adheres via gentle suction, rendering the level of protection to sperm and pathogens theoretically much greater than that of the diaphragm, because the cap completely surrounds and encloses the cervix (see Figure 1). The contraceptive efficacy of cap versus diaphragm, in the two available trials, indicates a similar level of protection against unplanned pregnancy [55]; but some of this protection in the case of the diaphragm is likely owing to simultaneous use of spermicide. Much remains to be determined regarding actual use-effectiveness of the cap as a contraceptive or for disease prophylaxis in populations needing dual protection.

5.3. Cervical Caps—Effectiveness: User Aspects. From the user's perspective, there are a great number of advantages to this particular barrier [56, 57]. It can be used without the partners' knowledge, inserted long before sex, and can be used with the male condom. The cap should be compatible with all forms of contraception and could be theoretically quite important in offsetting increased risk of STI/HIV acquisition with hormonal contraceptives or IUDs if used concurrently. The cap may be used for multiple acts without reapplication of spermicide or removal, at a continuous high level of contraceptive efficacy for at least 48 hours, according to present FDA labeling; published data indicate longer wear is possible without safety concerns [58]. Cap devices may be adapted for microbicide release [59]. These devices are in general small, simple, and inexpensive to manufacture, as well as being highly portable, durable, and resistant to temperature and other environmental conditions. The Femcap, as the only currently approved and marketed cervical cap, is made of silicone, thus maximally resistant with no need for replacement over many years [60, 61] (Figure 2).

The user advantages above point to potentially large gains in effectiveness over other cervical barriers when used as an anti-STI/HIV method. The limited field experience with the device in developing country populations suggests acceptability is sufficiently good for larger trials [62, 63]. Evidence from other hard-to-reach populations such as

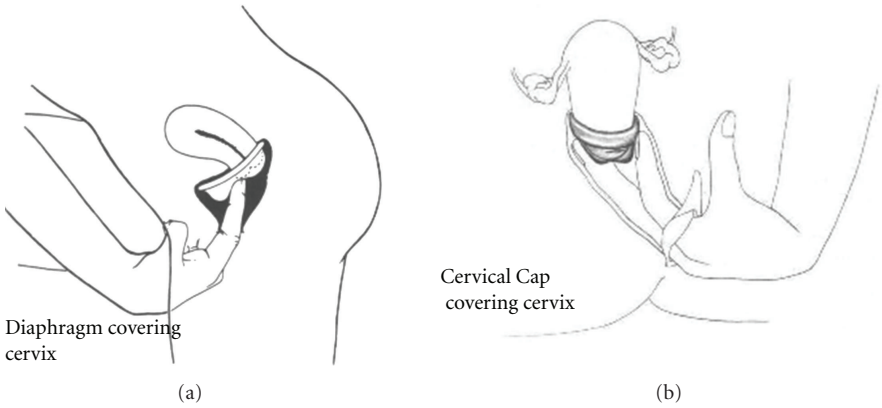

Figure 1: Diaphragm versus cervical cap placement. Courtesy of Rebecca Chalker, *The Complete Cervical Cap Guide*, copyright 1987.

Figure 2: Femcap (courtesy of Alfred Shihata).

substance-using women suggests the same [64]. An energetic research agenda could bring large STI/HIV prevention gains to potentially diverse populations of women in need. Yet poor global promotion of this device has led to low clinician familiarity, negative attitudes, and consequent low awareness and demand among women [60, 65]. The cervical cap needs an influential champion.

6. Conclusion

There is substantial lack of incentive to altering current FP policy, due to real concerns about the risks of pregnancy for women and children, especially in resource-poor countries. DMPA, as a long-acting, highly promoted, popular contraceptive for women, has a clear public health advantage that extends beyond reducing unplanned pregnancy rates to the reduction of maternal mortality and vertical transmission of HIV infection. Filling the void left by discontinuation of this method will be neither convenient nor simple. Nevertheless, we cannot let the difficulties be an obstacle to change. Numerous other contraceptive options exist and must be deployed with enthusiastic provider support. The price couples pay for contraception need not be HIV infection. The recently-confirmed increased HIV risk with DMPA use has thrown into bold relief our slow progress at entrusting women with a meaningful range of choices in contraception that would also protect them from disease. Increased expectations of women to make up the gap in new HIV infections acquired due to DMPA, by somehow suddenly exerting an extraordinary level of control over male condom use, places the burden squarely on women rather than health systems to adapt and is not a realistic solution. Greater emphasis must be given to full frank informational counseling, and expanded options that women may learn and practice autonomously to reduce HIV risk concurrently with practice of contraception. A change in direction could also promote real bridging and integration across RH, HIV, and FP "camps", thus opening up new opportunities to better serve women and couples in our public health mission. Finally, the renewed focus on female barrier methods should prompt an accelerated research agenda and important step-ups in funding, both for new technologies we have started to explore, as well as conventional barriers we have yet to exploit. Culling and generalizing proven, effective approaches to female condom promotion remains well within our global capabilities and as yet unrealized. An additional technology with the potential to reduce sexual HIV risk, so far neglected, but calling for revival and an invigorated research campaign, is the cervical cap.

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Review Article

Meeting the Contraceptive Needs of Key Populations Affected by HIV in Asia: An Unfinished Agenda

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Like all women, women living with and at risk of acquiring HIV have the right to determine the number and timing of their pregnancies and to safely achieve their reproductive intentions. Yet, many women in Asia affected by HIV lack access to family planning services and experience disproportionately high rates of unintended pregnancy and abortion. Programs that have succeeded in promoting condom use and providing HIV prevention and treatment services in this region have largely missed the opportunity to address the contraceptive needs of the key populations they serve. The importance of better linkages between family planning and HIV policies and programs is now widely recognized by global health policymakers and donors. However, to date, most of the efforts to improve these linkages have been conducted in Africa. Greater attention is needed to the developing, implementing, and evaluating of integrated family planning/HIV approaches that are tailored to the political, cultural, and public health context in Asia. In this paper, we describe the use of and need for family planning among key populations affected by HIV in Asia, discuss the challenges to effectively addressing of these needs, and offer recommendations for strengthening the linkages between family planning and HIV policies and programs in the region.

1. Background

The HIV/AIDS epidemic in Asia is characterized as concentrated. The national adult prevalence of HIV is still under 1% in the majority of countries in the region, but exceeds 5% in many most-at-risk populations (MARPs), including men who have sex with men (MSM), injecting drug users (IDUs), sex workers, migrants, and sexual partners of these groups. Overall declines in HIV prevalence achieved in the region during the last decade are offset by pockets of high prevalence within these key populations. For example, while national HIV prevalence in India remains at a low 0.3% [1], HIV rates among some MARPs, such as female sex workers (FSWs), can be as high as 41% [2].

Despite the overall low prevalence rates, the large population sizes of many Asian nations mean that about 4.8 million people were living with HIV in the region in 2010, 1.7 million (35%) of whom were women [3]. From 1990 to 2002, the proportion of Asian women with HIV increased from 21% to 35% of all adults, but has since stabilized and has stayed below the global level of 52% [3]. While the majority of women with HIV were infected by their intimate partners, many are also at risk for or acquired HIV through sex work [3]. Substantial investments have been made in condom promotion and other HIV prevention and risk reduction programs targeting female sex workers and other women at risk for or living with HIV. Many of these programs have been successful in slowing the spread of HIV. However, attention to the other sexual and reproductive health needs of women, particularly the prevention of unintended pregnancy, has been largely absent from these programs.

Like all women, women living with and at risk of acquiring HIV have the right to determine the number and timing of their pregnancies and to safely achieve their reproductive intentions. In addition, enabling women living with HIV to prevent unintended pregnancies is an important and cost-effective strategy for preventing mother-to-child transmission (PMTCT) of HIV [4–11]. Galvanized by public health

leaders and human rights advocates, the importance of better linkages between family planning and HIV policies and programs is now widely recognized by global health policymakers and donors [12]. However, most of the advocacy, programmatic efforts, and research to improve these linkages have been conducted in Africa. Efforts to identify and address the reproductive health needs of women and men affected by HIV in Asia have been scant by comparison.

Asia differs substantially from Africa in terms of the nature of the HIV epidemic, health system organization and constraints, culture, and socioeconomic development. While some lessons for advancing family planning and HIV linkages may be drawn from Africa, the Asian context necessitates strategies tailored to the unique circumstances of the region. In this paper, we argue that greater efforts are needed to identify and implement effective strategies for meeting the contraceptive needs of women and couples affected by the concentrated HIV epidemic in Asia. Drawing on English-language published peer-reviewed literature as well as grey literature (including unpublished program reports, white papers, and conference presentations), we describe what is currently known about the use of and need for family planning among key populations affected by HIV in Asia. We then use this evidence to inform a discussion of the various challenges to effectively addressing the family planning needs of key populations in Asia, and offer recommendations for strengthening the linkages between family planning and HIV policies and programs in the region.

2. Family Planning Needs among Key Populations in Asia

The majority of data on unintended pregnancy, family planning practices, and abortion among people affected by HIV in Asia are from female sex workers, and to a lesser degree, women and couples living with HIV.

As a result of successful condom promotion policies and programs focused on key populations, in 2009 about half the countries in the region reported that at least 80% of female sex workers used a condom with their most recent client [3]. When used consistently and correctly, condoms are effective at preventing both sexually transmitted infections (STIs) and unintended pregnancy. Indeed, many women at risk of or living with HIV report using condoms specifically for pregnancy prevention. In Cambodia, 87.3% of the FSWs surveyed reported relying exclusively on condoms for both contraception and STI/HIV prevention [13]. In a survey of recently or currently pregnant women living with HIV in six countries in Asia, condoms were reported as the most known (88%), available (83%), used (79%), and preferred (64%) method of pregnancy prevention [14].

However, the potential for dual protection against STIs and unintended pregnancy that condoms offer is often not realized. Despite encouraging reports of condom use with clients [15–19], many FSWs do not use them consistently or correctly [14–16], and often women are forced to or will accept additional money in exchange for not using a condom [15–17]. Data from China suggests that FSWs who are also injecting drug users have particularly low rates of condom use with clients [17]. Correct and consistent condom use with regular, nonpaying partners of FSWs, such as boyfriends or husbands, is even less typical. Only 13.5% of FSWs in Bangladesh [16], between 12.7 and 45% in China [17, 20], 26.7% in Hong Kong [21], and between 11 and 50% in India [18, 19] report consistently using condoms with their regular, nonpaying sexual partners. Additional evidence from India suggests that people living with HIV who are not involved in sex work also struggle to use condoms with regular sexual partners, with one-third of men and one-quarter of women reporting inconsistent use [22].

Use of contraceptives other than condoms by key populations in Asia varies widely across countries. Among FSWs in India and Afghanistan who were not pregnant, infertile, or desiring pregnancy, up to 53% and 65%, respectively, were using noncondom family planning methods [19, 23]. Contraceptive use was much lower among young or HIV-positive FSWs in India [19]. Research from Cambodia also suggests use of noncondom family planning methods among FSWs is low (between 1.6 and 5.2%) [13]. Information on dual method use (condoms plus another modern family planning method) is limited, but data from India suggests it is low among FSWs [24, 25] and women and couples living with HIV [26].

Although not extensively documented nor uniformly calculated, existing data reveal FSWs in Asia have a higher than average unmet need for family planning compared to the general population. For example, 60% of FSWs surveyed in Bangladesh [16] had an unmet need for family planning compared to 16.8% of married women ages 15–49 [27]. In China, 47% of FSWs surveyed [20] had an unmet need for family planning, while only 2.3% of married women ages 15–49 reported an unmet need [27]. The evidence from China also suggests that FSW with unmet family planning need tend to be younger, unmarried, less likely to already have children, newer to sex work, and less educated [20]. High rates of unintended pregnancies have also been documented among key populations in Asia. One study in India found that 70% of the repeat pregnancies among women living with HIV were both unplanned and unwanted [28]. Data from a study covering six countries in Asia showed that on average 37.1% of women living with HIV reported their most recent pregnancy was unwanted (Bangladesh 33.3%, Cambodia 43.5%, India 10.3%, Indonesia 33.0%, Nepal 47.5%, and Vietnam 53.2%) [14].

Abortion is legal in many Asian countries, and its common use among key populations in the region provides further evidence that many experience unintended pregnancies and have an unmet need for reliable contraception. Recent or lifetime abortion rates among FSWs in several countries in Asia are often higher than the national average [13, 15, 16, 19–21, 23]. For example, compared with the 5% of all Cambodian women of reproductive age estimated to have had an abortion in 2000, more than a quarter of FSWs reported having aborted a pregnancy, despite 94% also reporting consistent use of condoms with clients [15]. Twenty-six percent of FSWs surveyed in India had experienced abortion [19], compared to a general rate of 3.1 abortions per 1000 Indian women [29]. Analyses from Vietnam also indicate

higher than average rates of abortion among women living with HIV. In addition, knowledge of a positive HIV status has been associated with an increased tendency to seek an abortion [30, 31].

3. Challenges to Meeting the Contraceptive Needs of MARPs

A limited but growing body of evidence from the region suggests that greater attention is needed to meet the contraceptive needs of key populations at risk of or living with HIV. However, various political, societal, cultural, and health system challenges converge to restrict access to family planning for these women and couples.

3.1. Policy Barriers and Funding Gaps. Restrictive laws and policies in several countries pose major barriers for key populations to access high-quality contraceptive services and realize their reproductive rights. For example, in India, women under the age of 18 are restricted from receiving family planning services. In Bangladesh, despite recent improvements in the policies for married women, unmarried women are officially prohibited from receiving popular and effective contraceptive methods such as injectables or implants. These types of policies present real challenges for women such as FSWs, who are often young or unmarried.

Despite the high absolute numbers of HIV infections, HIV remains a low national health priority in most Asian countries given the low overall proportion of the population affected. As such, adequate funding for programs targeting key populations continues to be problematic. While programs reaching sex workers have been critically important in the region's HIV response, funding for these programs has been steadily declining since 2007 [3]. With shrinking funds, programs become less able to offer comprehensive services. Moreover, national disparities in the allocation of funds can prevent critical resources from reaching vulnerable populations. For example, in India, the states with high HIV prevalence also have the highest contraceptive prevalence. Although key populations in high HIV prevalence states may have a high unmet need for family planning, the majority of the government's limited resources for strengthening family planning service delivery go to other states where the contraceptive prevalence is lowest among the general population.

Furthermore, a large proportion of HIV activities in Asia is supported through external funding. While the commitment to supporting family planning services for clients with HIV continues to grow among funders, specific guidance on how HIV/AIDS funds may be allocated for this purpose is not always clear, and program managers are often faced with difficult decisions about how to mobilize and deploy resources for integrated activities.

3.2. Stigma and Discrimination. The stigmatization of key populations is distributed across the policy, program, and service delivery continuum. Stigmatization can be rooted in an overall lack of female empowerment, an individual's involvement with sex work, and/or a positive HIV status. Challenges at the policy level to ensuring access to family planning services for key populations are not limited to the aforementioned restrictive laws and funding, but also often involve pervasive and systematic discrimination by authorities across the health and legal system. Furthermore, the low political importance assigned to the sexual and reproductive health of key populations is exacerbated by the criminalization of behaviors that put key populations at risk. For example, in countries where sex work is illegal, the police may use the possession of a condom as evidence of criminalized behavior. To avoid arrest some FSWs refrain from carrying them [3], which could increase the likelihood that condoms will not be used during sexual encounters with clients.

Female sex workers and women living with HIV are also routinely stigmatized by healthcare providers in mainstream health facilities, through refusals of service, abusive treatment, or the provision of inadequate or inappropriate care [3]. FSWs in Afghanistan have reported being less likely to visit regular health clinics due to fear of being reported to local authorities [23]. In a survey of recently pregnant women living with HIV from six Asian countries, 41.6% reported difficulty finding a gynecologist to care for them during their pregnancy due to their HIV status, and 18% were not satisfied with the confidentiality afforded to them [14].

This type of provider bias and discrimination is a substantial barrier to the provision of comprehensive health services, including family planning, for key populations. In a study from India, physicians and clients alike reported that the family planning counseling delivered to men and women living with HIV focused exclusively on condoms, with only minimal discussion of other contraceptive method options [26]. This data reflects a common concern among HIV program planners that providing nonbarrier family planning methods to high-risk clients will be detrimental to or even reverse the progress achieved on rates of condom use for STI/HIV prevention [13, 14]. However, evidence suggests that access to or use of noncondom contraception does not decrease condom usage among people living with or at risk of HIV [32, 33]. Additional data from several Asian countries suggest that women living with HIV are sometimes encouraged to avoid pregnancy or to undergo sterilization or abortion by their healthcare providers based on their HIV-positive status [14]. These types of limited, biased, or coercive fertility discussions not only result in unmet contraceptive need, but also are violations of women's reproductive rights.

3.3. Program and Service Delivery Challenges. As a result of policy barriers and stigma, women affected by HIV often only access health services through targeted STI/HIV interventions aimed at key high-risk populations. These siloed programs, however, often miss opportunities to address clients' other sexual and reproductive health needs. For example, these programs promote and provide condoms explicitly for the prevention of STIs and HIV. They often do not directly address considerations for using condoms as

a family planning method (e.g., emphasizing consistent use with regular partners), discuss the importance of dual method use, offer other more reliable contraceptive method options, or provide emergency contraception.

Due to the narrow focus of STI and HIV services, the providers staffing these programs may not have the required training or capacity to appropriately address the family planning needs of their clients. In addition, referrals from STI/HIV sites to mainstream family planning services are currently inadequate, given the stigmatization of key populations and their general avoidance of those facilities. Even though family planning services may be geographically available through mainstream health facilities, some women at risk for or living with HIV may be reluctant to access them due to provider biases and concerns about service quality and confidentiality.

3.4. Lack of Operations Research and Programmatic Guidance for Asia. Globally, the evidence base for effectively linking family planning and HIV policies and services continues to grow, with more data emerging that suggests integrating family planning and HIV services can improve health outcomes. However, little of this evidence has been generated in Asia. To date, the integrated family planning and HIV programmatic interventions implemented, evaluated, and published have been almost exclusively limited to the African setting. A 2009 systematic review of evidence for linking family planning and HIV interventions included an analysis of 16 studies, only one of which was located in Asia [34]. Moreover, that study addressed the introduction of HIV services into standard family planning programs, not the integration of family planning within HIV interventions for most-at-risk populations [34]. Thus, the evidence base of best practices for effectively meeting the contraceptive needs of key populations living with or at risk of HIV in Asia remains limited.

A growing number of technical materials and tools are available to guide the integration of family planning and HIV programs. However, strategies tailored to a concentrated HIV epidemic are rarely included. While some elements of existing technical guidance on integrating family planning services into HIV programs are widely applicable (such as the range of contraceptive options appropriate for women and couples with HIV or the core messages to include in informed choice family planning counseling), some unique policy and programmatic considerations are required within the context of concentrated epidemics. For example, programmatic guidance for the Asia region must address issues such as the systemic stigma experienced by most-at-risk groups, particularly when accessing healthcare. This type of stigma has implications for the design of appropriate and feasible referral-based models of integrated care, where sizable investment would be needed to sensitize health care providers and foster enabling environments.

4. Conclusion and Recommendations

Many women in Asia who are at risk of or living with HIV also have an unmet need for effective contraception. They experience high rates of unintended pregnancy and abortion and suffer from a lack of access to comprehensive, rights-based sexual and reproductive health services. Strategies for addressing the contraceptive needs of women and couples with HIV are emerging from research and programs in Africa [34–43]. However, the Asian context presents a scenario requiring a tailored approach for effective integration of family planning and HIV services, beyond those designed for and evaluated in an African or generalized epidemic setting. Advocates, policymakers, funders, and program planners must include considerations for concentrated epidemics within the global dialogue on strengthening the linkages between family planning and HIV services. Based on our understanding and interpretation of both global and region-specific evidence and information currently available, we offer the following recommendations for groups of key stakeholders.

4.1. Key Population Communities and Other Advocates

(i) Advocate for the immediate removal of restrictive laws and policies which bar access to the full range of contraceptive services for key populations.

(ii) Increase the expressed demand for comprehensive sexual and reproductive health services, including family planning, from clients visiting targeted STI/HIV interventions.

4.2. Policymakers and Donors

(i) Remove legal barriers to access to comprehensive sexual and reproductive health services in existing laws, policies, and guidelines.

(ii) Allocate adequate resources to improve linkages between targeted STI/HIV interventions and sexual and reproductive health services, including family planning, safe abortion, fertility and conception counseling, and PMTCT services.

4.3. Program Managers and Healthcare Providers

(i) Build the capacity of key population communities and networks to advocate for and raise awareness among peers of their right to and need for sexual and reproductive health services.

(ii) Leverage the strong HIV infrastructure in the region to deliver or improve access to comprehensive sexual and reproductive services.

(iii) Consider strategies to use postabortion care as an entry point for family planning screening, counseling, provision, or referral.

(iv) Address biases and related stigma by sensitizing and training providers on the comprehensive reproductive rights and options for all women, including key populations.

(v) Promote dual method use.

(vi) Track, monitor, and report on the impact of integrated services, including on completed referrals, method preferences and uptake, and reductions in unintended pregnancies and abortions among key populations.

4.4. Researchers

(i) Conduct operations research to identify the most effective ways of designing services to meet the contraceptive needs of key populations (including for high-risk groups such as IDUs and migrants), paying particular attention to effective dual method promotion and referral strategies.

(ii) Communicate the contraceptive needs of key populations to decision makers, including preferences for location and delivery of services, service delivery design, and contraceptive method options.

We have a growing understanding of the unmet contraceptive needs of populations affected by HIV in the Asia region, yet a dearth of evidence about how to effectively address those needs. Investments in targeted STI/HIV interventions for key Asian populations provide an important and promising platform for reaching these groups with family planning information and services. Efforts are warranted to strengthen the linkages between family planning services and targeted STI/HIV interventions for key populations in Asia and to evaluate their impact on improving reproductive health and HIV outcomes.

Conflict of Interests

The authors have no conflicts to disclose.

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