



INTEGRATING FAMILY PLANNING AND ANTIRETROVIRAL THERAPY: A CLIENT-ORIENTED SERVICE MODEL



EngenderHealth
for a better life

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AND ANTIRETROVIRAL
THERAPY:
A CLIENT-ORIENTED
SERVICE MODEL**



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EngenderHealth works to improve the health and well-being of people in the poorest communities of the world. We do this by sharing our expertise in sexual and reproductive health and transforming the quality of health care. We promote gender equity, advocate for sound practices and policies, and inspire people to assert their rights to better, healthier lives. Working in partnership with local organizations, we adapt our work in response to local needs.

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ACRONYMS AND ABBREVIATIONS

ART	antiretroviral therapy
ARV	antiretroviral (drug)
BCC	behavior change communication
CDC	U.S. Centers for Disease Control and Prevention
COC	combined oral contraceptive
DMPA	depo-medroxyprogesterone acetate
FP	family planning
HIV	human immunodeficiency virus
IEC	information, education, and communication
IDU	injection drug user
IUD	intrauterine device
LA/PM	long-acting and permanent methods
M&E	monitoring and evaluation
MIS	management information system
OI	opportunistic infection
PDA	personal digital assistant
PEPFAR	President's Emergency Plan for AIDS Relief
PIFP	provider-initiated family planning (assessment)
PITC	provider-initiated testing and counseling
PLHIV	people living with HIV
PMTCT	prevention of mother-to-child transmission (of HIV)
RH	reproductive health
SRH	sexual and reproductive health
STI	sexually transmitted infection
USAID	U.S. Agency for International Development
VCT	voluntary counseling and testing

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FAMILY PLANNING–INTEGRATED ANTIRETROVIRAL THERAPY SERVICES

The 2007 version of this publication, *Family Planning–Integrated HIV Services: A Framework for Integrating Family Planning and Antiretroviral Therapy Services* (Farrell, 2007), was developed for three main purposes:

1. To stimulate critical thinking regarding programmatic gaps related to the reproductive health (RH) needs of women and couples living with HIV
2. To examine the HIV assessment, prevention, referral, and/or other service needs of family planning (FP) clients
3. To assist community- and facility-based RH providers and supervisors in tailoring services to reflect the integrated needs of the communities they serve

The ACQUIRE Project (2003–2008), managed by EngenderHealth, field-tested the FP-HIV integration approach among interested program colleagues in Ghana and Uganda (Searing et al., 2008). Results showed that FP-integrated services were favored by clients, were acceptable to service providers (despite challenges), and offered opportunities to strengthen service systems.

This integration program guide focuses on the integration of FP within the provision of antiretroviral therapy (ART) services, capturing how the field of ART management has evolved as well as renewing a focus on reproductive rights. Since the original publication, several studies have furthered the case that integration of FP into specific HIV services is feasible, acceptable, and effective (for example, Adamchak et al., 2010). The objective is to offer a service to a client who may be in need of additional service(s)—in this case, FP—to “facilitate the uptake of contraception by HIV-positive individuals, helping to maintain their health, plan safer pregnancies, and reduce the rate of mother-to-child transmission of HIV” (Adamchak et al., 2010). For women and couples to make RH/FP decisions requires support from the health system and social networks, as well as protective policy and legal structures.

An integrated approach is one in which health care providers take the opportunity to engage the client in addressing health and social needs broader than those prompting the initial health encounter. Integration is a mindset that prompts providers to offer anticipatory assessment and to plan and evaluate services relevant to the clients’ desires, needs, and/or risks. Integrated FP-ART services aim to help women or couples living with HIV enjoy a satisfying sexual life, prevent unintended pregnancy, and achieve a desired pregnancy with minimal risk to their partner and offspring.

ART has transformed living with HIV into a manageable condition, allowing those able to adhere to effective therapy to enjoy a life expectancy on par with their non-HIV-infected peers. The EngenderHealth integration approach is grounded in a rights-based approach for informed and voluntary decision making. The acknowledgment of contraception as a reproductive right and as an essential human right has been affirmed through

several international conferences and treaties over the last few decades (for example, the Convention on the Elimination of All Forms of Discrimination against Women [1979], the International Conference on Population and Development Programme of Action [1994]), as well as Millennium Development Goal 5, which added an objective to achieve universal reproductive health care access [Target 5b]) (Hardee et al., 2013).

The integration approach presented in this guide encourages supervisors, planners, service providers, and community-based personnel to consider opportunities for operationalizing the integration of FP into the provision of ART in a way that responds to and respects clients' needs and desires. It may also create opportunities in one visit for follow-up with clients to discuss side effects, review adherence to ART and the chosen FP method, and facilitate resupply of both FP commodities and antiretroviral (ARV) drugs. Accomplishing this requires skilled staff and supportive health care systems that make it possible to provide counseling and offer quality integrated services.

FP plays an integral part in the prevention of mother-to-child transmission of HIV (PMTCT) (components 1 and 2 of the comprehensive PMTCT approach), and the literature abounds with examples of integrating FP and HIV counseling and testing (Asiimwe et al., 2005; Reynolds et al., 2006; Gillespie et al., 2009; and Baumgartner et al., 2012). There are also compelling reasons to make FP an integral component of HIV treatment: “In a study of 4,531 women from numerous treatment sites in Sub-Saharan Africa, one-third experienced a pregnancy within four years of ART initiation” (Myer et al., 2010; cited in Gay, Croce-Galis, & Hardee, 2012). Unfortunately, in practice, “the design and operation of most HIV treatment services do not explicitly acknowledge the likelihood or occurrence of pregnancy” (Myer et al., 2010: discussion, Para 5; cited in Gay, Croce-Galis, & Hardee, 2012). The goal of “provid[ing] voluntary family planning and safer pregnancy counseling for HIV-positive or discordant couples who desire pregnancy” is explicitly outlined in the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) blueprint (U.S. Department of State, 2012, page 32). This current guide will be useful for achieving this goal.

In Cameroon, a country with a large HIV disease burden (prevalence among those aged 15–49 hovering around 5% in 2009), a study showed that the reproductive intentions of women living with HIV remained poorly documented in the national program to improve access to ART. Women who were being treated with ARVs still strongly desired children, and the researchers concluded that “HIV care and family planning programs should be integrated more thoroughly to support [women living with HIV and AIDS in their] reproductive choices” (Marcellin et al., 2010). This is undoubtedly the case in many countries. Like all women, these women need information about and access to contraception. However, they also need to know how best to safely become pregnant if that is their desire (including reducing the risk of perinatal transmission and transmission to an uninfected partner, if applicable). They require information pertaining to safe motherhood and should be reached by efforts to reduce the risk of being lost to follow-up HIV care during the postpartum period.

Some populations, including sex workers, injection drug users (IDUs), people living in complex (humanitarian) emergencies, prisoners, and migrants may be at very high risk

of acquiring HIV and more likely to be HIV-positive. These populations may be most in need of both ARV treatment and FP services, yet least likely to have access to these health services. Adolescents, and in particular young HIV-positive women (both adolescent girls who were born HIV-positive and those who have acquired the infection since), may benefit from specific types of messaging and programming to address their reproductive intentions. Addressing these particular needs is beyond the scope of this program guide, but special outreach and peer education can prove useful in reaching these distinct groups.

PURPOSE AND DESCRIPTION

The purpose of this program guide is to assist readers in thinking through a successful and efficient plan for FP-ART service integration, but the principles apply for integrating core and additional services, whatever they may be.

The guide is divided into six sections:

- Background
- Overview of FP-ART Service Integration
- Considerations for Holistic Service Integration
- Strengthening Systems for Service Integration
- Monitoring and Evaluation
- Establishing Integrated Services

It can be used to develop an understanding of the concept of integration, to identify and address policy and systems considerations for effective integration, and to begin thinking about ways to assess the capacity for and the approach to FP integration within a core service.

SUGGESTED AUDIENCES AND USES FOR THIS PROGRAM GUIDE

This program guide has a potentially wide range of audiences and applications. The bullets that follow each suggested audience below propose recommendations for how the guide can be used in tandem with selected actions that can/should be taken to make service integration a programming reality. Our hope is that the following groups will find this guide helpful in thinking through some of these suggested steps and actions.

Donors

- Review the guide to become familiar with the content and process for service integration.
- Engage grantees in a discussion regarding plans for supporting service integration initiatives relevant to the needs in proposed settings.
- Break down vertical funding streams to support integrated service provision.

- Fund design, implementation, and monitoring and evaluation (M&E) of integrated interventions that strengthen health systems while addressing client needs.

Implementing Organizations

- Review the guide to become familiar with the content and process for service integration.
- Engage partners in discussions regarding plans for supporting service integration initiatives relevant to needs in proposed settings.
- Design/plan, implement, monitor, and evaluate integrated interventions that strengthen health systems while addressing client needs.
- Disseminate results to the broader international community and donors.

Technical Advisors, Policymakers, Facility Administrators, and Supervisors

- Review the guide to become familiar with the content and process for service integration.
- Identify appropriate stakeholders, including program counterparts, to introduce the integration materials, review them, and compare them with what is already in place in-country—if anything—or what is desired for service integration.
- Determine the level of integration¹ that will be adopted or adapted.
- Assist health policymakers to formulate and disseminate a policy statement on service integration and define the role they will play in facilitating integration.
- Provide technical support to facility administrators to operationalize service integration, including modification of supervisory tools to support changes in service and provider performance.
- Provide technical support to supervisors to complete forms modified to reflect integrated service activities and to support new staff practices.
- Provide technical support to supervisors and/or trainers to orient facility staff and the community to the integrated services.
- Assist tutors and trainers to introduce concepts and approaches for integrated services into preservice and in-service curricula.

Tutors and Trainers

Once integration learning objectives, content, and approach have been incorporated into preservice and in-service training curricula and learning activities:

- Orient or train supervisors, counselors, and clinical providers to carry out their respective functions in support of integrated services.

1. Level of integration refers to the feature(s) of FP services that can be sustained by the core service without compromising overall service quality (e.g., the addition of FP counseling and referral, or the addition of FP counseling and limited method provision, with referral for any methods not offered).

- Provide postorientation or posttraining follow-up to contribute to monitoring the quality of integrated services.
- Adapt orientations/trainings based on posttraining follow-up findings related to training needs.
- Where appropriate, orient translators to ensure an accurate explanation of integrated services to the client.

Counselors and Clinical Providers

- Carry out integrated services, as defined by stakeholder(s) and consistent with integrated service policies/guidelines.
- Document integrated service counseling and provision in the client's record.

Community Health Personnel

- Become familiar with the integration content to accurately present integrated service information and answer questions from women, families, and communities.
- Share what to expect as part of integrated service delivery with women, families, and communities.
- Provide FP methods that are within their scope of practice, or make referrals.



BACKGROUND

BACKGROUND

Integrated programming can take many forms, both within the health sector and between sectors (such as integration between health and environment programs). As such, there is no universally accepted definition of “integration.” Consistent with EngenderHealth’s history of client-oriented sexual and reproductive health (SRH) services, the definition of integration we use herein is *an approach in which health care providers use opportunities to engage the client in addressing broader health and social needs beyond those prompting the initial health care encounter*. This includes an assessment of what health service users and potential users deem to be important, of a site’s capacity, and of how the delivery systems of the core service(s) will accommodate necessary changes to meet the envisioned level of integration.

Integration of FP within ART services is just one aspect of the larger model of integration that EngenderHealth is addressing. EngenderHealth is committed to integrating FP within RH services by strengthening the FP component (where it exists), by revitalizing the FP element within a care package (such as postabortion care), and by introducing an FP linkage where it has not been historically operationalized (such as in HIV services). EngenderHealth’s rights-based integration approach focuses on the multiple facets that contribute to successful program design, including service delivery systems, clients’ rights, staff needs, gender equity, and tailored, evidence-based decision making for a given context. This approach is built upon EngenderHealth’s Fundamentals of Care (i.e., informed choice, clinical safety, and an ongoing mechanism for quality improvement) (ACQUIRE Project, 2006a; and ACQUIRE Project, 2006b).

A five-country study of integrated FP and HIV services (Adamchak et al., 2010) found the need for FP services to be less in HIV care and treatment than in HIV counseling and testing. One reason for this was that fewer women in care and treatment were sexually active, either because of widowhood or divorce or because a higher proportion were already using a modern method. However, “limited data are available on the access to and uptake of family planning services among women living with HIV at the population level” (WHO, UNAIDS, & UNICEF, 2011, page 149). A recent survey in Uganda found significantly greater unmet need for FP among women living with HIV (75%) than among those not living with HIV (34%) (Jhangri et al., 2012). They concluded that “[b]eing on antiretroviral therapy was not a predictor of having a lower unmet need for effective family planning methods.”

The fact remains that from 1950 until 2010, the number of women of childbearing age (aged 15–49) nearly tripled, from around 629 million to 1.8 billion; according to the median scenario of the United Nations *World Population Prospects*, by 2050 this number is expected to reach approximately 2.1 billion (UN, 2012). An ever-growing number of women of reproductive age need FP services. This is overlaid with a global adult (aged 15–49) HIV prevalence rate of 0.8% (WHO Global Health Observatory, 2011). There are striking regional variations, with an adult prevalence of 5% in Sub-Saharan Africa (Henry J. Kaiser Family Foundation, 2013). This region is also where an estimated 94% of the world’s children with HIV live (Henry J. Kaiser Family Foundation, 2013), and approximately 390,000 children were newly infected worldwide in 2010 (UNAIDS, 2011). In fact, the

majority of the world's women living with HIV are of reproductive age (though many may not know their HIV status). Reducing unmet need for FP so that all women who do not want to become pregnant now or in the future have access to contraception could have an important effect on preventing perinatal transmission of HIV. It also provides those who would like to conceive with options and guidance on how to do so safely.

UPDATED STATISTICS ON WOMEN LIVING WITH HIV

In 2012, 35 million people were living with HIV, and Sub-Saharan Africa accounted for 71% of that number (UNAIDS, 2013). Globally, women have higher HIV infection rates than men. In Sub-Saharan Africa, in 2011, women accounted for 58% of all people living with HIV (UNAIDS, 2012). This shows the importance of facilitating women's access to sexuality and RH education and integrated services, supported by changes in laws and policies that protect the rights of women.

Integration of FP with ART services offers an opportunity to support the basic human right of people living with HIV (PLHIV) to achieve their reproductive intentions. This is particularly important in settings where having children is vital to a woman's status. Assessing reproductive intentions should be a routine element of integrated FP-ART services and should be revisited and documented periodically over the course of long-term care and treatment. To accomplish this, the provider's responsibility is to enable PLHIV to make informed decisions about contraception, conception, and the prevention of HIV transmission (Bekker et al., 2011). The most basic way to operationalize integration is to offer *provider-initiated FP (PIFP)* as the standard for integrated service delivery, asking at least these three questions:

1. Would you like to have a child/another child?
2. When do you want a child/your next child?
3. What are you using to space births or prevent an unintended pregnancy?

For women or couples desiring to conceive, while minimizing the risk of HIV transmission, this resource and others cited herein offer practical guidance for reproductive intention counseling, including contraception; preconception counseling and management within ART services; safer conception strategies (for serodiscordant as well as seroconcordant couples²); and examples to enhance understanding of these strategies and their application in a variety of client circumstances. Expanding the range of possible entry points into care for HIV-positive women (for example, via antenatal care, psychosocial support, and other SRH services) is essential for optimal RH outcomes, and can likewise increase access to ARVs (Gay, Croce-Galis, & Hardee, 2012).³ For additional notes on addressing reproductive intentions, see Appendix A, which reproduces Bekker et al., 2011.

2. In a serodiscordant couple, one partner is HIV-positive and the other is HIV-negative; in a seroconcordant couple, both partners share the same HIV status.

3. See the Provision and Access section under "Treatment," at www.whatworksforwomen.org/chapters/13-Treatment/sections/29-Provision-and-Access.

Despite the evidence and the obvious need to accommodate women's multiple health needs, service delivery points and health systems face many challenges to realizing integration of services. For one, there are several service modalities to consider. Service integration has been defined in the literature as "(1) co-location of different services within the same facility, even if those specific services remain separately staffed; (2) training of personnel to provide multiple services; (3) provision of tools, processes, and training to better link separate services; (4) strengthening of linkages, referral, and follow-up between facility levels; and (5) harmonization of logistics systems, such as data collection, drug and material distribution, transportation, and supervision across services" (Pfeiffer et al., 2010).

A plethora of societal factors must be considered as well. Some studies have shown that providers stigmatize the sexuality of women living with HIV (for example, Bianco, Mariño, & Sacco, 2010), expecting that they either will refrain from sex or will not have children. Yet, post-HIV diagnosis, most women with HIV remain sexually active (Wilson et al., 2010). In some settings, providers have been known to coerce persons living with HIV (Messersmith et al., 2012) by insisting on the use of a provider-dependent method (e.g., an intrauterine device [IUD], hormonal implants, surgical contraception) and/or threatening to withhold treatment unless they agree to use such a method (Strode, Mthembu, & Essack, 2012; Women of the Asia Pacific Network of People Living with HIV, 2012; and MacCarthy et al., 2012).

Health care providers can thus miss the opportunity to discuss a woman's reproductive intentions. In addition, for women living with HIV, as with all women, reproductive intentions vary and can change over time. A woman who has recently learned that she is HIV-positive may have different needs than a woman who has known her HIV status for numerous years. A woman with multiple children already may have different needs and desires from a woman without children. Some women living with HIV will want to know how they can achieve a pregnancy while reducing the likelihood of HIV transmission to their infant and sexual partner; others will want to know which contraceptive options are best for preventing a pregnancy (see page 17 and Appendix B for important background information about potential interactions between FP methods and ARV drugs). All will need to know about dual method use. Personal bias on the part of a provider may act as a barrier to providing the most effective or appropriate FP methods to PLHIV.

Concerns raised by a 2011 analysis (Heffron et al., 2012) about a possible link between use of the injectable hormone depo-medroxyprogesterone acetate (DMPA) and increased vulnerability to HIV infection prompted a World Health Organization (WHO) experts meeting to examine the validity of the findings. The team concluded that women living with HIV or at high risk of HIV can still safely use all hormonal contraceptives and strongly advised the simultaneous use of male or female condoms (WHO, 2012a).

Discussing sexual desires and behavior is often an obstacle for providers and clients, especially when trust is limited and discussion of sexual matters is not the cultural norm. Community attitudes, including shared misconceptions about contraception or contraceptive methods, can influence an individual's (or a partner's) opinions and subsequent decisions regarding contraception. For men who have sex with men or who

are bisexual, for women who have sex with women or who are bisexual, and for IDUs, illegality and cultural norms that stigmatize this behavior can jeopardize discussion of actual sexual risks and needs.

Sensitivity to the SRH needs of women and couples living with HIV, particularly their right to enjoy a safe and satisfying sex life, to plan for safer conception of desired pregnancies, and to effectively prevent unintended pregnancies, makes efficient planning for FP integration with ART services crucial and timely as a larger population cohort moves into its reproductive years. Gender considerations and interventions are central to client-responsive service integration (see the Community and Gender section, pages 26–29). What is the best way, then, in which to provide FP within ART treatment in an efficient, client-responsive way?



OVERVIEW OF FP-ART SERVICE INTEGRATION

OVERVIEW OF FP-ART SERVICE INTEGRATION

Significant programmatic challenges remain to realize the potential that integration of FP with HIV services (ART in particular) can offer at the supply, enabling environment, and demand levels. EngenderHealth's Supply–Enabling Environment– Demand (SEED)⁴ Programming Model™ is a comprehensive programming framework premised on the idea that programs addressing SRH will be more robust and sustainable if they work on synergistic interventions that address the multifaceted determinants of health (EngenderHealth, 2011).

Some key components of **supply** include sufficient infrastructure and reliable access to commodities and other supplies and equipment. There must be an appropriate number of trained clinical and management staff and adequate administrative, financial, and management systems to support continuous (high-quality) service provision. Where FP-HIV integration is concerned, supply-side factors that need to be considered include an assessment of the strength of the *core* service (HIV treatment) before integration or the inclusion of additional services, such as FP, are contemplated. An analysis of provider time demands and schedules, whether they have been trained to provide additional services (such as FP), and provider biases for or against certain methods depending upon an individual's HIV status, should likewise occur. Some studies show that providers were generally *not* too busy to provide an integrated package of services, particularly during certain times of the day, but that there was a dearth of FP training, guidelines and other resource materials, supportive supervision, and systematic screening to assess clients' unmet need. A recent qualitative study involving providers of integrated services (FP into postnatal care) in Kenya showed that they “experienced increased job satisfaction, an increase in client repeat visits and uptake in services and reduced workload per provider but were challenged by low salaries, lack of psychosocial support, lack of supplies, long session times and long waiting times” (Mutemwa et al., 2013). Consequently, there is a need to analyze *how* to reorganize work, to revamp and expand the monitoring system to include the new service(s), and to accommodate an expanded requisition system that would include FP supplies and equipment in addition to those needed to provide HIV services.

Key to fostering a supportive **enabling environment** is taking a broad perspective, from the national level to the involvement of community members and civil society, to examine a “range of interlinked sociocultural, economic, and policy factors [that] influence both the functioning and sustainability of health services, as well as social norms and practices” pertaining to health (EngenderHealth, 2011, page 26). Where the enabling environment is concerned, it is important to conduct a thorough scan of what policies, regulations, and financing exist to support integration at the national level. Do diverse ministries work together on these topics (where HIV and AIDS, FP, and maternal and child health may be separate in terms of policy or program development, departments, and funding)? Representatives of the diverse ministries involved in making service integration function

4. For more information and to download a copy of the SEED™ *Assessment Guide for Family Planning Programming*, go to www.engenderhealth.org/our-work/seed/.

can collaborate to assess what service guidelines have already been written, what training exists and is taking place, what cadres of health care workers can perform multiple services, and whether there is an adequate supply chain to meet increased demand. At the community level, the enabling environment may take into account such potential social barriers as gender norms, stigma faced by certain people or groups (such as PLHIV), and/or a lack of knowledge that may impede an individual's ability to access preventive and curative services. The cost of services, distance to services, whether there is a functional referral system in place, provider attitudes, and service quality are all important aspects of fostering a supportive enabling environment. These issues would need to be addressed by very different and tailored interventions. Working through community health teams, community-based organizations, and community structures and leaders can increase information dissemination. Community resource persons can also function as champions for integrated services.

Demand originates in part from current service users who continue to want to patronize particular services. However, demand can also be generated among a group who may wish to avail themselves of services, such as FP, only if they were to possess more information about and access to them. Once FP is integrated into ART services, there will be a need to inform clients about the full range of available services, through posters, brochures and pamphlets, or discussions at the time of the client-provider interaction, to stimulate demand for the expanded range of services and allow demand to be met. Demand can be generated among potential users via radio announcements or programs, community outreach, theatrical events, and/or peer education. Advocacy, communication, and social mobilization efforts should ensure that messages are gender-sensitive and/or promote the transformation of gender norms to allow for men's use of services too (or use of services by couples). Ensuring that high-quality services are accessible and highlighting the benefits (fewer appointments, less time traveling to more than one facility, opportunity cost) are particularly useful.

INTEGRATED FP-ART SERVICES—WHAT DOES THE CLIENT NEED?

Each site for ART service delivery offers opportunities for integrating FP information and some level of service provision in a gender-sensitive and respectful manner. The following can be offered:

- FP- and HIV-related information, education, and communication (IEC) and behavior change communication (BCC) materials
- Health monitoring (history-taking; ongoing assessment of fertility desires and pregnancy risks; screening for and treatment of sexually transmitted infections [STIs], including those that can result in infertility; and physical assessment, including essential laboratory services, when indicated)
- PIFP, which involves asking every woman or adolescent girl about her pregnancy intentions at each visit, providing FP counseling on a wide range of methods (including counseling with a partner, if the client consents), or offering information on safer conception interventions

- Provision of comprehensive, accurate information to allow for informed and voluntary decision making, including provision of counseling for individuals (women/men) and/or couples (FP, including condoms and dual method use, safer conception, and HIV prevention and risk reduction)
- Provision of the client's FP method of choice, tailored to reproductive intentions (including dual method use), and with discussion of satisfaction with the method(s) currently used (if applicable)
- Referrals for FP methods not available on-site, as well as for RH or other health services
- Provision of information on how FP can be successfully combined with ART and how misconceptions about FP use during ART can be addressed/corrected
- Discussion with the woman/couple before conception of the issues concerning HIV and pregnancy (including an increased risk of maternal mortality) (Rosen et al., 2012; Menéndez et al., 2008)
- Discussion with and counseling of women living with HIV about perinatal transmission risks, strategies to reduce those risks, potential effects of HIV or its treatment on pregnancy, the risk of transmission during breastfeeding, and the fact that pregnancy itself does not accelerate HIV disease progression (MacCarthy et al., 2009 [adapted from Aaron & Criniti, 2007])
- Provision of information on gender and sexuality, including on negotiation and skill-building to encourage use of condoms
- Description of treatment procedures, which may include referral and provision of medications and/or FP commodities

NOTE

In a South African study of couples desiring to conceive in which one partner was HIV-positive and one was HIV-negative (or one partner's status was unknown), participants expressed openness to receiving advice from health care workers on safer conception interventions that may target both men and women, including serodiscordance counseling and promotion of contraception (Matthews et al., 2013) (see Appendix A: Guidelines for Safer Conception, page 69).

COSTS ASSOCIATED WITH SERVICE INTEGRATION

Costs and savings for integrating FP and ART are context-specific and depend on a number of variables, including where services stand in terms of integration (if ART and FP services exist separately at the facility and there is a desire to integrate them, or if one of the services—FP or ART—is not occurring at this point and there is a desire to introduce a new service into the service that is currently provided). While there is a strong rationale for integration when it comes to addressing an individual client's multiple service needs (and perhaps capturing a greater breadth of clientele, such as male partners, adolescents,

etc.), the evidence of cost-effectiveness remains inconsistent, depending on facility type, services that are being integrated, the degree to which services are integrated, the desired model of integration that one chooses to adopt (co-location within the same facility [the “one-stop shopping” model], referral-based, cross-training of a single provider, etc.).⁵ Integrated services do hold out the possibility of generating savings in comparison with stand-alone services. One study found that integrating FP services into ART saved approximately \$25 for every dollar spent (Stover, Dougherty, & Hamilton, 2006). Integrating FP and HIV services was a cost-effective approach for offering more women living with HIV access to FP, thereby reducing the number of new HIV infections resulting from perinatal transmission or transmission to an uninfected partner, and reducing the costs associated with subsequent treatment services for HIV-infected children and/or care and support for orphans (Stover, Dougherty, & Hamilton, 2006). Many factors, however, contribute to variations in cost savings for integrated services. For example, when supplies are not reliably available or when there is a low client load, the average cost per client increases and staff may be underutilized.

Health care resources are often limited in many of the countries where the burden of HIV compounds the demands on an already fragile health care system. Under the right conditions, service integration in such places can be a viable option for increasing the efficiency of service management. Making integrated services available at one location helps increase service utilization by alleviating customary client barriers, such as by reducing travel costs and out-of-pocket health care expenses (e.g., paying for one set of services rather than paying for multiple services, lessening the opportunity cost of time spent away from home or work responsibilities, or reducing the cost of travel to one appointment, as opposed to multiple trips). Integrated services can also help reduce costs on the service delivery side associated with duplication of services or functions (The Integration Partnership, 2012).

BENEFITS AND CHALLENGES OF INTEGRATING FP WITH THE PROVISION OF ART

In addition to numerous anticipated benefits, there are certainly distinct challenges to realizing FP-ART service integration. Health care decision makers express concern about effectively providing integrated treatment without overwhelming the integrity of existing services and about staff mastering knowledge and maintaining skills in more than one service area, if that is the chosen model. These concerns become more acute in resource-constrained settings. The goal of integrating services in a systematic way is to create services that are accessible and easy for clients to navigate. As discussed previously, there are a number of different designs, but the ideal is to have the services offered in one location, by the same provider (*if feasible*), while giving service staff the support they need by modifying customarily separate health services’ management systems (financial systems, the health management information system [MIS], supervision approaches) to either be provided together or in a closely coordinated fashion. The FP component of care will reflect the unique needs of individuals living with HIV to improve their SRH outcomes (fertility

5. See the discussion, for example, in Church & Mayhew, 2009.

decision making, contraceptive options in relation to HIV status, and use of ART or drugs to treat opportunistic infections [OIs]). It will address the needs of women living with HIV to reduce the likelihood of HIV transmission while achieving desired fertility goals.

Integrated services often invoke the image of a facility where a client could have all of her/his health needs met during one encounter. This may or may not be feasible or appropriate, depending on the service's capacity. There are a number of service modalities. Services may be offered by the same provider in one visit, or “the provider of one service actively encourages clients to consider using the other service *during that visit*” (Foreit, Hardee, & Agarwal, 2002); this is particularly important if the needed services are beyond the capacity or the skill set of the attending provider. Integrated FP-ART services may be offered within the same facility or location during the same operating hours (internal referral), or they may be offered by external referral (e.g., an ART site referring a client to an FP service site outside the ART service delivery point).

The *benefits* of incorporating FP into existing ART programs include that such an approach:

- Optimizes ART with FP as a component of care, capturing missed opportunities to counsel women and couples on safer conception, contraceptives, dual protection, and other sexuality-related issues while providing HIV services
- Increases the pool of people who might not normally be reached through traditional FP clinics—e.g., youth (single and married), men, sex workers, men who have sex with men but who also have female partners, and IDUs
- Links treatment options with preventing unintended pregnancy or planning for desired pregnancy (efficiency of service provider and client time)
- Provides preconception counseling to optimize positive health outcomes for the woman, her sexual partner, and the baby and to prevent the spread of HIV
- Challenges misconceptions about the interactions between ART and FP methods
- Can help clients use condoms more consistently and effectively with both regular and casual partners
- Can provide information about, and make it convenient for clients to initiate, dual protection by offering counseling, instructions for the dual methods chosen, and provision of both methods in one setting or during one client-provider encounter
- Expands the provider's skill set, preparing him/her to perform required tasks
- Can increase job satisfaction because staff are more comprehensively addressing client needs
- Can diminish referral barriers to accessing FP information and methods, especially where a trusting rapport has already been established between the provider and the client (Where referral is the integration modality, it can strengthen the coordination *between* the two units to increase access to FP information and services.)
- Ensures that HIV and AIDS is considered as part of making informed and voluntary FP decisions

The *challenges* of incorporating FP into existing ART services include that such an approach:

- Requires buy-in on the part of providers and elimination of existing provider bias prior to integration
- Requires health care personnel to acquire knowledge and develop new skills that they may not be amenable to or interested in learning
- Adds time to counseling encounters, can increase workload, and can increase client waiting time, particularly when staffing levels are low⁶
- May make monitoring of quality improvement or performance improvement more intricate because of the added service elements and changes in service provision
- Requires establishment of new provider partnerships and conscientious documentation for continuity of care if the integration modality is coordinated care between two sets of providers (e.g., FP providers will need to consult with HIV care providers, and case management will demand consultation between nurses, physicians, and PLHIV)
- Requires facilities to incorporate FP into their record keeping, activity reporting, commodity logistics, and management of services consistent with the type(s) of methods provided
- Requires assessment of the attitudes of male and female community members and networks of PLHIV regarding FP in general, specific FP methods, and their use in the presence of HIV
- Requires tailoring FP messages and materials to address the needs of an HIV-positive population
- May overload the provider with too many tasks, as well as burdening the client with more information than he or she can absorb at one time

EMERGING MODELS OF ART SERVICE DELIVERY

Recent innovations to increase clients' access to ART services after years of scaling up facility-based services have focused on provision of medications and support through lower-level facilities (DeCroo et al., 2009), community-based personnel (Kipp et al., 2011), and client group-linked models (DeCroo et al., 2011). However, for integration to be effective as described, a functioning referral system *must* be in place to provide accessible and affordable coordinated care.

6. Client load is already expected to increase due to changes in WHO guidance pertaining to treatment initiation. New clinical recommendations promote expanding eligibility for ART to adults, adolescents, and older children with a CD4 count of 500 cells/mm³. WHO also recommends giving priority to individuals with severe or advanced HIV disease and those with CD4 counts of 350 cells/mm³ or less. It is recommended that ART be initiated regardless of CD4 count for people with active tuberculosis who are living with HIV, people with both HIV and hepatitis B infection with severe chronic liver disease, HIV-positive partners in serodiscordant couples, pregnant and breastfeeding women, and children younger than 5 years of age (WHO, 2013). Previous guidance had recommended starting treatment with a CD4 count less than or equal to 200 cells/mm³; the change reflects scientific evidence showing improved patient outcomes (see also Konde-Lule et al., 2011).

Emerging types of ART service delivery include the following community-based and lower-level health service models:

- **Lessons learned during ART down-referral:** In Tete, Mozambique, clients on ARVs were rapidly down-referred from a provincial hospital to four urban clinics in large numbers without careful planning. The result was loss of clients to follow-up, an overload of the service delivery system, and inadequate capacity at receiving clinics. Evidence is growing that most of the time, ART can be initiated at the clinic level; however, successful initiation of ART at lower level facilities or down-referral requires careful assessment of the site's capacity, along with preparation of the site, staff, and clients (DeCroo et al., 2009).
- **ARV refills by community-based personnel, to increase access to treatment:** In rural Uganda, clients received follow-up visits, adherence monitoring through pill counts, assessment for the presence of adverse effects, and ARV refills from trained community volunteers supported by the health care system (clinical officers/nurses accepting referrals) and the community. Results showed increased ARV use by women and better treatment outcomes in the community-based treatment model, with slightly better cost-effectiveness per successfully treated client when compared with the facility-based model (Kipp et al., 2011).
- **Distribution of ART treatment through client groups linked to service sites (Tete, Mozambique):** In this type of service, clients who were stable for at least six months with CD4 counts equal to or greater than 200 cells/mm³ were informed about community ART groups, invited to form a group (composed of not more than six individuals), and trained to carry out four main functions: (a) facilitate monthly ART distribution to other group members; (b) provide adherence and social support; (c) monitor outcomes; and (d) ensure that each group member consults a health care provider at least once every six months. Each ART group was linked to a health care facility for treatment management (DeCroo et al., 2011). (*Note:* The most recent WHO recommendations call for all national AIDS programs to initiate ART for adults living with HIV when their CD4 cell count falls to 500 cells/mm³ or less—when their immune systems are still strong [WHO, 2013]).

LEVELS OF FP INTEGRATION WITH ART SERVICES

Throughout this program guide, we chart a progression from more general to more specific concerns pertaining to FP-ART integration. In this section, we look more closely at what is doable, depending on the setting. To make the process of integration manageable and practical for a variety of service settings, we examine *levels* for integrating FP into ART services. By this, we mean making a determination as to whether an existing service, such as HIV care, is able to integrate an additional feature or features (such as FP, and up to which methods) without compromising core service quality (e.g., without increasing client waiting time, staff workload, or other aspects of service quality). Integrated FP-HIV care and treatment services need to be tailored to the setting and available resources. Facilities or programs can select a level of integration that they can successfully achieve and sustain, offering a progressive range of services depending on their capabilities and resources.

The chart on page 16 illustrates five possible levels for integrating FP with ART services, based on emerging and existing ART service models. Though EngenderHealth's longstanding focus has been on strengthening facility-based services, these integrated services can also be offered through mobile service mechanisms, by client groups linked to service sites and/or community-based personnel, including those who provide services in people's homes.

DESCRIPTION OF FACILITY-BASED SERVICES PROVIDING ART

Primary-level services are the first level of contact between the individual and the health care system, providing essential health care services through primary health care centers. Primary-level services can accept downward referral from secondary-level facilities (e.g., from the district hospital to a health center/clinic) and can provide adherence counseling, ARVs, and patient monitoring (Decroo et al., 2009).

Initiation of ART services has customarily been located at secondary- and/or tertiary-level facilities, as described below:

Secondary-level services provide curative services, handle more complex health conditions than at the primary level, and are the first referral level. They can provide counseling and testing, ARVs (second-line drugs), laboratory support for patient monitoring, adherence counseling, and social support or referral for social support.

Tertiary-level services are central referral hospitals. They can provide counseling and testing, ARVs (second-line drugs), laboratory support for patient monitoring, adherence counseling, and social support or referral for social support. Tertiary care facilities provide specialist curative care, manage most complex conditions, and support training programs.

INTEGRATING FP INTO ART SERVICES FOR ON-SITE PROVISION OF CONTRACEPTIVE INFORMATION, COUNSELING, AND METHODS: OPTIONS WITHIN VARIOUS LEVELS OF A HEALTH SERVICE DELIVERY SYSTEM

This is intended as an example that can be adapted to your local situation and health system structure.

LEVELS OF INTEGRATION

LEVEL A	LEVEL B	LEVEL C	LEVEL D	LEVEL E
<p>Provides all of the following functions:</p> <ul style="list-style-type: none"> • Provides FP information to clients accessing ART, PMTCT, STI, VCT, or provider-initiated testing and counseling (PITC) and tuberculosis services. • Performs risk/intention assessment for pregnancy or spacing. • Counsels on FP methods, methods' ability to prevent STI and HIV infection, method choices available and where to access them, dual protection, potential drug interactions with hormonal methods,* and side effects.† • Provides condoms, and instructs for and demonstrates correct use. • Provides emergency contraceptive pills. • Refers for other methods not offered on-site. 	<p>Provides all Level A functions plus:</p> <ul style="list-style-type: none"> • Provides oral contraceptives, with instructions for use.‡ • Counsels on potential ARV drug interactions with oral contraceptives.‡ • Provides management of method-related side effects and complications. • Provides follow-up or refers for follow-up. 	<p>Provides all Level B functions plus:</p> <ul style="list-style-type: none"> • Provides injectable contraception, with instructions for use. • Cautions to return on schedule for reinjection. • Provides management of method-related side effects and complications. • Provides follow-up or refers for follow-up. 	<p>Provides all Level C functions plus:</p> <ul style="list-style-type: none"> • Provides intrauterine device (IUD), with instructions for use. • Provides implant, with instructions for use. • Provides management of method-related side effects and complications. • Provides follow-up or refers for follow-up. 	<p>Provides all Level D functions plus:</p> <ul style="list-style-type: none"> • Provides surgical contraceptive methods, with instructions for self-care, and provides follow-up.

Level of encounter/facility	
Client groups linked to facility	Community health worker linked to facility
Primary health care facility (Note: Injectables can be provided at Level B if community health workers are trained to offer them.)	Secondary-level facility
Secondary and tertiary-level facility	Secondary and tertiary-level facility

Notes: Gender dynamics should be explored and sexuality information provided at each level of care. For Footnotes, see page 17.

Table Footnotes

* Women at *high risk of HIV* can continue to use all existing hormonal contraceptive methods (Category 1: oral contraceptives, contraceptive injectable hormones, patches, rings, and implants) without restriction. However, because of the inconclusive nature of the body of evidence on the progestogen-only injectable contraceptive and risk of HIV acquisition, women using progestogen-only injectable contraception should be strongly advised to also always use condoms (male or female) and other preventive measures. Condoms must be used consistently and correctly to prevent infection (WHO, 2012a). (See text box below for more information.)

† Management guidance for FP and ARV side effects is beyond the scope of this guide. For management of contraceptive method–related side effects, see specific method chapters in *Family Planning: A Global Handbook for Providers* (WHO, 2011a). For management of ART-related side effects, see specific method chapters in *Family Planning: A Global Handbook for Providers* (WHO, 2011a). For management of contraceptive method–related side effects, see: WHO, 2007, pages H32–33, H42–45, H56–58, and H59–62. Where there is a theoretical or known potential for drug interaction between hormonal contraceptives and ARVs, management should focus on (a) preventing contraceptive failure or minimizing side effects due to elevated or reduced estrogen/progestin levels through method change or dual method use (e.g., condoms with hormonals) and/or (b) ensuring ARV efficacy by changing either the contraceptive method or the ARV (Brown, Paul, & Kashuba, 2009).

‡ Some ARVs *may* interact with combined oral contraceptives:

- All nonnucleoside reverse transcriptase inhibitors—e.g., efavirenz—interact with combined oral contraceptives, increasing the concentration of ethinyl estradiol; however, the clinical significance of this interaction is unknown.
- Protease inhibitors—e.g., atazanavir and darunavir—decrease levels of ethinyl estradiol when combined with ritonavir, though the effects appear to be minimal.
- These changes may decrease the effectiveness of oral contraceptives or could potentially increase the risk of estrogen- or progestin-related side effects. (See Appendix B for specific interactions between ARVs and combined oral contraceptives.)

CONTROVERSY REGARDING HORMONAL CONTRACEPTION AND HIV

In the wake of study results presented at the 2011 International AIDS Society Conference and published online in *Lancet Infectious Diseases* linking use of the injectable contraceptive depot-medroxyprogesterone acetate (DMPA) with an increased vulnerability to HIV infection among both men and women (Heffron et al., 2012), a WHO consultation meeting comprising staff from the U.S. Agency for International Development (USAID) and the U.S. Centers for Disease Control and Prevention (CDC) and WHO experts (among others) issued a technical statement concluding that women living with HIV or at high risk of HIV can still safely use all methods of hormonal contraception to prevent unintended pregnancy (Medical Eligibility Criteria Category 1—no restrictions). Since the body of evidence remains inconclusive, the group strongly advised that women who are using progestogen-only injectable contraception and who are at high risk of HIV simultaneously always use male or female condoms and undertake other preventive measures against HIV (WHO, 2012a). While the Heffron et al. study results deserve serious attention, the study’s methodological limitations also warrant consideration, including but not limited to: 1) that the study was not initially designed to examine if hormonal contraception impacts the risk of HIV; 2) that contraceptive use was self-reported (no data were collected on adherence); 3) that the sample of women using hormonal contraception was small (limiting the study’s power); 4) that choosing to use hormonal contraception may alter one’s risk of HIV exposure (with users of hormonal

contraception perhaps having higher coital frequency and lower or less consistent condom use); 5) that confounding factors were not measured (such as use of condoms, method switching, and frequency of sex); and 6) that the findings were inconsistent with those of previous studies (Polis, Phillips, & Curtis, 2012; Morrison & Nanda, 2012).

One modeling study that looked at the impact of injectable progestin use and HIV on maternal mortality in four African countries found that if injectables were removed from the method mix without being replaced by an IUD or combined oral contraceptives in 70–100% of the women, that up to nine additional maternal deaths would occur for each case of HIV averted (Rodriguez, Reeves, & Caughey, 2012). An analysis of data from Kenya, South Africa, and Zimbabwe found that a shift from DMPA to oral contraceptives or male condoms could result in 600 additional unintended pregnancies due to the lesser degree of efficacy; a shift from DMPA to no method could result in an additional 5,400 unintended pregnancies per 100 HIV infections averted. A general conclusion was that it would not be warranted to withdraw DMPA from the method mix, due to the inconclusive evidence and the consequences for women and families of not ensuring access to all methods of contraception (Rodriguez, Reeves, & Caughey, 2012; Jain, 2012). Injectable contraception is the most commonly used method of hormonal contraception in Sub-Saharan Africa and is “an effective, easy-to-use method that women can use without the knowledge of their sexual partner, if necessary.... For women who are HIV-positive and using antiretroviral therapy, injectables also offer a highly effective method of contraception that is not expected to cause adverse drug interactions with antiretroviral medications” (Gay, Croce-Galis, & Hardee, 2012).

Updated WHO medical eligibility criteria for contraceptive use (WHO, 2010), which were reviewed in light of the Heffron study results, recommended no restrictions or generally no restrictions for hormonal contraceptive use (the pill, implants, IUD) in the presence of HIV and for those on ARV therapy. Again, women who are using progestogen-only injectable contraception and who are at high risk of HIV are urged to simultaneously always use male or female condoms. But, providers who only recommend condoms to HIV-positive women are thus omitting viable options that can further enhance FP effectiveness, in addition to providing protection against HIV infection.



**CONSIDERATIONS
FOR HOLISTIC
SERVICE
INTEGRATION**

CONSIDERATIONS FOR HOLISTIC SERVICE INTEGRATION

Support on at least four levels is required to operationalize integration: the policy level, the program level, the service site level, and finally the client and community level. It is important here to recall the interrelated elements of the SEED programming model™ to holistically realize an integrated FP-ART program. In this section, we will provide a brief description of the operational levels at which integration needs to take place, followed by an example of each. We will provide a list of illustrative requirements and then outline questions that may be pertinent at these various levels to decide the appropriateness and feasibility of a chosen level of integration. The questions do not represent an exhaustive list of points; additional questions specific to the setting or context that require consideration will likely be generated.

POLICY AND PROGRAMMATIC SUPPORT FOR INTEGRATION

Integration at the Policy Level

For FP-integrated ART services to function effectively and efficiently, policies must provide guidance to the administrative and service delivery levels of the health care system. An illustrative list of policy and programming requirements appears on page 21. For a well-thought-out integrated service, FP and ART service administrators and policymakers would coordinate and jointly plan service delivery guidance to achieve integration of FP with ART services throughout the health care structure.

EXAMPLE

In 2008, Tanzania established a policy environment supporting the integration of FP with HIV services. The government revised its national policies for HIV and AIDS care and treatment to include FP as a core component, including screening for unintended pregnancy, counseling, and referrals (Fleischman, 2012, page 11).

Integration at the Program Level

For service integration to be functional at the program level, policy changes related to FP or ART services need to be incorporated into existing activities at the central, regional, and district levels of planning. To facilitate the management of integrated services, assignment of human resources, M&E guidance, logistics protocols, and financial allocations all should be considered from the outset of the program.

EXAMPLE

The Zambia Prevention, Care, and Treatment Partnership (ZPCT) II is a large-scale HIV program where FP-HIV integration is happening in six provinces, with PEPFAR funding. The Zambian Ministry of Health has strongly endorsed FP as part of the national PMTCT program, both as an HIV prevention strategy and as a way to prevent unintended pregnancy. ZPCT II is assisting the Ministry of Health to strengthen and expand HIV clinical and prevention services, relying on a referral-based integration model that integrates FP into care and treatment, PMTCT, and ART services. On-site referrals are provided to those who desire a method. There are limitations, like the number of completed referrals not being tracked. However, having FP “incorporated into the core project interventions” as a “mutually reinforcing project [element]” serves to institutionalize it as an essential program component and enhances the likelihood that FP-HIV integration will be sustained over time (FHI 360, 2012). Project activities focused on integration have encompassed provider training, task shifting, referrals, attention to commodity security, M&E, and supportive supervision, among others.

Illustrative Policy and Programming Requirements for Integrating FP and ART Services

Policy and **programming** requirements might include the following:

- Defining the FP-integrated HIV service tasks for each cadre of health personnel and other personnel, both facility- and community-based
- Articulating FP-integrated ART content for preservice training of health personnel
- Articulating the standard of care for services occurring within the same facility or where services are linked between facilities (provided either on a daily basis or on designated day[s]), in relation to:
 - Staff performance and training
 - Availability of FP-integrated services at each level of service delivery, including partner notification, where operational or feasible
 - Service record keeping
 - Mechanisms to ensure reliable availability of essential drugs, commodities, and supplies
- Establishing standards for supervision and management of integrated services (reflected in assessment and monitoring tools)
- Establishing budgetary allocations to support integrated services

- Conducting gender analysis, to ensure that service delivery and creation of IEC/BCC materials are done in a gender-sensitive manner and at the least do not reinforce inequitable gender norms (see pages 26–29)
- Establishing an essential drug list that reflects FP-HIV integration (FP methods, instruments, and supplies; ARV medications; medications for the prevention and treatment of OIs; laboratory reagents and supplies)
- Ensuring that commodity acquisition and storage guidelines are consistent with the chosen level of FP-ART integration.

? Questions for consideration at the policy level might include:

- What policies exist already to support integration at the national/local level?
- What policies and protocols (programmatic, financial, and management) need to be modified to facilitate integration and maximize clients' access to integrated services, particularly for youth, low-income individuals, unmarried persons, and/or other designated populations?
- Where does the overall responsibility lie for financial and management support of integrated services?
- What roles do existing gender norms play in contributing to (low) uptake of FP and/or ART services? What policy statement can be created to address these dynamics?

? Questions for consideration at the program level might include:

- How do we best provide information on FP and ARVs to support groups for women, men, and couples, including couples who are serodiscordant?
- What integrated service delivery tasks can be shared⁷ among staff to balance the workload?
 - What work, if any, would need to be done at the policy level for task sharing or task shifting to be supported?
- Where does the overall responsibility lie for financial and management support of integrated services?
- What roles do existing gender norms play in contributing to (low) uptake of FP and/or ART services? What service could be added, or intervention designed, to address these dynamics?

7. Task sharing denotes a strategy in which health care workers take on additional tasks to share the overall workload, rather than shift existing tasks to others (Walsh et al., 2010).

SERVICE LEVEL

Integration at the Service Site Level

FP and HIV service providers should be trained to incorporate the following skills: risk assessment; counseling; provision of contraceptives; provision of other types of HIV services; management of side effects and complications; referral for contraceptives not provided at the ART service site; preconception counseling; and consultation with the client's HIV care provider and/or referral for HIV service components not provided at the FP site.

EXAMPLE

In 2007, The AIDS Support Organization (TASO) in Mbale, Uganda, integrated FP into their HIV care and treatment services, offering condoms, oral contraceptives, emergency contraceptive pills, and injectable hormones on-site, with referral for long-acting and permanent methods (LA/PMs). Site providers and counselors were trained to provide these methods, and service delivery systems were modified to accommodate the additional features of FP-integrated services. In 2009, the FP method mix was expanded to include the IUD and implants (Searing et al., 2008).

Illustrative Requirements for Integrated FP-ART Service Delivery

- Service delivery guidelines for management, supervision, and provider functions are informed by policies.
- Supervisory tools reflect standards for integrated FP-ART services.
- Staff are trained in FP and ART, as well as oriented to the level of integrated services for their setting.
- Staff are trained to educate clients on gender and sexuality, including how to engage partners of clients in a way that supports women's reproductive decision making (McCleary-Sills, McGonagle, & Malhotra, 2012).
- Staff are trained in safer sex and safer conception counseling for women and couples (with the woman's consent), including serodiscordant couples.
- The facility's physical structure is conducive to privacy, client flow, and the accommodation of additional equipment and supplies, or the facility structure has the capacity to be modified to achieve these ends.
- IEC/BCC materials include messages about dual protection or dual method use, and staff have been advised on counseling approaches for emphasizing dual protection. (Service providers should investigate what job aids and client information products are available and locally appropriate. Some potential sources include the Knowledge for Health [K4Health] Project and WHO.)

- The essential drug list reflects FP-HIV integration (FP methods, instruments, and supplies; ARV medications; medications for the prevention and treatment of OIs; laboratory reagents and supplies).
- Commodity acquisition and storage guidelines are consistent with the chosen level of FP-ART integration.
- Service delivery statistical reporting forms reflect activities for the integration of FP and ARV treatment.
- Expanded and/or strengthened referral systems facilitate clients' access to FP methods that are not provided on-site, to other health services, and/or to social and legal support services, with a built-in feedback mechanism to the referring provider/facility.

NOTE

In some settings, ongoing ART services are supported by periodic mobile medication delivery, as well as by text messaging and follow-up. During these encounters, clients' health and psychosocial well-being are assessed between facility-based visits for laboratory monitoring and medical management. In this type of service delivery, FP should also be incorporated into the existing messaging and counseling, along with: the provision of FP methods, depending on the cadre of staff; the availability of equipment, drugs, supplies, and space (room, privacy); and the client volume per mobile visit period. Mobile services would also make referrals to static FP sites for methods that they or the ART sites are not able to provide.

? Questions for consideration at the **service delivery level** might include:

- What are priorities for clients? Providers?
- What technical/clinical content needs to be included in training or updates to ensure quality integrated services?
- What needs to be done at the facility-based service delivery level to establish and maintain user-friendly integrated services for women/men/couples/youth/key populations?
- What processes are in place to use data to enhance decision making and improve integrated services?
- How does the physical space need to be reorganized to ensure privacy/confidentiality and facilitate client flow?
- What might be done within integrated services to help streamline commodity logistics management and ensure a reliable stock of commodities?
- How would work need to be (re)organized to accommodate FP counseling, method provision, or safer conception counseling (while minimizing inconvenience to clients, such as longer waiting times)?

COMMUNITY LEVEL

Integration at the Community Level

The community plays a crucial role in disseminating information and in shaping attitudes and perceptions, and it can influence behavior, including the use or nonuse of facility-based services. The FP or ART services should reflect responsiveness to clients' and community needs for integrating fertility management and HIV prevention, detection, and treatment activities.

EXAMPLE

The USAID-funded ACQUIRE Project and local partners in Ghana developed the Family Planning for Healthy Living (FPHL) project to reach PLHIV with the message that FP can help them “to prevent unintended pregnancies, minimize the risk of infecting their partners, and plan their families to maximize the safety of mother and child” (Subramanian et al., 2008). The project aimed to foster FP champions from among trained peer educators, providers, and support group members, grooming them to become role models for their peers and FP advocates in their communities. Seventy-five PLHIV from support groups in four regions of Ghana were trained as peer educators by the project (e.g., trained to use job aids to deliver FP messages at monthly support group meetings). Selected providers were trained in FP for PLHIV prior to the workshop and then were invited to participate in the peer educator trainings. Trained providers also attend the support groups to help answer questions and to encourage interested members to seek FP services.

Illustrative Community-Based Integrated Service Tasks

- Protect clients' rights to informed and voluntary decision making in support of fertility desires, regardless of HIV status
- Provide FP information and counseling, including on dual protection/dual method use, to clients accessing ART
- Supply condoms and other selected FP methods (methods that community personnel have been trained to provide) to clients accessing ART
- Facilitate FP referrals for clients who access ART where FP services are not available on-site
- Support clients within ART services to use their chosen method(s) successfully, and periodically assess whether they want to switch to a different method
- Counsel couples on reproductive intentions, FP, and safer sex (if the woman wants/consents to couples counseling)
- Conduct awareness-creation activities with men concerning FP methods for themselves and their partner, and include opportunities to engage women and men to reflect on, and challenge, inequitable gender norms in relation to FP and HIV

- Facilitate the creation of gender-equitable norms, including fostering couple communication about sexuality
- Carry out nonstigmatizing community activities to create awareness of FP-integrated ART services, and increase FP access through the inclusion of networks of women, men, and youth living with HIV

We will explore community and gender considerations in greater depth in the next section.

? Questions for consideration at the **community-based service delivery level** might include:

- What additional resources (e.g., time, personnel, materials, salaries, benefits, per diem, transportation reimbursements, or other incentives) would be needed to help community-based personnel perform the designated tasks?
- What would be necessary for community-based integrated services to protect the privacy and confidentiality of clients' HIV status and FP practices?
- How could capacity be created to effectively plan and implement male-focused awareness-creation activities that foster respect for women's rights and access to FP and HIV services?
- How would the existing training and supply acquisition and distribution systems need to be modified for community-based HIV personnel to provide oral contraceptives? To provide injectable contraception and/or implants, where feasible?

COMMUNITY AND GENDER IN SERVICE INTEGRATION

NOTE

A resource that may be useful for those who have experience in working on gender or who can rely on an experienced gender team is the C-Change Compendium of Gender Scales (<http://www.c-changeprogram.org/content/gender-scales-compendium/index.html>). For more information on gender programming, please refer to the Program H (<http://www.promundo.org.br/en/activities/activities-posts/program-h-manuals-download/>) and Program M (<http://www.promundo.org.br/en/sem-categoria/program-m-materials/>) manuals.

The EngenderHealth integration model builds on community collaboration to inform the design of facility-based services. Where they exist, networks of PLHIV are a key community resource. These networks ensure realistic consideration of the needs of PLHIV, so that plans for services will achieve their intended goals. Engaging in ongoing dialogue with the community, including networks of PLHIV, and understanding the specific barriers that they face will help health care decision makers, health service managers, supervisors, and facility- and community-based providers tailor service delivery to meet the expressed need for integrated services. This includes providing networks and groups of women living with

HIV with accurate information on FP, as well as information on safer conception, for those who wish to have children.

Community-based workers may include individuals who have been identified by their communities and trained to provide a host of services. Such personnel have long been involved in providing FP beyond the confines of static structures, from peer or group education sessions to limited method provision. They may also have been trained to provide psychosocial support to persons accessing HIV services, to include HIV prevention messages, to offer some level of risk assessment, or to refer people for HIV counseling and testing or PMTCT services.

Community-based workers can form a crucial part of the enabling environment, serving as key resource persons to:

- Address social barriers
- Introduce the benefits of services to the wider community
- Become equipped with the knowledge, skills, and tools needed to engage members of the broader community and support community action planning
- Actively involve advisory groups in decision making around program design, budgeting, implementation, and evaluation
- Recognize men as SRH clients in their own right, as well as key partners for interventions

Community-based workers may have formal or informal links with ministries (e.g., Health, Labor, and Gender/Women/Family Affairs). Community health workers may or may not receive salaries or stipends; facility-based staff or the relevant ministry personnel to whom they have an operational link usually provide some supervision.

Addressing gender norms is a critical component of community collaboration. The term “gender norms” refers to societal messages that dictate what behavior is appropriate or expected for women and men. Some examples of gender norms that can directly influence contraceptive use and HIV risk include norms that give the male partner greater status and power in the relationship, that tolerate violence by the male partner, that expect a woman to be submissive to her spouse, that accept men and women as naturally and exclusively heterosexual, that promote discrimination, and that tie masculinity and femininity to the number of children a man or woman has. Gender norms that allow men greater authority or decision-making power can make it inherently more difficult for women to negotiate condom use or even when and how sex will happen in a relationship. Addressing gender norms can motivate men to seek health care services for themselves in addition to supporting the health care-seeking behavior of their sexual partners, including successful use of a chosen FP method.

When a couple is serodiscordant, engaging a partner in integrated FP-ART services is critical for minimizing the risk of disease transmission and for planning and supporting sustained behavior change for healthy living. One study related to RH decision making in South Africa found that men’s desire for children and misunderstanding of HIV

serodiscordance contributed to increased HIV risk behavior (Matthews et al., 2013). Some (inaccurately) assumed that if their partner was HIV-positive, they were HIV-positive too, and therefore precautions were not necessary. Negative associations with condom use in a community can additionally erode the negotiating power of an HIV-positive individual with her/his partner. Better communication, understanding of serodiscordance and its implications, and interventions intended to help transform gender norms are needed to ensure that couples act together on shared reproductive intentions in ways that minimize risk. Effective couples counseling integrates gender and addresses issues of power and inequity in relationships (including violence and coercion), which are barriers to any attempt to promote effective communication. Capacity building for effective couples counseling can have far-reaching benefits for clients and providers.

For men to benefit from integrated FP-ART services, programming must include male representation through community outreach and networks of PLHIV. It must also gather perspectives on ways to help men gain access to information, counseling, and services in a manner that promotes a caring and protective role for themselves and their families. Actively engaging men can inform approaches to where, how, and when information and services would be most convenient to access (e.g., via men's health clubs, peer outreach, employee services, and evening or weekend clinics). For gender equity to be realized in integrated services, providers require training to competently and confidently discuss SRH with men, including questioning inequitable norms and providing services to men who have sex with men, as these men may also have female partners. While traditional health care centers may be constrained by public-sector regulations concerning days and time of services, referral links between public-sector facilities and nongovernmental or community-based male-oriented services could fill this gap. When integrating services, or when implementing any new services or service changes, program designers should seek to understand the potential impact of these changes on gender equity.

Health programs can be placed along a continuum of gender-neutral to gender-sensitive to gender-transformative (see box). This program guide makes the case that FP-HIV integration will be best served by ensuring that programming is gender-sensitive, at a minimum, moving toward gender-transformative. This means ensuring that gender is included in all phases of programming, from assessment and design to implementation and M&E.

Communicating about and providing services related to HIV and FP through gender-sensitive or gender-transformative programming can yield numerous specific benefits, including the ability to:

- Challenge many of the root beliefs and attitudes that underpin gender inequity and how inequity impacts people's access to health information and services
- Address gender norms or attitudes that present barriers to effective HIV care and treatment and to FP access and use
- Address attitudes and behaviors based on gender norms that make communication related to HIV and FP difficult

- Promote equitable attitudes and healthier, nonviolent relationships
- Develop and disseminate messages and materials that are gender-equitable, or at the very least, avoid inequitable messaging
- Develop clear procedures for consent and couples counseling and address gender inequities that may come up in couples counseling
- Develop programming that engages men while ensuring that women's/girls' rights and empowerment are also promoted

? Questions for consideration might include:

- What will be the impact on both men and women (and their access to services)? Engaging key stakeholders can be a part of the process of answering this question, as can conducting focus group discussions with men and women in the community.
- Does the way in which services are provided reaffirm inequitable gender norms in the community?
- Are equitable norms being promoted through messaging and IEC materials?
- Are stigma and discrimination based on sex, sexual orientation, gender identity, drug use, sex work, HIV status, and/or ethnicity being addressed?
- Will promoting men's participation in the project undermine or support women's empowerment and autonomy?

GENDER CONTINUUM*

Gender-neutral programs do not take gender into account. They ignore the fact that gender norms in any given community will have an impact on a project or how project objectives impact gender norms.

Example: The provider gives a contraceptive method(s) to a woman without engaging in any discussion of how to negotiate desired fertility with her partner.

Gender-sensitive programs recognize and respond to existing gender norms and inequities and seek to implement strategies that adjust to these norms. These projects try to mitigate any harmful impact on gender relations.

Example: In addition to providing a method, the provider discusses how a woman can negotiate her desired fertility.

Gender-transformative programs actively and explicitly examine and try to change existing and harmful gender norms to achieve both health and gender objectives.

Example: Providers conduct education campaigns in the community on women's reproductive rights, irrespective of HIV status (for HIV-positive and HIV-negative women).

**Adapted from: WHO, 2003; and Kambou et al., 2006.*

For more information about integrating gender, see PRB, 2009.





**STRENGTHENING
SYSTEMS FOR
SERVICE
INTEGRATION**

STRENGTHENING SYSTEMS FOR SERVICE INTEGRATION

This section addresses how EngenderHealth's model for strengthening health systems in support of facility-based FP/RH services can be applied to integration. It covers considerations for supervision, training, logistics, referral, and record-keeping systems.

This systems approach helps leadership, managers, and staff at public-sector, private-sector, and nongovernmental organizations strengthen their capacity to:

- Supervise providers and staff to ensure that the Fundamentals of Care (see box below) are appropriately implemented
- Plan and administer provider and staff training to ensure that they have up-to-date knowledge and skills in FP, ART, and supporting functions
- Reliably secure, store, and distribute supplies, equipment, and commodities
- Refer clients for FP services, as well as any other needed services that are not available at a given site
- Accurately record service statistics for FP within ART services

See Appendix C (pages 112–121) for illustrative indicators by client reproductive intention—Table 1: Safer conception or Table 2: Desire to avoid a pregnancy.

In all of the areas highlighted in the text that follows, quality standards for integrated FP-ART service delivery should be met in static, community, home-based, and mobile delivery modalities.

SUPERVISION

Supervisors play an important role in supporting staff to successfully adopt, master, and apply new skills, such as those required to integrate FP activities within HIV care and treatment services. Facilitating change is one of the most challenging functions that a supervisor may face. The concept of facilitative supervision, which is based on widely accepted quality management principles, is one that emphasizes mentoring, joint problem solving, and two-way communication between a supervisor and those being supervised (The ACQUIRE Project, 2008). Using facilitative supervision can offer supervisors and their staff a mechanism to ease the change process and promote team building and participatory problem solving.

The EngenderHealth model for quality is the Fundamentals of Care (ACQUIRE Project, 2006), which consist of three elements:

1. *Ensuring **informed and voluntary decision making***. This is the process by which an individual arrives at a decision about health care based upon an understanding of complete, up-to-date information. To make an informed choice about RH, a client must have access to a full range of service options and understand the information—benefits and risks—relevant to the choice. Through effective client-provider interaction and appropriate counseling and referral, providers enable an informed and voluntary decision-making process.
2. *Assuring **safety for clinical techniques and procedures***. Clinical safety is a critical issue for both clients and providers and refers to the procedures that are conducted and the clinical environment in which they are carried out. Clinical techniques and procedures are considered safe when skilled providers practice in accordance with updated, evidence-based standards, guidelines, and infection prevention protocols, within a physical structure appropriate for managing clinical services.
3. *Institutionalizing a mechanism for ongoing **quality improvement and assurance***. Ensuring high-quality services is a continuous process requiring strong management, quality assurance, and supervision systems that create an enabling and supportive environment. Quality improvement/performance improvement/participatory learning and action tools can guide the establishment of such mechanisms and their implementation. Providers, managers, supervisors, communities, and clients all have essential roles to play in effective quality improvement and quality assurance processes.

Incorporating the COPE[®] principles and approach⁸ is a way to build on facilitative supervision to empower staff to effectively identify and solve integration problems that may emerge, to assist supervisors and staff in communicating more effectively, and to help supervisors leverage resources (materials, staff, commodities, funds) from higher administrative levels by describing what is needed to maintain an ongoing mechanism for carrying out and monitoring the quality of integrated services.

8. COPE[®], which stands for client-oriented, provider-efficient, is a relatively simple process for improving quality in health services. COPE encourages and enables service providers and other staff at a facility to assess the services they provide jointly with their supervisors. Using various tools, they identify problems, find the root causes, and develop effective solutions. The self-assessment process raises participants' awareness of good practices based on international standards. The approach also creates a sense of ownership in the quality improvement process. More information on COPE can be found in the *COPE Handbook* (EngenderHealth, 2003a) and various COPE toolbooks focused on specific areas of health care (www.engenderhealth.org/pubs/quality/cope.php).

TRAINING

Training is an invaluable tool for quality improvement; it prepares staff to competently perform new functions or improve or expand their skills. Integrating FP into ART services requires a comprehensive and deliberate training effort that must address attitudes as well as update knowledge and skills. With improvement in PLHIVs' life expectancy due to HIV care and treatment, they have more interest in the future; their quality of life, sexual satisfaction, and fertility management (including minimizing the risk of HIV transmission during childbearing) become vital considerations. HIV providers who have focused almost exclusively on counseling for the prevention of STIs (including HIV) and for adherence to treatment are now increasingly required to become skilled at and comfortable with counseling to explore women's/couples' reproductive intentions.

While training is necessary for acquiring new knowledge, expanding a range of skills, and improving performance, it is not sufficient to bring about integration. Provider bias is a tremendous barrier to the ability of PLHIV to access RH information so as to make informed decisions and manage their fertility. Attitudes take time to change, and expecting a one-time FP training to bring about the desired change is unrealistic. Service integration must involve all staff, including those with backgrounds and functions not related to health. For example, receptionists and other support staff will need to be oriented to integration and provided with experiential learning that addresses their attitudes, as will nurses, midwives, clinical officers, and physicians providing direct care. If the staff being trained do not have a health background, it may take time for them to grasp the necessary technical knowledge to perform expanded tasks. Therefore, training plans will need to include a progressive series of on-site refresher training events to build on previous sessions and introduce the use of job aids, in addition to providing continuous supervision and mentoring for all cadres of staff. Clients may also be trained as peer educators or counselors.

Depending on the level of integration that a site adopts (the degree to which a site offering HIV services decides to/is able to integrate FP), staff may be on a steep learning curve. They will need to learn how to provide FP counseling for informed choice and details of FP methods, including their mode of action, instructions for use, drug interactions, and management of side effects. Orientation to the use of job aids to help the newly trained provider or counselor function competently and effectively and to master the content more quickly should be an integral part of the FP training. Integrated service delivery training should include content on sexuality and gender equity and norms, as well as exercises applying the content to illustrative client situations and skills building for couples counseling. Posttraining follow-up is crucial to support the new FP practices and functions, including those that promote gender equity within ART services. Follow-up can be provided by the trainers or by similarly trained supervisors, either alone or in coordinated visits.

Training content that supports the integration of FP into ART services must be consistent with agreed-upon or approved posttraining functions. It must include the practical application of knowledge, attitudes, and skills learning and of demonstrated competence before staff can independently serve clients (see Levels of Integration, page 16). Service

site supervisors and senior managers will need to determine whether a centralized group-based or structured on-the-job approach to training will be the most time- and cost-efficient and the least disruptive to services.

LOGISTICS

The functionality of the logistics system is another vital component to the success of integration. Both HIV and FP programs rely on commodities for prevention, such as condoms and other contraceptives. In early efforts to integrate services, HIV and FP commodity logistics systems were completely separate; this division was further reinforced by donors and by Ministry of Health systems. For integration to be successful at the service site level, attention must be given to how the division between donors and health ministry systems can be reconciled to eliminate administrative barriers, so as to reliably secure and distribute supplies and commodities. When donors and higher administrative levels are in harmony, dialogue between FP and HIV logistics managers and service supervisors can be facilitated, as they examine how best to coordinate acquisition, distribution, and inventory recording processes to ensure that they have a sufficient, reliable stock of FP (and HIV) supplies, equipment, and commodities. Where forms for separate services exist, modifications can be made to ensure that one form covers both sets of services (i.e., HIV drug and supply requisition forms that include FP commodities, instruments, and supplies).

Global Fund resources are available to procure an expanded range of contraceptives as well as condoms. In the recent past, not many countries had taken advantage of this funding opportunity. Countries can emphasize their need for procurement of FP commodities in their HIV and Health Systems Strengthening proposals (Hardee, Gay, & Dunn-Georgiou, 2009, pages 29–30).

REFERRAL

Few FP or HIV service providers may be able to deliver a complete range of services on-site. Consequently, it is crucial that FP and ART services explore the resources available in the community. When referral sites are identified to complement integrated services, it is then necessary to develop, modify, or strengthen a referral mechanism to ensure that clients receive the indicated or requested services without being lost to follow-up. An effective referral mechanism means that two or more services must develop a more intentional relationship (e.g., mapping core services, regularly meeting to troubleshoot tracking, and addressing follow-up and ongoing service gaps). Where FP and ART service sites have a predominantly female client pool, efforts to engage a male partner may require modifying the referral system to facilitate men's participation—for example, by offering hours for male services and/or by hiring staff for male client-provider interactions. Settings with providers skilled at couples counseling may also need to be identified if that capacity cannot be developed or will take time to do so within the integrated services.

The referral system to support FP-integrated ART services should provide the following information to the client:

- The location of the referral site
- Hours of service
- Fees
- Directions to the referral site, transport options, the amount of time needed to get to the site, where to go within the referral site, and who to ask for/contact person

This basic information should be available to clients in written or graphic form. Information related to the type of referral should include anticipated waiting time for services, duration of the visit, and waiting time for results.

Effective referral includes:

- An easily retrievable/accessible list of referral sites, locations, and contact persons for each site (one that is routinely updated)
- Clear and strong government policies to efficiently link levels of referral
- Use of service delivery guidelines for referral where these exist, and development of referral guidelines where these are absent
- Assurance that the referral (accepting) site has the appropriate resources to respond to clients' needs (skilled staff, equipment, supplies, and medications to handle conditions beyond the capacity of the referring site)
- A monitoring mechanism for the referral system to determine “what works,” including a functioning communication/feedback system between the referring facility and the site accepting the referral (form, phone, other), to support timely information sharing and continuity of care
- A unified MIS to facilitate continuity of care
- A mechanism for client follow-up (including assessing how well the follow-up mechanism is functioning)
- A safety net for the poor (such as transport subsidies for clients who cannot afford the cost of traveling to the referral site; vouchers or accreditation schemes to reduce financial barriers; and removal of fees at the referral site)
- Institutionalized values for confidentiality, such as joint orientation of staff and community to the value of confidentiality and how to protect it as the foundation for helping the referral system work

Adapted from: PATH, 2001, and Murray, 2010.

RECORD KEEPING

As health services shift away from a focus on single components of care (FP, HIV, antenatal care) to integrated services, data collection tools and approaches to recording and reporting data need to be adapted accordingly. When FP is integrated into ART services, tools will need to be modified to capture the FP activities contributing to a more comprehensive set of service performance statistics that will feed into national government data collection.

In government health systems, however, altering MIS forms can be a complex, lengthy process. Service sites have used a variety of approaches to track the agreed-upon service data while waiting for national forms and records to include the integrated service component's indicators:

- Creating additional areas for FP data on the HIV or ART recording and reporting forms
- Adding FP forms to the HIV or ART forms
- Redesigning the daily log book to include FP data and tallying the combined data on standardized forms by using additional plain sheets of paper to show the FP data
- Developing a temporary system to have HIV clinic staff report FP service statistics to appropriate departments (even within the same institution)

Most of these are interim solutions, to be used while decision makers in the health care system explore what works and what does not before investing in formal alterations to the MIS.





MONITORING AND EVALUATION

MONITORING AND EVALUATION

A full discussion of monitoring and evaluation (M&E) methodologies is beyond the scope of this program guide. We assume that users will have a background in program M&E or will be able to draw upon staff members with those skills. Related resources that may provide further assistance can be found at www.unwomen.org (see also <http://toolkits.urbanreproductivehealth.org/toolkits/measuring-success/indicators>). M&E is key to generating evidence to design, plan, and implement program interventions. M&E can confirm what is and is not working, so that timely and informed decisions can be made.

Ideally, M&E should be part of program design and should be considered before interventions begin. To ensure this, program design should include a needs assessment, an explanation of how the program will work (a framework), a clear goal and measurable objectives, and a plan that describes how the program will be monitored throughout its implementation and evaluated upon completion.

Once these steps are in place, signs of progress toward the goal and objectives must be determined through the use of indicators. Indicators are specific and measurable signs of change or progress toward the desired objective. Appendix C offers a number of examples of **process** and **output** indicators.

When thinking through the M&E design of integrated FP-ART programs, the goal is for all PLHIV using ART services to receive an initial assessment and then periodic reassessments of their reproductive intentions. Clients should be given FP counseling so they can make informed decisions about options to conceive with reduced risk of HIV transmission and/or to prevent unintended pregnancy while enjoying a healthy sex life. To this end, we have included two tables (see Appendix C, pages 112–121) showing **illustrative** indicators for integrated FP-ART services, based on the client's reproductive intentions.



ESTABLISHING INTEGRATED SERVICES

ESTABLISHING INTEGRATED SERVICES

Having explored the specific systems requirements involved in integration, we move to approaches for integrating FP and ART services. This section provides a) a detailed guide for assessing site capacity to integrate services; b) a description of concrete approaches for service integration; and c) considerations for the sustainability of integrated services. Conclusions and next steps are also discussed.

PLANNING FOR SERVICE INTEGRATION

To begin the process of integrating FP and ART services, decision makers and/or managers, providers, and potential users of the services should generate a common vision of what client-oriented integrated services will look like. When a client-oriented integrated service model is clear—taking into consideration broader SRH needs—core services should be assessed to identify internal resources and gaps and to determine both the needs and the interventions to be addressed for successful service integration.

The examples we supply beginning on page 50 illustrate what quality integrated FP-ART services might look like. Such services would include risk assessment, prevention and risk-reduction counseling, HIV counseling and testing, PMTCT, and care and treatment.

The level of integrated FP-ART services will depend on the facility's capacity to achieve and sustain these services without compromising core service quality. The degree to which integrated FP-ART services can be sustained should be determined at the policy, community, facility, and systems levels. Initially, local HIV and FP data should be analyzed to guide discussions about the level of integration that a site can support. A reliable supply of equipment and commodities is required for providing contraceptives as an integral component of ART services.

The chart that follows offers questions for consideration to assess the capacity of a facility to achieve the desired level of integration and the areas that will need to accommodate change for service integration to be functional. For each question, there are implications to consider and discuss, based on one's setting and infrastructure. Answering these questions can help determine in a systematic way what would be involved in achieving and sustaining the desired level of integration. These questions can be streamlined or tailored to create a rapid assessment tool to fit local circumstances.

ASSESSING THE CAPACITY OF YOUR FACILITY/PROGRAM TO PROVIDE INTEGRATED SERVICES: QUESTIONS AND IMPLICATIONS

Goal: To facilitate changes within the health care system to support integrated FP-ART services

QUESTION	YES/IMPLICATIONS	NO/IMPLICATIONS
Policy		
<p>Are national policies in place that delineate health personnel tasks for integrated FP-HIV service delivery? (See Levels of Integration chart, page 16.)</p>	<ul style="list-style-type: none"> Disseminate widely and orient managers, supervisors, service providers, and the community to the integrated standard of care 	<ul style="list-style-type: none"> Requires identifying health system and community stakeholders to contribute to the development of policies that support integrated services
<p>Are there service delivery guidelines for FP to be included in ART, based on WHO Medical Eligibility Criteria? Are these guidelines accessible to providers?</p>	<ul style="list-style-type: none"> Disseminate widely; review periodically to maintain currency with rapidly changing scientific recommendations; orient staff to using service delivery guidelines <i>Suggested resource:</i> WHO, 2010. 	<ul style="list-style-type: none"> Requires identifying health system stakeholders to develop service delivery guidelines for integrated services and to develop a dissemination and orientation plan within the health sector and in the communities being served
<p>Are there any policy barriers to integrating services—for example, age limits for FP use, parity restrictions, or stipulations that unmarried youth cannot access FP?</p>	<ul style="list-style-type: none"> Identify partners to advocate for change using emerging evidence-based and cost-benefit approaches 	<ul style="list-style-type: none"> Requires that staff continue to keep abreast of policy changes that may impact integration of services
<p>Are donors receptive to supporting integration?</p>	<ul style="list-style-type: none"> Maintain a dialogue with donors for strategic and appropriate investment of resources for integrated services 	<ul style="list-style-type: none"> Requires advocacy to help donors understand what integration entails, the emerging evidence base, and cost efficiencies of integration
<p>Are there policies that facilitate data-gathering on gender, gender norms, and their impact on FP or ART services?</p>	<ul style="list-style-type: none"> Increase policy awareness among staff and use data to tailor programs and services 	<ul style="list-style-type: none"> Requires advocacy at the policy level to develop gender norms guidance, indicators, tools, and processes, with facilitation by a gender norms transformation advisor
Cost		
<p>Does/will the health system's financing mechanism cover integrated FP-ART services?</p>	<ul style="list-style-type: none"> Ensure rational use of these funds toward their designated ends, through demonstrating solid results 	<ul style="list-style-type: none"> Requires policy-level advocacy and interventions for health financing coverage

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ASSESSING THE CAPACITY OF YOUR FACILITY/PROGRAM TO PROVIDE INTEGRATED SERVICES: QUESTIONS AND IMPLICATIONS (cont.)

Goal: To facilitate changes within the health care system to support integrated FP-ART services

QUESTION	YES/IMPLICATIONS	NO/IMPLICATIONS
Cost (cont.)		
<p>Has a budget line for FP commodities, instruments, and ARV drugs, equipment, and supplies been established within the HIV sector?</p>	<ul style="list-style-type: none"> Disseminate budget guidelines within the health care system; evaluate periodically against cost assessment reviews to ensure adequate funding to support integrated services 	<ul style="list-style-type: none"> Facilitate the development of a budget, including necessary commodities and supplies for both FP and HIV treatment, based on cost assessment evidence, if feasible
IEC/BCC		
<p>Do client brochures reflect messages integrating FP and HIV services?</p>	<ul style="list-style-type: none"> Include materials in service delivery, information sharing, and community outreach 	<ul style="list-style-type: none"> Identify materials development resources (content developer and funding) to incorporate messages about FP-ART integration
<p>Do the facility's posters visibly reflect integrated FP-HIV/ART messages?</p>	<ul style="list-style-type: none"> Periodically update and rearrange to attract clients' attention 	<ul style="list-style-type: none"> Develop appropriate messaging and determine effective placement of posters in service delivery areas
<p>Have messages been disseminated in other ways (i.e., via radio broadcasts or programs, peer education, community mobilization, etc.)?</p>	<ul style="list-style-type: none"> Periodically monitor results of messaging and update content of messages 	<ul style="list-style-type: none"> Explore ways to disseminate integrated messages widely and cost-effectively
<p>Are IEC/BCC integration materials gender-sensitive, based on the results of gender analysis?</p>	<ul style="list-style-type: none"> Periodically monitor the consistency of messaging with the gender analysis results 	<ul style="list-style-type: none"> Develop a plan for conducting gender analysis, and use the results to tailor IEC/BCC messages and materials
Counseling		
<p>Do existing ART services provide counseling on fertility decision making and FP, including FP method provision?</p>	<ul style="list-style-type: none"> Assess periodically through supervision using standardized FP-integrated HIV service performance tool 	<ul style="list-style-type: none"> Identify points on the continuum of HIV services for integrating FP counseling, method provision, and monitoring of method use

Goal: To facilitate changes within the health care system to support integrated FP-ART services

QUESTION	YES/IMPLICATIONS	NO/IMPLICATIONS
Counseling (cont.)		
<p>Are providers knowledgeable about and comfortable with providing integrated FP-ART counseling?</p>	<ul style="list-style-type: none"> Assess periodically through supervision using standardized integrated FP-ART service performance tool (e.g., counseling checklists) 	<ul style="list-style-type: none"> Assess learning needs and determine most cost-effective and efficient mode for performance improvement (This could be one-on-one or group training, or coaching as part of facilitative supervision.)
<p>Do providers protect the client’s right to privacy (auditory, visual) during service delivery (counseling, procedures)?</p>	<ul style="list-style-type: none"> Periodically assess privacy measures in the physical space 	<ul style="list-style-type: none"> Determine ways to protect clients’ privacy—auditory and visual
Referral		
<p>Are there organizations providing FP or HIV (VCT/PITC, care and treatment) as stand-alone services?</p>	<ul style="list-style-type: none"> Explore possibilities for coordinating services to support referral linkages 	<ul style="list-style-type: none"> Build broader/higher-level referral network; explore linkages with higher levels of the health care system; explore possibility of coordinating services outside of the community, to be able to make referrals
<p>Are there easily accessible referral sites for other FP/RH and/or HIV-related needs within walking distance of the facility or via affordable transport?</p>	<ul style="list-style-type: none"> Document and update the referral list periodically; share with staff for use with clients 	<ul style="list-style-type: none"> Identify resources for FP method provision (e.g., long-acting and permanent methods [LA/PMs]), if not available on-site, and establish a referral link with these sites or providers
<p>Is there an effective referral mechanism between FP and ART (VCT/PITC, OI) services?</p> <p><i>Note: “Effective” means that the client gets from his/her point of origin to the referral site, with communication between the sites to ensure continuity of care.</i></p>	<ul style="list-style-type: none"> Assess periodically for efficiency and effectiveness 	<ul style="list-style-type: none"> Identify resources for FP method provision (e.g., LA/PMs), if not available on-site, and establish a referral link with these sites or providers Establish or strengthen feedback mechanism to ensure that clients are not lost to follow-up and that the referring provider receives information about what services the client received

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ASSESSING THE CAPACITY OF YOUR FACILITY/PROGRAM TO PROVIDE INTEGRATED SERVICES: QUESTIONS AND IMPLICATIONS (cont.)

Goal: To facilitate changes within the health care system to support integrated FP-ART services

QUESTION	YES/IMPLICATIONS	NO/IMPLICATIONS
Physical Structure		
<p>Does the structure have space to accommodate increased client volume (adequate toilet facilities, waiting space, counseling rooms, etc.)?</p>	<ul style="list-style-type: none"> Periodically assess for optimal use of space 	<ul style="list-style-type: none"> May require consideration of how to rearrange existing space, if possible, use of an alternative site, or use of a different model of integration (i.e., referral linkages, special service days or hours, or client-managed resupply)
<p>Does the physical structure allow for privacy (auditory, visual) and confidentiality of client records?</p>	<ul style="list-style-type: none"> Periodically assess adequacy of privacy and confidentiality measures 	<ul style="list-style-type: none"> Assess resources so as to invest in equipment and structural changes if needed changes exceed the site's ability to provide privacy and confidentiality, even with rearranged space
<p>Are the facility structure, timing of services, and staff welcoming to men? Couples? Young women? Young men?</p>	<ul style="list-style-type: none"> Periodically survey clients (males, couples, youth) about their satisfaction with the space, hours, and services 	<ul style="list-style-type: none"> Determine reasons for "no," decide what is possible, and identify service resources for men, couples, and youth
Staffing		
<p>Are staff available to provide FP counseling and method provision in ART services?</p>	<ul style="list-style-type: none"> Assess the need to reorganize work to accommodate additional tasks 	<ul style="list-style-type: none"> Understand that the variety of methods that can be provided may be limited and increase reliance on referral; or explore the feasibility of task shifting or task sharing
<p>Are ART staff trained in FP counseling and method provision?</p>	<ul style="list-style-type: none"> Conduct periodic updates to maintain currency 	<ul style="list-style-type: none"> Conduct a training needs assessment that includes when, where, how, and by whom training will be provided, as well as the cost and training approach that will be used (This may limit the range of methods that can be provided and/or it may increase reliance on referral.)

Goal: To facilitate changes within the health care system to support integrated FP-ART services

QUESTION	YES/IMPLICATIONS	NO/IMPLICATIONS
Staffing (cont.)		
Are ART staff trained in the system for maintaining a supply of FP commodities, instruments, and supplies?	<ul style="list-style-type: none"> Assess periodically for adequacy of stock 	<ul style="list-style-type: none"> Orient staff and supervisors to use the system effectively to maintain adequate supplies for integrated service delivery
Do staff attitudes facilitate FP-ART integration?	<ul style="list-style-type: none"> Monitor and support positive attitudes 	<ul style="list-style-type: none"> Plan for experiential learning interventions to foster positive attitudes about integrated FP-HIV services
Do service providers/counselors demonstrate respect for the rights of HIV-positive women and couples to make decisions about their fertility (consistency of screening for needs, body language, choice of words)?	<ul style="list-style-type: none"> Monitor and support desired behavior 	<ul style="list-style-type: none"> Orient staff to the rights of the client to make independent fertility decisions, regardless of HIV status Address provider bias, stigma, and discrimination
Are service providers/counselors aware of the current WHO Medical Eligibility Criteria for contraceptive use by women who are HIV-positive and by women taking ARV therapy?	<ul style="list-style-type: none"> Monitor and conduct updates, as indicated 	<ul style="list-style-type: none"> Update staff on current guidelines and recommended practices, including dissemination of materials
Are ART providers aware of current information on ARV and OI drug interactions with hormonal contraceptives?	<ul style="list-style-type: none"> Monitor and conduct updates, as indicated 	<ul style="list-style-type: none"> Update staff on current guidelines and recommended practices, including dissemination of materials
Are HIV and FP staff performing infection prevention procedures to standard?	<ul style="list-style-type: none"> Monitor and conduct refreshers, as indicated 	<ul style="list-style-type: none"> Correct any problems immediately when observed and conduct refresher and supervisory monitoring of infection prevention practices
Management and Supervision		
Do managers/supervisors have a written plan for monitoring the proposed integrated services?	<ul style="list-style-type: none"> Monitor system changes made to accommodate integration per the plan; problem-solve with staff, as needed; reinforce effective practices 	<ul style="list-style-type: none"> Develop monitoring plans consistent with the level of integration

continued on next page ►

ASSESSING THE CAPACITY OF YOUR FACILITY/PROGRAM TO PROVIDE INTEGRATED SERVICES: QUESTIONS AND IMPLICATIONS (cont.)

Goal: To facilitate changes within the health care system to support integrated FP-ART services

QUESTION	YES/IMPLICATIONS	NO/IMPLICATIONS
Management and Supervision (cont.)		
Have supervisors been trained in the integration skills that they are expected to support?	<ul style="list-style-type: none"> Conduct periodic updates to ensure currency 	<ul style="list-style-type: none"> Orient supervisors on how to facilitate integration and maintain quality of services
Do supervisory tools reflect FP-ART integrated staff performance? Monitoring of service systems?	<ul style="list-style-type: none"> Continue to use the tools to guide observations and to provide on-the-spot correction or coaching 	<ul style="list-style-type: none"> Modify the tools to reflect the level of integrated services
Do service statistics reflect FP-ART integrated activities?	<ul style="list-style-type: none"> Monitor to maintain completeness and accuracy of documentation 	<ul style="list-style-type: none"> Modify MIS forms consistent with the level of integrated services
Do supervisors review client records and service statistics when monitoring integrated services?	<ul style="list-style-type: none"> Monitor to maintain completeness and accuracy of documentation 	<ul style="list-style-type: none"> Ensure that supervisor is knowledgeable about standards for documenting integrated services in client records and service statistics⁹
Logistics		
Have FP commodities, instruments, and supplies been added to the standardized list for ART services? Do national supplies consist of a wide range of contraceptive options?	<ul style="list-style-type: none"> Monitor periodically for consistency with recommended standards of care 	<ul style="list-style-type: none"> Review standardized equipment, supply, and drug list to provide the determined integrated FP-HIV services
Is there a mechanism for maintaining a reliable supply of FP and HIV service needs?	<ul style="list-style-type: none"> Monitor the degree to which staff use this mechanism correctly; monitor the frequency of stock-outs 	<ul style="list-style-type: none"> May require accessing supplies from alternative sources or not providing services for which supplies cannot be reliably obtained

Drugs, Equipment, and Supplies (should reflect local standards)

List the drugs, equipment, and supplies required for FP services and ART services separately for facility-level or community-level activities. FP method options should be as wide as possible to satisfy clients' needs for delaying, spacing, and limiting births. Assess the commodity logistics system's performance before integration is attempted with another service.

9. There may be central-level changes to health information forms to reflect FP-integrated services. If not, sites may have taken the initiative to develop their own registers to capture FP activities (e.g., referral to FP; source of referral; FP counseling; method provision; change of method(s); management of side effects; and referrals or management of method-related complications).

Goal: To facilitate changes within the health care system to support integrated FP-ART services

QUESTION	YES/IMPLICATIONS	NO/IMPLICATIONS
Community Partnerships and Resources		
Does the community understand/ believe in the benefits of integrated services?	<ul style="list-style-type: none"> Engage the community in planning and monitoring integrated services; cultivate champions from within the community 	<ul style="list-style-type: none"> Create awareness regarding integrated FP-HIV services and the associated benefits and challenges; engage the community in deciding the scope, structure, and need for integrated services
Are there organizations of PLHIV in the community?	<ul style="list-style-type: none"> Include representatives of PLHIV, so they can contribute their perspectives in planning and monitoring integrated services 	<ul style="list-style-type: none"> Explore the feasibility of establishing PLHIV networks, to help develop a community-based group in the area and funding for HIV-positive women’s networks
Are there other organized groups (of women, grandmothers, men, youth, orphans, sex workers, other key populations) with which to collaborate to promote access to and use of integrated FP-ART services?	<ul style="list-style-type: none"> Reach out to identified groups, orient them to service integration, and hold dialogues with these groups for their input, to ensure client-responsive integrated service modifications and promote use 	<ul style="list-style-type: none"> Explore the potential for people with common interests to form community or support groups that would be oriented to and promote use of integrated services
Are there ongoing community outreach activities into which FP-ART integration awareness activities can be incorporated?	<ul style="list-style-type: none"> Collaborate with community outreach program(s) to incorporate awareness-creation activities and to develop a referral mechanism 	<ul style="list-style-type: none"> Collaborate with community resources to develop a mechanism for creating awareness of integrated services and to create referral linkages
Are there influential persons who can be allies/champions in promoting behavior change?	<ul style="list-style-type: none"> Sensitize influential individuals as a resource to endorse healthy sexual and reproductive behavior and to promote use of integrated services 	<ul style="list-style-type: none"> Identify potentially supportive influential or popular figures and groom them to endorse healthy sexual and reproductive behavior and use of integrated services

EXAMPLES OF FP-INTEGRATED ART SERVICES

The following are examples of what FP-ART services can look like in practice. The examples also illustrate some of the ways in which integration (in its various modalities) has proven beneficial to health outcomes.

EXAMPLE 1: ADDRESSING STIGMA

In what has been labeled a “promising practice” by the Center for Health and Gender Equity (CHANGE) in terms of service provision in a way that is confidential and anonymous and that reduces stigma and discrimination, Profamilia, the International Planned Parenthood Federation affiliate in the Dominican Republic, provides a broad range of SRH services (FP, VCT, postexposure prophylaxis, and HIV treatment and care) through its clinics. This is in contrast to the public sector, where treatment and care for PLHIV is routinely provided through separate clinics. For example, a woman in the waiting room at Clínica Evangelina Rodríguez, Profamilia in Santo Domingo could be there for any number of different services, thus assuring more privacy and confidentiality in a country where HIV is still highly stigmatized. An interdisciplinary team made up of health care workers and educators receive training. In addition, there is ongoing, mandatory training to combat stigma and discrimination against people living with HIV, with “documented firing for breaches.” The interdisciplinary team approach and levels of increased privacy and confidentiality afforded to clients are both seen as contributing factors to successful client outcomes (i.e., increased CD4 counts).

(Mir Mesejo et al., 2006; Hardee et al., 2009)

EXAMPLE 2: REFERRAL MODEL

Nigeria has one of the highest numbers of PLHIV in the world (approximately 3 million), and more than half of infected adults (58%) are women. GHAIN, the largest PEPFAR-funded HIV program globally, began pilot testing integration of FP in its HIV program (HIV care and treatment, ART, and PMTCT) in 2007 at 71 public health facilities serving people of low socioeconomic status in urban and rural areas. Before this, FP and HIV services were co-located but maintained distinct registers, reporting, supply chain management, financing schemes, consultation rooms, coordinators, and provider training. An HIV provider would seldom mention FP, and an FP provider would not normally encourage an FP client to know his/her HIV status. While the two services remained separate in this model, GHAIN focused on “formalizing” referral linkages and M&E between the FP and HIV clinics. The model involved updating provider skills, providing on-the-job support, supplying cross-disciplinary job aids, formalizing referrals between clinics (while maintaining parallel supply chain management systems), adding HIV data to the national FP register (and vice versa), training on the use of the modified registers, and streamlining data flow from the facility to the state and federal levels. An integration focal point person was

(cont.)

identified to oversee day-to-day integration activities in the HIV and FP clinics. As a result of the intervention, “clients at the HIV clinics were routinely counseled on family planning methods; those who intended to use family planning methods were given a referral letter to a family planning clinic, irrespective of their HIV status. At the family planning clinic, clients... were counseled on HIV and consenting clients were given a referral letter to [an HIV counseling and testing] clinic for testing.”

The model was considered ideal in this setting in terms of capitalizing on the range of services that a given client may need, while also maintaining much of the existing systems structure: “Changes in the scope of [provider] responsibility were not as pronounced” as having one provider deliver both HIV and FP services in a single session, requiring significant additional technical training.

Results of the analysis revealed a significant increase in the mean attendance at FP clinics, from 67.6 consultations per facility per month prior to integration to 87 following integration ($p < 0.0001$). Monthly mean couple-years of protection likewise rose significantly, from 32.3 preintegration to 38.2 postintegration ($p = 0.0090$). While eight different methods of contraception were offered, it should be noted that condoms represented more than half of all methods dispensed (55.4%), signaling perhaps an overt emphasis on HIV prevention rather than on the most effective FP. FP clients referred from HIV clinics increased from 14.1% the first month to 27.4% in Month 9. The participation of male clients in FP services was also higher among those receiving a referral from HIV services. Distinct barriers were discussed, but overall the findings showed significant increases in FP service attendance and contraceptive uptake, largely due to referrals from HIV services.

(Chabikuli et al., 2009)

EXAMPLE 3: INTEGRATION IN PRACTICE

At the Kola Diba Health Center in Ethiopia, there is a fully functional FP/HIV integration model. While acknowledging that the extent FP can be integrated into HIV services differs, there is agreement that all HIV services that integrate FP should provide screening for unmet need, “promotion of dual method use; provision of condoms and other contraceptives according to training and availability; accurate information about all contraceptive methods; counseling for women or couples with HIV who desire a safer pregnancy; and referrals for contraceptive methods that the provider is not able to directly offer.” Since 2011, all ART clients receive FP counseling at the health center. The Health Center Director oversees and meets regularly with an interdisciplinary team of ART, VCT, PMTCT, HIV, and FP department heads. A system to track FP services in ART has been devised to capture the clients served and the method mix, with 72% of clients shown to be practicing dual method use, 16% using hormonals only, and 8% using condoms only.

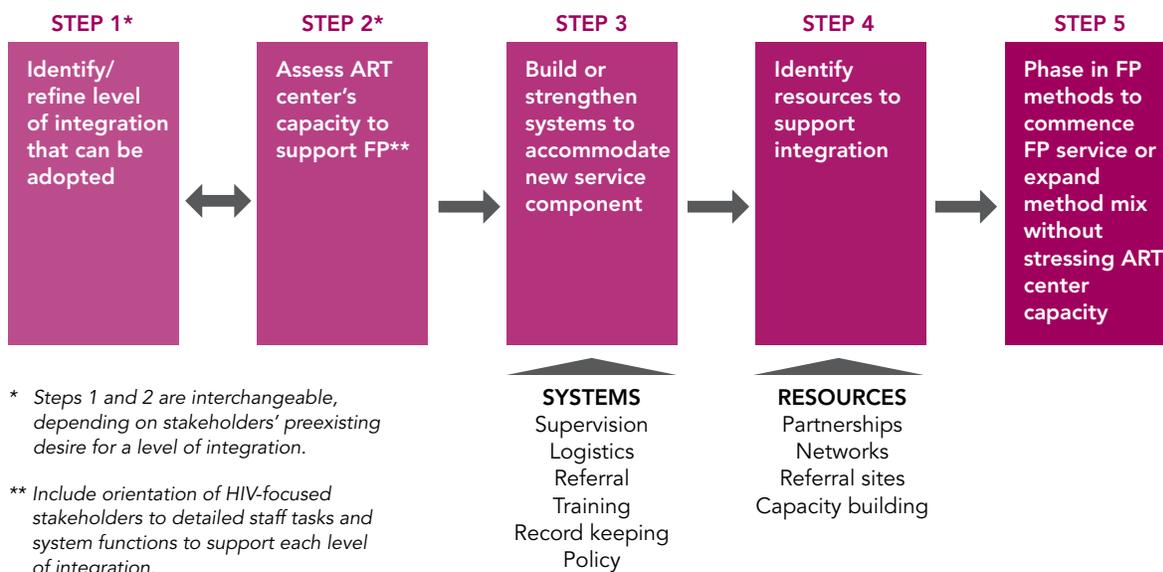
(Pathfinder International, 2011)

APPROACHING INTEGRATION OF FP WITH ART SERVICES

EngenderHealth has designed, implemented, and evaluated a programming model that simultaneously addresses Supply, Enabling Environment, and Demand interventions for service delivery (the SEED™ programming model). The Five-Step Integration Approach (introduced below, and based on this model) supports the planning, implementation, and monitoring of service integration consistent with the capacity of the service site. The integration approach focuses on strengthening the various service delivery systems most likely to be affected when a new component of care is added. *While this approach was initially used for integrating FP with ART services, the approach can be applied to other service integration opportunities* (e.g., FP-integrated maternal and child health services or fistula services) and can be used to facilitate the introduction of a new method into the method mix within an existing FP service (e.g., implants).

Where the policy and program environment are supportive of integration, facility managers are better able to plan and implement integrated services. Creating a relationship of respect and trust between the staff, clients, and community is key to the success of integration. Where and when feasible, the physical structure of the facility, all staff, and service hours should accommodate service users and their partners.

The Five-Step Integration Approach to support the process of integrating FP with ART services:



STEPS 1 and 2

- Form a group/team of key staff from departments that will be needed to achieve integration. Such a team would include clinicians, supervisors, managers, counselors, stores managers, pharmacy staff, receptionists, community outreach staff, home-based care providers, and housekeeping. Include male and female community members and PLHIV network representatives, to be called upon as needed; this will ensure maintenance of a client focus within the assessment process. Persons who are familiar

with gender analysis or who are aware of gender influences in service use would be an asset to ensure that planned interventions minimize gender barriers. These team members will participate in information gathering to assess clients' need for services, as well as the feasibility of integrated FP-ART services.

- Assess the prevailing attitudes and biases of community members regarding FP and HIV. Ensure that the opinions, concerns, and suggestions of women, men, and PLHIV networks are heard.
- Check in with community and with PLHIV network representatives being served regarding the value of integrated FP-ART services, how they envision using the services, and how they would like to see the services organized.
- Determine, with input from local community stakeholders, what level of integration may be most appropriate, and define the scope.
- Map existing FP and ART services in the immediate area and the location(s) of accessible referral sites.
- Use or adapt site assessment tools (facility audit, client interviews, and staff/supervisor interview forms) to make a determination about what level of integration will be feasible to adopt.

STEPS 3 and 4 (may take place simultaneously or in close coordination)

- After assessing the facility's service delivery systems, including an analysis of current provider workload, build or strengthen systems for supervision (standards and guidelines), logistics (commodity supply system for FP), referral (for methods that the ART center does not provide), record keeping (to reflect the FP or integrated service activities), and training (for improving provider knowledge, skills, and attitudes).
- Identify resources needed to design, implement, monitor, and evaluate integrated services, assess requirements for sustaining integrated services, build in what is needed (as feasible), and identify tools to support integration.
- Provide technical assistance for using the expanded/modified FP commodity requisition system to ensure maintenance of FP commodities and supplies.
- Analyze costs to start up and sustain integrated services compared with vertical side-by-side services.
- Analyze or use gender norms data to tailor implementation of service integration.
- Cultivate complementary partnerships with networks of PLHIV, community groups, and facilities that can provide LA/PMs.
- Strengthen the capacity of partners as necessary through group meetings, formal trainings, etc. (such as at a referral site where capacity building may need to take place), so that staff FP knowledge and skills are up to date.

- Develop a plan for implementing integrated FP-ART services over an agreed-to period of time and for monitoring services using identified benchmarks, including input from the community, from PLHIV network representatives, and from clients.
- Begin implementing FP-integrated ART services.

STEP 5

- Based on service performance monitoring, determine and agree on additional FP methods (including selected LA/PMs) that might be provided on-site without burdening the ART center's capacity to provide quality services.
- Identify the period of time needed to conduct method-specific assessment and prepare the site to include additional FP method(s) and their corresponding staff tasks, if assessment results are supportive.
- Conduct ongoing monitoring of service performance, quality, and responsiveness to client needs.

If the results have been favorable after applying the proposed Five-Step Approach for integrating one service with another (i.e., FP with HIV/ART) and monitoring the performance of the integrated services, there will likely be a desire to scale up integration throughout the health system. Some ministries and nongovernmental organizations may have had early commitments to service integration on a large scale. However, very often, what is supported on a small scale may be challenging to implement widely, for a variety of reasons. Planning for successful scale-up must include collaboration with key stakeholders to: reach consensus on expectations for scale-up; ensure that sociocultural and institutional factors are considered in the scale-up interventions, and that those interventions are tested in a setting where they will actually be scaled up (tested in routine conditions and existing resource constraints); create plans to assess and document the implementation process; and use the results to advocate for the necessary investment (policy, financial, health systems strengthening) to make service integration effective (WHO and ExpandNet, 2011). For details on designing and implementing successful scale-up of service innovations such as integration, see also WHO and ExpandNet, 2009, and WHO and ExpandNet, 2010.

SUSTAINABILITY CONSIDERATIONS FOR FP-ART INTEGRATED SERVICES

Consideration must be given to how integrated FP-ART services can be sustained beyond the initial investment of resources. Sustainability of integrated services requires that the program design and implementation be aligned with the Ministry of Health's and national AIDS agency's priorities to promote the national government's goal of reducing HIV *and* increasing access to SRH (notably FP) services. Fostering facility and community connections can help reduce the workload through the sharing of selected tasks. Maintaining a quality improvement and quality assurance system can help to identify problems early on and engage staff and supervisors in problem solving in a manner that will be relevant to the local situation so that services remain available—and robust.

Ensuring that FP integration is accommodated into the core service's systems as an essential element of quality care can lead to sustainability over time.

Areas of consideration for planning sustainable integrated services are listed on the following pages.

Policy

Integrated services are likely to be sustainable where advocacy results in:

- Formation of a joint task force between FP and HIV departments in ministries to help coordinate service integration activities and maintain government commitment and leadership
- A strategy for use with donors to move away from vertical funding toward more flexible arrangements to address the systems needs of integrated services
- Policies and budgetary allocations to support the maintenance of integrated services
- Removal of service barriers through periodically revised/updated policies and service delivery guidelines
- Establishment of training standards for health personnel (preservice/in-service) to include concepts and content on FP-HIV integrated services
- Women's rights to RH (support for women to achieve their reproductive intentions, and prevention of violence against women, coerced abortion or coerced sterilization for women [including those living with HIV], discrimination, and gender bias)
- Community engagement in support of the program
- Gender-equitable policies, including constructive male engagement and male-oriented services
- Youth-oriented education and services
- Scale-up of successful integration service models through appropriate strategy, planning, and budgeting

Program

Integrated services are likely to be sustainable within a facility that has:

- Received funding for integrated services and has clearly demarcated responsibility for accountability
- Established/maintained training capacity to prepare health care personnel who are sensitive and skilled to provide integrated FP-ART services consistent with the adopted level of integration
- Explored the value and feasibility of task shifting or task sharing
- Set up a functional mechanism to ensure facilitative supervision and ongoing quality improvement

- Obtained IEC materials on FP and HIV for clients and communities, including networks of PLHIV, to inform clients about the range of services available
- Ensured the consistency of FP and HIV integrated service messaging at all entry points of the health care system (primary health care, ANC, PMTCT, etc.) and through mass media
- Allocated space for reorganization of work, including space for private counseling and service provision
- Established a referral network, including a mechanism for feedback on services received by clients who have been referred
- Established a logistics monitoring system for FP and ART commodities
- Modified its health information management records to reflect service integration data
- Set up a monitoring and evaluation system designed to collect data on integrated indicators and to assess the quality of integrated services, including client satisfaction

Community

Identifying and collaborating with preexisting community networks and/or community-based services is key to sustainability. A program flourishes and is sustainable when collaboration with the community results in:

- Strong relationships among communities and community- and facility-based services
- Demand for, use of, and input into organization of integrated services
- Community health personnel who are prepared to provide integrated FP-HIV services within their scope of practice
- Means for reaching men, youth, couples, and PLHIV, as well as women's groups, with integrated messages and services
- Objective assessment by clients of their behavior and the extent to which their behavior may place them at risk of HIV infection and/or unintended pregnancy
- A supportive environment in which women/couples can make informed decisions about achieving their reproductive intentions and ability to enjoy a healthy sexual life
- The fostering of a caring and supportive community environment for and with PLHIV
- Partnerships to develop action plans for sustaining, expanding, and/or increasing integrated service use

Social Marketing

Social marketing can support the sustainability of integrated services by:

- Including strategies to promote the marketing of condoms (female as well as male) among an expanded range of contraceptives, dual protection, and information about and referrals for HIV counseling and testing and other HIV and RH services

Adapted from: Pathfinder International, 2000, page 17; and WHO, USAID, and Family Health International, 2009.

CONCLUSION

CONCLUSION

The justification for integrated FP-ART services is compelling. All women and couples, regardless of their HIV status, have a right to access contraception and to achieve their fertility desires. FP-integrated ART services can offer PLHIV opportunities to safely plan desired pregnancies, thus reducing perinatal transmission of HIV and transmission to a potentially uninfected partner, as well as prevention of unintended pregnancy. Addressing the sexuality and RH needs of individuals who are living with HIV can have far-reaching effects on the health and well-being of current and future generations, as well as on the economic stability of families, communities, and countries.

A vision of integrated FP-ART services is one with staff who are nonjudgmental, respectful, caring, and welcoming to clients and their partners; one with providers who are skilled in supporting women/couples to effectively manage their sexual and reproductive lives in a more holistic way; one where needed multidisciplinary referral links are efficiently coordinated, and the care is safe and of high quality. For this vision to be realized, integrated FP-ART services require coordinated efforts among donors, administrative and service delivery systems, and personnel who may not have provided integrated services before. Integrating FP and ART services adds complexity to service management, but this can be minimized when sites assess their ability to sustain a level of integration that is consistent with the capacity of their core services and resources.

Integration of FP with ART services is just one aspect of the larger model of integration that EngenderHealth is addressing. The EngenderHealth approach focuses on strengthening service delivery systems through support for achieving and maintaining the fundamentals of care. It is our aim that this program guide will assist you in thinking through a successful and efficient plan for service integration, whatever the core and additional service(s) will be.

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APPENDIXES



APPENDIX A

GUIDELINES FOR SAFER CONCEPTION

Note: The following guidance is reproduced from *The Southern African Journal of HIV Medicine*, Vol. 12, No. 2, 2011, pp. 31–44.

GUIDELINE ON SAFER CONCEPTION IN FERTILE HIV-INFECTED INDIVIDUALS AND COUPLES

L-G Bekker, V Black, L Myer, H Rees, D Cooper, S Mall, C Mnyami, F Conradie, I Mahabeer, L Gilbert, S Schwartz

Ninety years ago the isolation of insulin transformed the lives of people with type 1 diabetes. Now, models based on empirical data estimate that a 25-year-old person with HIV, when appropriately treated with antiretroviral therapy, can expect to enjoy a median survival of 35 years, remarkably similar to that for someone of the same age with type 1 diabetes. It is high time we normalised the lives of people living positively with HIV. This includes the basic human right to conceive and raise children. HIV-positive individuals may be in serodiscordant relationships or in seroconcordant relationships. As health care providers, it is our responsibility to ensure we understand the opportunities and risks of natural conception in these scenarios, so that we can help our patients to make informed decisions about their own lives. Most of all, it is our duty to make family planning in the setting of positive prevention as safe as we can. This includes informed decisions on contraception, adoption, fostering, conception and prevention of mother-to-child transmission.

Some months ago a dedicated group of individuals, invited and sponsored by the Southern African HIV Clinicians Society, came together in Cape Town to devise guidance in this area, recognising that there are ideal strategies that may be outside the realm of the resource constraints of the public sector or health programmes in southern Africa. This guideline therefore attempts to provide a range of strategies for various resource settings. It is up to us, the providers, to familiarise ourselves with the merits/benefits and risks of each, and to then engage patients in meaningful discussions. All the above, however, is based on the premise and prerequisite that the subject of family planning is actively raised and frequently discussed in our patient encounters.

1. INTRODUCTION

Across South and sub-Saharan Africa, the vast majority of HIV-positive individuals are adults of reproductive age. Before universal access to effective antiretroviral therapy (ART), traditional medical wisdom generally discouraged childbearing because of the risk of HIV transmission (both to uninfected partners and from mother to child) and the reduced survival of infected parents and children. In the era of ART, HIV/AIDS has come to be viewed as a manageable chronic illness. In addition to leading to dramatic reductions in morbidity and mortality of HIV-infected parents, use of highly active antiretroviral therapy

(HAART) in Europe and North America has driven the virtual elimination of paediatric HIV infection, and in southern Africa PMTCT programmes have greatly reduced paediatric infections.¹

Although many patients feel uncomfortable discussing it with their health care providers, many HIV-infected adults are sexually active. In advanced HIV infection fertility is reduced, but the incidence of pregnancy increases with ART initiation,² through increased sexual activity and attitudinal changes in hopes and desires for the future. South Africa has an estimated 1 million births annually, and an estimated 29% of these occur in women living with HIV. Other southern African countries have similar antenatal HIV prevalence rates. A substantial proportion of these pregnancies are unplanned, despite effective contraception being a critical component of the prevention of mother-to-child transmission (PMTCT) of HIV/AIDS programme. However, many HIV-infected women and men want to have children, either immediately or at some time in the future. Reproduction is a basic human right,³ and for many women having a child is part of their life plan. Indeed, in many parts of southern Africa being without a child attracts significant stigma.⁴

In this context, dealing with issues of fertility and childbearing should be seen as part of routine HIV care. Clinicians are responsible for identifying and supporting the fertility desires of their HIV-infected patients – both in the interests of ‘normalising’ the lives of people living with this chronic infection, and to help ensure that conception, pregnancy and delivery take place with the least possible risk to the mother, her partner, and the resulting child.

This consensus guideline for the Southern African HIV Clinicians Society has been formulated through a process of consultation with the South African health services in mind. It is designed to assist clinicians to identify patients’ fertility desires, and to give safe and effective conception guidance to a presumed fertile couple where one or more partners are HIV infected. We have considered ‘resource-intensive’ clinical settings, such as the private sector, where technologically advanced assisted reproduction technologies may be available, as well as ‘resource-limited’ settings such as most public sector health facilities across the region. It is understood that these two levels are often not clearly demarcated, and it is recommended that providers should become familiar with which services documented here are available to patients in their setting. While we present the

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We are indebted to Karin Richter and Polly Clayden for their insightful and helpful comments on this guidance document.

optimal management for safest conception, there is recognition that state-run and resource-limited clinical settings may not yet facilitate or fund these interventions. In these cases we have attempted to quantify the increased risk that not meeting these standards would incur for your patient. While specialist referral is not contraindicated for those couples in whom one or both partners are suspected of having compromised fertility, these advanced fertility interventions will not be covered in these guidelines.

The guideline is divided into three sections. The first section discusses how the clinician can raise the issue of childbearing and help identify the fertility desires of HIV-infected women and men, with a brief discussion on contraceptive strategies for women who do not wish to become pregnant. The second part focuses on the management of individuals and couples who do desire a pregnancy, with emphasis on the management of HIV disease and co-morbidities before attempting conception. This includes specific conception strategies for HIV-seroconcordant positive couples and serodiscordant couples. Finally, several key issues are discussed, and a series of illustrative scenarios have been appended to the guideline to assist with their understanding and implementation.

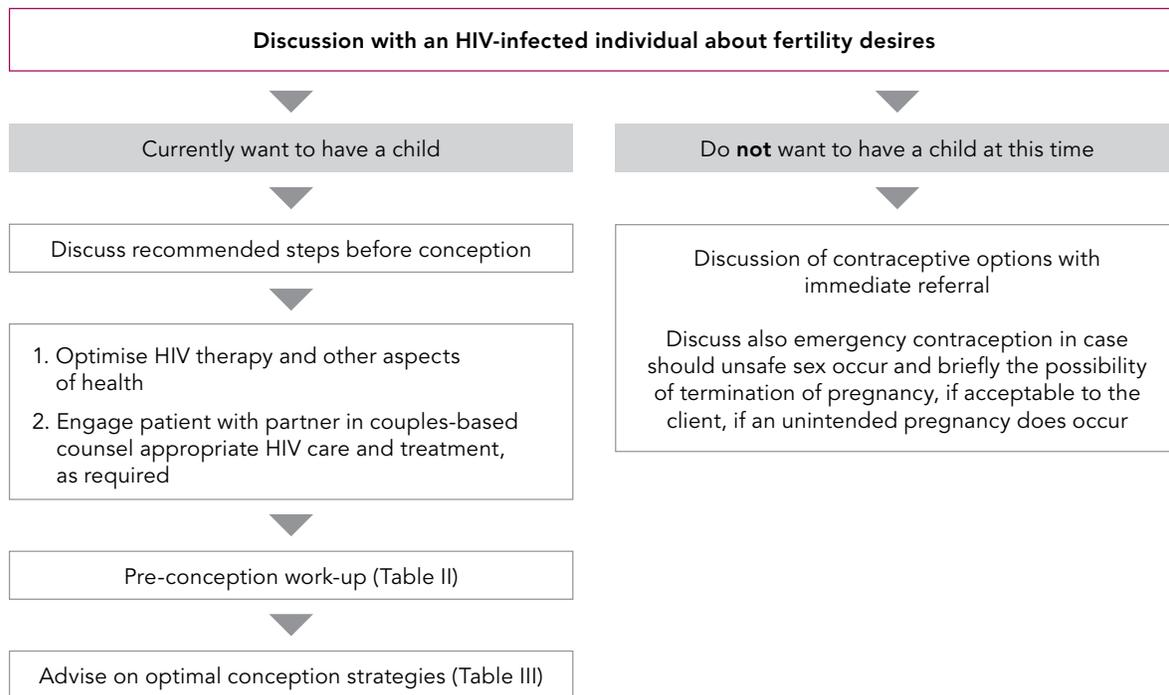
The guideline has been devised with an eye on international norms but also with a keen view to local resource issues. The change in the natural history of HIV infection and reduction in MTCT as a result of ART has led to a re-evaluation of the ethical and moral arguments previously used to deny assisted reproduction to HIV-infected patients. Increasingly, parenting is regarded as a realistic option for couples where one or both partners are infected, and the demand for reproductive management is rising. It is also imperative to provide some measure of protection to both the uninfected partner and the uninfected fetus. This guideline attempts to provide some pointers to how this can be done more safely in the southern African context.

2. DISCUSSING FERTILITY AND CHILDBEARING WITH HIV-INFECTED WOMEN AND MEN

The first step towards addressing the issues of fertility and childbearing is to regularly and repeatedly raise these with HIV-infected patients, to understand their desires and related health care needs (Fig. 1). Issues about fertility choices should be discussed with both bring their partners in for further consultation should this be appropriate. Local research demonstrates that the majority of individuals attending HIV care and treatment services have never had an open discussion about fertility and childbearing with their health care providers.⁵ When these discussions do take place, patients report that the tone is strongly judgemental – often discouraging individuals from childbearing regardless of their desires – with an exclusive focus on the need for contraception and condom use.⁶

Ensuring that patients have a basic understanding of HIV transmission and conception is fundamental to safer conception in HIV. Basic information for this can be obtained online in ‘Pregnancy in our lives’ at <http://www.tac.org.za/community/files/file/TreatmentLit/2010/PregnancyInOurLivesEnglish2010.pdf>

FIG. 1. FLOW DIAGRAM TO APPROACH PREGNANCY-RELATED ISSUES IN HIV-INFECTED WOMEN AND MEN



To introduce this topic, the health care provider may find the following discussion points useful and informative:

- the number of living children, the age of the patient's youngest child, and/or the number of other children the patient may help to care for, and how easy or difficult they find their child care responsibilities
- the health of their existing children, including whether any child is HIV infected
- the partnership status of the patient, the number of children the patient has with their current partner, and perceptions of a partner's desires.

Because of the stigma around sexual activity and pregnancy for HIV-infected individuals, raising issues of fertility and childbearing can be sensitive for many patients. In these discussions, the use of 'normalising' statements – for instance, pointing out that many other patients are grappling with these issues – may help patients to feel comfortable expressing their own thoughts and opinions.

Typically discussions will focus on female patients, but it is critical to note that male partners can have a strong influence on women's fertility-related desires and decisions. These issues are often highly relevant for male patients, and local studies have shown that HIV-infected men are at least as likely as women (often more so) to want another child.⁷ Male or female patients may wish to return with their partners to discuss fertility and related issues with the health care provider, and we strongly recommend a couples-based approach to these issues (see following page).

Throughout this discussion, the objective of the provider should be to assist patients in arriving at their own informed choice about their fertility desires. Key aspects of information that providers may share which can help the patient arrive at an informed decision include: the patient's current health status and their prognosis; their age; the possibility of HIV transmission if the partner is HIV negative; and the probabilities of having an HIV-negative child given appropriate interventions. Other topics the provider may raise with a patient include: current versus desired family size; partner, family and community influences on fertility desires; whether any existing children are HIV infected; and the current and future resources required in caring for a child. These discussions may include an evaluation of some of the alternatives to childbearing, including adoption (Box 1).

BOX 1. OTHER OPTIONS TO CONSIDER IN MAKING A DECISION AROUND FERTILITY AND CHILDBEARING

In discussing the desire to have a child with HIV-infected women and men, there are several potentially useful options that patients may not be aware of. These include:

- An HIV-infected male partner may consider HIV-negative sperm donations from an HPCSA-accredited facility in South Africa (appropriate accreditation bodies should be sought in other southern African countries), or in low-resource settings from an HIV-negative man.
- Adoption may be possible through an approved facility, or through a social worker. Note that chronic illnesses (including HIV) are not a contraindication, provided the illness is well controlled and the adopting parents are relatively healthy.
- Surrogacy may be an option (i.e. another woman carries the pregnancy for the couple), but this would only be acceptable if the male partner is HIV negative. Surrogacy is not widely practised in South Africa.
- Not to have or formally adopt a child, but to focus on becoming more involved in the care of children in the family or community.

Ultimately these discussions should help to identify the patient's current fertility intentions, which in turn indicate various possible health care interventions. Specifically, providers should encourage patients to decide between:

- (a) wanting to become pregnant immediately (i.e. actively trying to conceive), versus
- (b) not wanting a child now, but considering a possible pregnancy in the future, versus
- (c) the desire to not become pregnant at all.

For patients who remain unsure of their choice, option (b) above (not wanting a child in the present, but reserving the possibility of a child in the future) may be a useful default position, as it holds options open and seeks to emphasise that individuals' fertility

intentions may change over time. For example, an HIV-infected woman who does not want a child at present may decide to have a child in the future. Or, a couple who wants a child at present, and has one, may decide afterwards that they do not want more children. As a result, it is important to raise issues of fertility and childbearing at regular intervals during the course of chronic HIV care, even if these are brief discussions to confirm previous decisions. Briefly documenting the discussions between patient and provider can be useful as a reference for future consultations and as a cross-reference in a busy public sector clinic.

3. CONTRACEPTION FOR THE HIV-INFECTED INDIVIDUAL OR COUPLE WHO DOES NOT WANT A CHILD

While this guideline focuses on the needs of individuals and couples who wish to conceive, local research suggests that the majority of HIV-infected individuals are not actively trying to conceive and do not at present want a child.^{5,6} HIV care and treatment services are ideally suited to address family planning needs.⁸ A range of detailed resources are available on appropriate contraception among HIV-infected women and men (see references). However, a few key points emerge from the literature on this subject.

First, there are a number of effective contraception options that may be used safely by patients living with HIV.⁹ Choices may be somewhat restricted in the public sector to barrier methods (such as male and female condoms), injectable progestins and combined oral contraceptive pills. Although availability in the public sector may be limited, intra-uterine contraceptive devices (both copper IUCDs and progesterone IUCDs) are very effective long-acting methods that can be used safely in HIV-infected women, and their use deserves further attention. Male or female sterilisation should be considered for individuals or couples who are certain that they do not wish to become pregnant in the future. In making recommendations about which method to recommend, the efficacy of the different methods should be considered. If a woman is unwell and a pregnancy could impact on her health, a highly effective method should be recommended. If she does not want to use these methods and an unplanned pregnancy would not be a problem, the condom should be considered.

Table I (page 76) shows the relative effectiveness of the common contraceptive methods, the safety of using each method in HIV-infected women, and whether there is any increased risk of transmission to partners.

HIV-infected women will have the same general contraindications to use as the general population of women.¹⁰

For women who can negotiate condom use, we strongly recommend that all patients who require effective contraception be advised to practise dual method use – the concurrent use of a highly effective contraceptive method and a male or female condom. Because of the relatively high failure rates of condoms, this approach should be recommended even to women who report consistent condom use. Women who do not currently want a pregnancy but are reluctant to use contraception should be offered contraceptive counselling at every subsequent opportunity.^{10,11}

TABLE I. EFFECTIVENESS OF THE COMMON CONTRACEPTIVE METHODS, AND THEIR SAFETY IN HIV INFECTION

Method	Failure rate/100 woman-years	Impact on disease progression	Increased HIV transmission to partner	Impact on HAART or tuberculosis treatment
Oral combined oral contraceptive	0.2 – 3	No conclusive evidence of harm: can use	No conclusive evidence of harm: can use	Drug interaction with some NNRTIs: do not use Drug interaction with rifampicin and related TB drugs: do not use
DMPA and NET-EN (injectable progestins)	0 – 2	No conclusive evidence of harm: can use	No conclusive evidence of harm: can use	HAART: can use, no need to increase dose or injection frequency TB drugs: can use, no need to increase dose or injection frequency
Male condom	Careful use: 0.4 – 8 Typical use: around 10	None: may prevent re-infection	Barrier method protects partner	N/A
Female condom	Careful use: 5 Typical use: 21	None: may prevent re-infection	Barrier method protects partner	N/A
Copper IUCD	0.1 – 0.3	Evidence on safety reassuring: can use	Limited evidence but reassuring: can use	No interactions
Levonorgestrel IUCD 20	0.1 – 0.3	Limited evidence of safety reassuring: can use	Little evidence but extrapolating from Cu IUCD can use	No interactions
Male and female sterilisation	Female 0 – 0.5 Male 0 – 0.2	No evidence but unlikely: can recommend	No evidence but unlikely: can recommend	N/A

NNRTI = non-nucleoside reverse transcriptase inhibitor.

4. THE HIV-INFECTED INDIVIDUAL OR COUPLE WHO WANTS A CHILD

A significant proportion of HIV-infected individuals will desire a child, and may be actively trying to conceive at the time of a clinical consultation. In consulting these individuals, there are several important considerations that the HIV clinician should keep in mind.

Natural conception – unprotected intercourse. The risks of HIV transmission depend on HIV plasma viral load, the presence of sexually transmitted infections, and the length and frequency of exposure.

The impact of HIV viral load. Plasma HIV-1 ribonucleic acid (RNA) levels can be correlated with the sexual transmission of HIV. Viral load is the single greatest risk factor for all transmission modes. ART reduces the plasma and genital HIV viral load in the infected individual to undetectable levels.¹² In a study of 415 HIV serodiscordant couples in Uganda, 21.7% of initially uninfected partners became infected over 30 months of follow-up, translating to a transmission rate of approximately 12 infections per 100 person-years.¹³ No transmission events occurred in couples in which the infected partner had a plasma HIV-1 RNA level of less than 1 500 copies/ml, and the transmission risk increased as plasma HIV-1 RNA levels increased. For every 10-fold increase in viral load, there was a >2-fold risk of transmission. Plasma HIV-1 RNA levels generally correlate positively with the concentration of HIV in genital secretions, rectal mucosa and saliva, although inflammation can stimulate local replication.¹⁴ Other studies have shown that transmission events may be observed at a very low plasma HIV-1 RNA level, suggesting that plasma HIV-1 RNA level is not the only determinant of transmission.^{15,16} These data suggest that transmission probability drops markedly in people with naturally controlled viral loads or with ART controlled viral loads.^{15,16}

Clinical research in discordant couples. Findings from a large multinational clinical study conducted by the HIV Prevention Trials Network (HPTN) recently showed that men and women infected with HIV reduced the risk of transmitting the virus to their sexual partners through initiation of oral ART. The study, known as HPTN 052, was designed to evaluate whether immediate versus delayed use of ART by HIV-infected individuals would reduce transmission of HIV to their HIV-uninfected partners and potentially benefit the HIV-infected individual as well. Findings from the study were reviewed by an independent Data and Safety Monitoring Board (DSMB). The DSMB concluded that initiation of ART by HIV-infected individuals substantially protected their HIV-uninfected sexual partners from acquiring HIV infection, with a 96% reduction in risk of HIV transmission.¹⁷

So what are the risks for natural conception and unprotected intercourse? One of the difficulties in counselling serodiscordant couples on natural conception methods involving unprotected intercourse is that the risk to the uninfected partner is difficult to quantify, but can certainly not be quoted as zero. Mathematical models cite a risk of 1 in 100 000 per act of intercourse. In practice, viral shedding in semen has been reported to occur even in men fully suppressed on ART.¹⁸

A recent retrospective study of 551 semen samples analysed in HIV-1-infected men undergoing sperm washing identified 15 cases of detectable HIV-1 in ejaculated semen in men with a long-term undetectable plasma viral load through use of ART, highlighting

a need for caution when couples consider a natural conception approach.¹⁹ In the case of serodiscordant couples where the woman is HIV-positive, the evidence is equally concerning: detectable HIV has been identified in follicular fluid and endometrial samples from a series of HIV-positive women undergoing in vitro fertilisation (IVF), even when plasma viral load was suppressed fully through the use of ART.²⁰

Three studies have analysed infection risk in serodiscordant couples attempting to conceive naturally. The first was a prospective study conducted before the widespread use of ART and examining the risk of unprotected intercourse timed to the fertile window in 96 discordant couples where the male was infected. Four seroconversions were noted in the female partners, 2 during pregnancy and 2 post partum.²¹ The seroconversions were identified in couples in whom condom use after conception and outside the fertile window was inconsistent. A more recent, retrospective study attempted to quantify the risks of unprotected intercourse in discordant couples where the man had an undetectable viral load through use of ART for at least 6 months. There were no seroconversions in 62 discordant couples who conceived.²² Apart from the small sample size, the study is further weakened by the fact that seroconversions were not analysed in couples who failed to conceive, where the risk might be enhanced by repeated exposures. The only study to prospectively assess viral transmission risk in serodiscordant couples attempting to conceive naturally, where the man was fully suppressed on ART and additional pre-exposure prophylaxis (PrEP) was used in the female partner, involved only 22 couples.²³

4.1 Engaging Couples

While we typically see patients in individual consultations, ideally HIV care and treatment services should discuss fertility and childbearing jointly with female and male partners. There are several distinct advantages to a couples-based approach. First, because partnerships have an important influence on fertility decisions, consulting with couples can be useful in helping individuals and their partners arrive at appropriate informed decisions about fertility. Second, the health of both partners is important towards safe conception and pregnancy, and delivering care to both partners may therefore be necessary. Third, if a couple is struggling to conceive, there are specific investigations and interventions for both women and men, and investigating and treating one partner only may lead to suboptimal outcomes. However, this entails disclosure of HIV status between partners, which can be a major challenge. At the minimum, the HIV status of both partners must be known and disclosed in order to manage this process safely and effectively.

Despite the importance of a couples-based approach, there are circumstances where an individual desires a child but does not know the serostatus of their partner, or desires a child in the absence of a regular partner or a partner who is willing or able to attend the clinic. These situations present particular challenges (see ‘Special issues’, page 88).

WHAT SHOULD BE COVERED IN PRECONCEPTION COUNSELLING?

Preconception counselling should ensure an informed choice about reproductive options, including the inherent risks and costs of each treatment and the likely chances of success.

It must include:

- a summary of the available data on safety for each method together with advice on additional methods of reducing risk, such as limiting intercourse to the fertile window, or early initiation of ART
- regular screening for sexually transmitted infections
- the need to identify evidence of reduced fertility or sterility at an early stage in either or both partners
- the possible use of pre-exposure prophylaxis.

The discussion should balance the risk of natural conception with that of more established risk-reduction methods such as sperm washing or risk-free options such as donor insemination. Although timed unprotected intercourse may be the only option for discordant couples in resource-limited settings, this has risk.

Preconceptual counselling should also address:

- The possibility of treatment failure and how the couple would cope if they successfully had a child but the infected parent became more seriously ill or died.
- Those electing to have assisted conception with sperm washing have to understand that this is a risk-reduction method and not a risk-free method.
- When the female partner is HIV-positive they need to understand the risks of MTCT and the methods used.
- They should plan and agree to attend an antenatal clinic once pregnant to ensure that they receive the best possible advice to minimise MTCT risk.

4.2 Optimising HIV Therapy and Addressing Other Health Concerns

As with any chronic condition, optimising the health status of an HIV-infected couple prior to conception is an important step both to facilitate conception and help ensure a safe pregnancy. In the case of HIV, this means:

4.2.1 Documenting the HIV status of both partners.

The recommended strategies to conceive vary depending on the serostatus of both partners, with key differences in optimal strategies for HIV-seroconcordant positive couples, and for HIV-serodiscordant partners (where either the male or female partner is HIV infected). HIV counselling and testing is a prerequisite if the HIV status of both partners is not known.

4.2.2 Identifying and managing co-morbidities.

This includes HIV-related co-morbidities, most notably opportunistic infections such as tuberculosis (TB), as well as other medical conditions that may influence the pregnancy, such as epilepsy or diabetes. For conditions with short-term management (e.g. TB or acute infections), we recommend delaying attempts at conception until treatment is completed. For chronic conditions that will require treatment throughout pregnancy, it is necessary to avoid potentially teratogenic medications and ensure optimal management before proceeding.

4.2.3 Determination of health status for HIV-infected partners.

All HIV-infected patients should undergo thorough clinical assessment and have a CD4 count to determine eligibility for ART before conception. In settings where viral loads are available, these should be included as part of this work-up. However, it should be noted that an undetectable plasma viral load does not necessarily mean that there is an undetectable viral load in the genital tract.

4.2.4 ART initiation as appropriate.

Given the benefits of ART in reducing viraemia and reducing the risk of HIV transmission (in addition to its benefits for adult health), ART initiation in eligible individuals and optimisation of appropriate therapy is necessary before proceeding. Ideally, given the data above, any HIV-infected patient wishing to conceive and therefore contemplating unprotected sex should have an undetectable viral load before doing so. This would imply ART for at least 3 – 4 months prior to sexual intercourse. World Health Organization (WHO) guidelines and a number of southern African countries have adopted short-course HAART for PMTCT regardless of CD4, stopping after delivery in women whose baseline count was >350 cells/µl and in whom formula feeding will be implemented, and after cessation of breastfeeding in those women who choose to do so. While current South African national guidelines call for ART initiation in pregnant women with CD4 cell counts <350 cells/µl, clinicians should consider the initiation of ART in a non-pregnant woman with a CD4 count of <350 (ideally this should be <550) cells/µl who is attempting to conceive. It is hoped South African PMTCT guidelines will adopt the strategy of HAART for all pregnant women, continuing HAART for maternal health in women with CD4 <350 cells/µl, and cessation of HAART after pregnancy or breastfeeding in women in whom CD4 counts are >350 cells/µl depending on the infant feeding method of choice. Care is needed in the selection of regimens preconception and in pregnancy, and the risks and advantages of using any antiretroviral with potential teratogenicity (such as efavirenz (EFV)) should be considered in the first trimester. In discordant couples where the man is infected, similar consideration should be given to initiating ART with CD4 counts of >350 (ideally 200 – 550) cells/µl if he and his negative partner are trying to conceive. It is hoped that with the HPTN 052 results¹⁷ (HIV acquisition was reduced by 96% in discordant heterosexual couples where the HIV-infected partner commenced ART at CD4 levels between 350 and 550 cells/µl compared with those in whom it was commenced at 250 cells/µl or with onset of AIDS), the recommendations above can be modified to that described as ‘ideal’.

For an ART-eligible HIV-infected woman who conceives while not on ART (and may be diagnosed in pregnancy), therapy should be initiated as soon as possible using pregnancy-friendly regimens (at least by the end of the first trimester), as the duration of ART received during gestation is an important determinant of MTCT risk.²⁴ For women who are not ART eligible (do not need ART for their own health), PMTCT interventions, focusing on short-course antiretroviral prophylaxis regimens according to national PMTCT guidelines, should be initiated when appropriate (see Box 2). Suggested pregnancy-friendly regimens would include a boosted protease inhibitor (PI) in the first trimester (if the CD4 count is >250 cells/ μ l) or an EFV-based regimen after the first trimester. A nevirapine-based regimen can be used throughout pregnancy if the starting CD4 count is <250 cells/ μ l.²⁵

4.2.5. Optimisation of ART.

For male or female partners who are either initiating or already established on ART, evidence that therapy is optimised is required before attempting to conceive. This should include evidence of high levels of adherence and immune recovery, and preferably documented virological suppression for at least 4 – 6 months.

BOX 2. PRINCIPLES OF REDUCING MOTHER-TO-CHILD HIV TRANSMISSION

This is not intended to be a comprehensive guide to PMTCT. Please see the reference below for details.

- Ideally all HIV-infected women should already be on ART as part of preconception management; this should be continued throughout pregnancy and breastfeeding.
- If a woman is not on ART, initiate ART as soon as possible irrespective of CD4 cell count, using the appropriate antiretrovirals to avoid teratogenicity, and reduce side-effects and pill burden.
- Women with a baseline CD4 cell count \leq 350 cells/ μ l should continue ART indefinitely for their own health.
- Women with a CD4 cell >350 cells/ μ l who elect to breastfeed should continue ART until the baby is weaned.
- Women with a baseline CD4 count >350 cells/ μ l may discontinue ART after delivery.
- In situations where the above cannot be applied, local PMTCT guidelines should be followed.

Additional reading

National Department of Health. The South African Antiretroviral Treatment Guidelines 2010 (2010). <http://www.doh.gov.za/aids/index.html>

4.3 Preconception Work-up

Table II (page 83) shows recommended basic investigations that may be undertaken in primary care facilities in the preconception work-up of an HIV-infected couple who

desires a child, with adaptations for resource-limited and resource-intensive settings. At a minimum, all women should receive HIV-related investigations as well as syphilis screening, haemoglobin measurement, and physical examination with visual inspection of the cervix for abnormalities and for signs of sexually transmitted infections. Consider a Papanicolaou smear (Pap smear) in resource-intensive settings; this may be extended to include a full screen for TORCH infections (congenital infections: toxoplasmosis, rubella, CMV and herpes simplex and other congenital infections) and viral hepatitis, a Pap smear, and a full blood count.

In resource-intensive settings, patients who are struggling to conceive may be referred to specialist fertility services for further work-up, including assessment of luteinising hormone levels in women and sperm assessment in men. Couples found to be non-fertile may be candidates for assisted reproductive technologies.

4.4 Safer Conception Strategies

The tools at our disposal to make conception safer in seroconcordant and serodiscordant couples now include (some are proven, some experimental, and they are not listed in any particular order):

- HAART and viral load suppression in the positive partner(s)
- timed, limited, peri-ovulatory, unprotected sex
- intra-uterine insemination
- intravaginal insemination
- male circumcision
- sperm washing
- surrogate sperm donation
- post-exposure prophylaxis (PEP) in the negative partner
- PrEP in the negative partner.

It is important to note that in deciding which strategies to use for safer conception while in an HIV-positive seroconcordant or discordant relationship, resources, risk and preference may play a role for both the patient and the provider.

TABLE II. PRECONCEPTION WORK-UP FOR HIV-INFECTED INDIVIDUALS DESIRING A CHILD IN RESOURCE-INTENSIVE AND RESOURCE-LIMITED SETTINGS

	Female partner	Male partner
Resource-intensive strategy	<p>CD4, HIV viral load, hepatitis serology (A); investigations for syphilis, CMV, rubella, HSV, toxoplasmosis; full blood count; Pap smear</p> <p>If on HAART preconception, adaptation of regimen as needed; ensure undetectable HIV Viral load in blood</p> <p><i>If difficulty conceiving:</i> lutenising hormone, referral for fertility assessment</p>	<p>CD4, HIV viral load, syphilis serology; laboratory investigations for other sexually transmitted infections</p> <p>If on HAART preconception, ensure undetectable HIV viral load in blood</p> <p><i>If difficulty conceiving:</i> referral for sperm assessment; fertility assessment</p>
Resource-limited strategy	<p>CD4, HIV viral load, syphilis serology; laboratory investigations for other sexually transmitted infections</p> <p>If on HAART preconception, ensure undetectable HIV viral load in blood</p> <p><i>If difficulty conceiving:</i> referral for sperm assessment; fertility assessment</p>	<p>CD4, syphilis serology; clinical assessment for other sexually transmitted infections</p> <p>ART and undetectable viral load also strongly advised</p>

CMV = cytomegalovirus; HSV = herpes simplex virus.

Table III (pages 84–85) shows the recommended conception strategies for serodiscordant and HIV-infected seroconcordant couples, stratified for resource-intensive and resource-limited settings. In all cases where unprotected sex with a positive partner or vaginal insemination with potentially infected semen is considered, both partners should be counselled about the risk of transmission and measures such as ART or prophylaxis, male circumcision, sperm washing and donor insemination. Which of these options are utilised will be determined by available resources and will determine the level of risk of transmission. Where unprotected exposure is embarked upon this should be in the presence of reasonable expectations for fertility, e.g. no evidence of reduced ovarian reserve or tubal damage, and no more than 6–12 cycles of peri-ovulatory sex should be performed unsuccessfully without considering referral for infertility investigation.

TABLE III. OPTIMAL CONCEPTION SUPPORT STRATEGIES FOR RESOURCE INTENSIVE AND RESOURCE-LIMITED SETTINGS, ACCORDING TO THE HIV STATUS OF THE COUPLE

	Seroconcordant (male and female HIV infected)	Serodiscordant (male HIV infected)	Serodiscordant (female HIV infected)
Resource-intensive strategy			
Female partner	<p>If on HAART preconception, adaptation of regimen as needed; ensure undetectable HIV viral load in blood; no use of efavirenz in the first trimester among HIV-infected women trying to conceive</p> <p>Conception: consider sperm collection with intra-uterine insemination; self-insemination possible; peri-ovulatory unprotected sexual intercourse only in the face of demonstrated undetectable viral loads</p> <p>If not on HAART preconception, maternal HAART initiation as soon as possible with appropriate regimen</p>	<p>Repeated HIV PCR testing before pregnancy</p> <p>Conception: undetectable viral load preferable; sperm washing and intra-uterine insemination</p> <p>Repeated HIV PCR during pregnancy with appropriate management if female partner becomes infected</p>	<p>If on HAART preconception, adaptation of regimen as needed; ensure undetectable HIV viral load in blood</p> <p>Conception: sperm collection with intra-uterine insemination</p> <p>If not on HAART preconception, maternal HAART initiation early in the second trimester</p>
Male partner	<p>Preconception HAART until un-detectable HIV viral load in blood and semen</p>	<p>Preconception HAART until undetectable HIV viral load in blood, semen</p> <p>Conception: sperm assessment; sperm washing with HIV PCR</p>	<p>Ongoing HIV testing; male medical circumcision where appropriate, especially if couple choose peri-ovulatory unprotected sexual intercourse for conception</p>
Resource-limited strategy			
Female partner	<p>If on HAART preconception, adaptation of regimen as needed; ensure high levels of adherence and CD4 monitoring; no use of efavirenz in women trying to conceive</p>	<p>Repeated HIV antibody testing before pregnancy</p> <p>Conception: unprotected sex during the fertile period (preferably while on ART with viral load control)</p>	<p>If on HAART preconception, adaptation of regimen as needed; ensure high levels of adherence and CD4 monitoring; consider ART for conception and pregnancy regardless</p>

TABLE III. OPTIMAL CONCEPTION SUPPORT STRATEGIES FOR RESOURCE INTENSIVE AND RESOURCE-LIMITED SETTINGS, ACCORDING TO THE HIV STATUS OF THE COUPLE (CONTINUED)

	Seroconcordant (male and female HIV infected)	Serodiscordant (male HIV infected)	Serodiscordant (female HIV infected)
Resource-limited strategy (cont.)			
	<p>Conception: consider sperm collection with self-insemination; peri-ovulatory unprotected sex possible under safe conditions. This would include undetectable viral loads if possible, timed sexual intercourse and limited exposures (see text)</p> <p>If not on HAART pre-conception, maternal PMTCT initiation asap with appropriate antivirals</p>		<p>Conception: sperm collection with self-insemination at the time of ovulation (avoiding spermicide-containing condoms)</p> <p>If not on HAART pre-conception, maternal PMTCT initiation as soon as possible with appropriate regimen</p>
Male partner	<p>If required, preconception HAART for at least 6 months with intensive adherence support and CD4 monitoring and viral loads monitoring</p>	<p>If required, preconception HAART for at least 6 months with intensive adherence support and CD4 and viral load monitoring</p>	<p>Ongoing HIV testing; male medical circumcision where appropriate, especially if couple choose peri-ovulatory unprotected sexual intercourse for conception</p>
PCR = polymerase chain reaction.			

4.4.1 Seroconcordant positive couples.

In resource-limited settings, sperm conception with self-insemination may be considered. Limited peri-ovulatory unprotected sex is a feasible approach to insemination, although both partners must acknowledge the potential risks associated with superinfection, and have a good understanding of how to time intercourse to the peri-ovulatory window (see Box 3, page 86). Superinfection occurs when an already infected individual becomes ‘re-infected’ with another strain of HIV that may or may not be drug sensitive. This is thought to be more common than first thought, although there are few case series. A study in Kenyan sex workers quantified the incidence at 4% per annum.²⁶

The implications may include increased viral load in someone not on therapy, or infection with a drug-resistant virus in someone who is. Ideally, even in resource-limited settings this risk can be further reduced in seroconcordant couples by ensuring viral load suppression during conception in both partners and self-vaginal inception. In resource-intensive settings, optimal conception may take place under the supervision of a specialist in

BOX 3. HOW TO DETERMINE A WOMAN'S FERTILE PERIOD

When a couple is living with HIV and attempting conception, determining a woman's fertile period is necessary to time peri-ovulatory intercourse. There are various ways in which a woman's fertile period can be determined. The methods described here presume normal fertility and require minimal resources. In situations where a woman's fertility may be impaired, more resource-intensive methods (such as day 21 progesterone measurements or serial ultrasound monitoring, with or without ovulation stimulation – clomiphene administration is usually performed in consultation with specialist services) may be used by a reproductive specialist. These more intensive methods may also be used in women living with HIV (who has presumed normal fertility) in order to increase her chance of fertility prediction.

Fertile dates

The average normal duration of a menstrual cycle is 28 days. The first day of a woman's menstrual period is considered to be day 1 of her menstrual cycle. Ovulation is assumed to occur half way through her cycle. Her fertile period would be from 5 days before predicted ovulation up until 1 - 2 days after ovulation. For example, in a woman whose cycle is 28 days long, this would mean that ovulation would be assumed on day 14. The woman's fertile period would therefore occur between days 9 and 16 of her menstrual cycle.

However, menstrual cycle length may differ considerably between women and may even differ from month to month for an individual woman. It is therefore essential that a woman keeps record of her menstrual cycle (typically taking into account the first day of her menstrual period) for at least 4 months in order to determine an average menstrual cycle length. It is important to explain to patients that regular menstrual cycles may not necessarily indicate that ovulation has occurred.

Ovulation prediction kits (for urine and saliva)

A number of over-the-counter products are available that enable ovulation prediction. These methods may utilise sampling and analysis of either urine or saliva, and detect the surge of luteinising hormone that occurs immediately before ovulation.

Basal body temperature (BBT) charting

A woman's body temperature increases by 0.25 - 0.5 °C during ovulation. Charting a woman's BBT daily will therefore result in a pattern that may assist her in predicting ovulation. For this method of ovulation prediction to be accurate, it is essential that the woman plots her BBT at the same time every day (preferably between 6 and 8 a.m.), before getting out of bed or drinking or eating anything. Attempt conception after the first rise in BBT has been detected. The chances of conceiving after the 3rd day of raised BBT are greatly reduced.

Cervical mucus monitoring

In addition to BBT, a number of other physiological changes occur around the time of ovulation that may be used to help time intercourse. Cervical mucous changes are used most commonly. During non-fertile days, the cervical mucus is thick and acidic. In contrast, during fertile days, the mucus undergoes a change to become thin, profuse, transparent and 'stretchy' (*spinnbarkeit*). A woman's awareness of these changes in her cervical mucus may help her to predict her fertile period.

reproductive medicine. In such contexts, sperm collection and intra-uterine insemination may be optimal. As discussed above, in all settings ART-eligible individuals should be stabilised on optimal therapy prior to conception.

4.4.2 Serodiscordant couples where the male partner is infected.

When the male partner is positive in a serodiscordant relationship he requires optimal medical therapy, including ART when indicated, to minimise the risk of transmission. In resource-limited settings, both partners should be counselled on the risks of transmission, and limited, timed, unprotected intercourse or sperm collection and self-vaginal insemination (Box 4) may be advised. In this scenario, the HIV-negative female partner requires regular HIV antibody testing throughout pregnancy to detect and manage possible seroconversion as soon as possible. In resource-intensive settings, a serodiscordant couple with a positive male partner is an indication for ‘sperm washing’ and intrauterine insemination, which affords the possibility of conception with minimal risk of male-to-female HIV transmission. PEP/PrEP may also be considered in this setting as protection for the HIV uninfected female partner although this is unproven (see later).

BOX 4. LOW-TECHNOLOGY SPERM COLLECTION AND SELF-INSEMINATION TECHNIQUES

Artificial insemination is the process whereby semen is introduced into the female reproductive tract other than by sexual intercourse. It may be intra-uterine or vaginal, the former being a specialist procedure. The latter is a low-risk procedure that can be carried out by a health care provider or by the patient herself.

It is advisable that vaginal insemination be attempted at the most fertile time in the menstrual cycle, which is approximately 2 weeks prior to menses. In a woman with a regular cycle this can be worked out per calendar, but other methodologies include using an ovulation predictor kit, which is commercially available and measures the LH surge. Other indicators include the quality of the cervical mucus and body temperature.

Semen needs to be provided in a clean receptacle, either by male ejaculation into a condom during intercourse or by male ejaculation into a clean specimen jar provided for the purpose. The semen (most men ejaculate 3 - 5 ml) should be inseminated as soon as possible.

Other equipment to carry out the vaginal insemination would include a ‘turkey baster’ (!), 5 ml plastic syringe or plastic discardable pipette. These items should be supplied to prospective female patients along with the instructions in the appendix.

4.4.3 Serodiscordant couples where the female partner is infected.

When the female partner is positive in a serodiscordant relationship, there are a wider range of options. It is beneficial for the uninfected male to have been circumcised. If he undergoes a male circumcision procedure, this should be at least 2 months before considering unprotected sex. With the woman’s HIV management optimised (viral load undetectable on ART), couples in resource-limited settings may attempt timed

peri-ovulatory unprotected sex with appropriate counselling on the risks of transmission. In this case, the male partner may benefit from PrEP or PEP and at the very least will require ongoing HIV testing to identify possible seroconversion. However, it is preferable and feasible to collect the semen of the uninfected male partner and perform vaginal self-insemination around the time of ovulation, thus avoiding the risk of female-to-male transmission. This procedure can easily be taught to the female partner and can be performed with ease in her own home. In addition, if a freshly collected seminal fluid specimen is brought to a clinic, vaginal insemination can easily be performed as a service. In resource-intensive settings, sperm collection and intra-uterine insemination in a female patient with undetectable viral load, would be a preferable option. See Appendix, 'Vaginal artificial self-insemination instructions'.

5. SPECIAL ISSUES

This guideline provides a general approach to safer conception and pregnancy in different situations involving HIV infection. However, there are several potentially common circumstances that are not directly addressed by the strategies described above.

5.1 Is It Ever Appropriate To Discourage Pregnancy In An HIV-Infected Individual Or Couple?

Ultimately the decision to have a child rests with the patient. However, there are several instances when a clinician may reasonably decide to discourage attempting to have a child. These may include:

- either of the couple has a viral load that cannot be suppressed
- non-disclosure of HIV status to a partner
- documented infertility in either partner
- conditions affecting fertility (although specialist fertility clinics may be able to intervene here)
- medical contraindications, such as active opportunistic/intercurrent infections.

5.2 What If An HIV-Infected Woman Desires A Child, But Does Not Have A Partner?

This raises the question of insemination from alternative sperm sources such as sperm banks, surrogacy and adoption. Should this possibility arise, it is worth knowing what the resources in your area are, what the stipulated eligibilities are and what resources are required for these services. In addition, this situation might be addressed by a sperm donation from a friend, in which case the HIV status of that friend should first be established.

5.3 Can We Use PrEP And/Or PEP To Facilitate Conception Without HIV Transmission In Serodiscordant Partners?

PEP for sexual assault survivors has been used for some time, and there is growing interest in PrEP to prevent transmission in serodiscordant partnerships. However, it is important to note that PrEP and/or PEP for discordant couples, initiated before or after sexual intercourse in situations where sperm washing/insemination is not available, have not been validated and could have significant implications for the health of the man, woman or a subsequent child.

While PEP efficacy has not yet been established in a randomised clinical trial, significant data have been collected from cohort studies that suggest that it is an effective intervention. PEP has been recommended for accidental exposure to HIV, either occupational or non-occupational, where the benefits of the medication clearly outweigh the risks. In the case of a serodiscordant couple wanting to conceive, the exposure would be planned. The use of PEP has been reported from a study in men who have sex with men (MSM) in Brazil, who were randomised to take PEP after a risky sexual exposure. The study, conducted by Schecter et al.,²⁷ demonstrated that people have difficulty recognising risk after the fact. This may be due to denial, substance abuse and other factors. Animal models have explored a number of different drug exposures both pre- and/or post-exposure.²⁸ Current PEP protocols generally state that antiretrovirals have to be given for 28 days after exposure. Some studies have reported that side-effects related to PEP occur in as many as 77% of users. Currently, then, for every episode of unprotected intercourse, the HIV non-infected partner would take 28 days of antiretrovirals with possible ART-related side-effects.²⁹

The evidence for PrEP is also still not well established. The most promising candidate drugs are tenofovir or emtricitabine/tenofovir disoproxil fumarate (FTC/TDF, Truvada). In November 2010, results from a phase III large-scale study, iPrEx, showed that PrEP provided an additional 44% protection from HIV acquisition in men exposed to HIV rectally.³⁰ The study enrolled 2 499 men and transgender women who have sex with men (who were all at high risk of HIV infection) from Peru, Ecuador, South Africa, Brazil, Thailand and the USA. Half the study subjects were given once-daily oral FTC/TDF and the other half was given a placebo. All subjects received monthly HIV testing and risk-reduction counselling. Among those taking FTC-TDF, 36 became infected with HIV during the trial, compared with 64 in the placebo group.

The FEM-PrEP clinical trial³¹ – implemented by FHI in partnership with research centers in Africa – was designed to study whether HIV-negative women who are at higher risk of being exposed to HIV can safely use a daily dose of FTC/TDF to prevent infection. Following a scheduled interim review of the FEM-PrEP study data in March 2011, the Independent Data Monitoring Committee (IDMC) advised that the FEM-PrEP study would be highly unlikely to be able to demonstrate the effectiveness of FTC/TDF in preventing HIV infection in the study population, even if it continued to its originally planned conclusion. The FHI subsequently concurred and has therefore decided to initiate an orderly closure of the study over the next few months. There are a number of possible

reasons for the study findings, including low adherence to the study regimen, a true lack of effect of the product among women (v. MSM), or other factors still to be determined.

There is more PrEP research being conducted (Table IV), with the studies on heterosexual transmission being undertaken in Africa in a variety of population groups. There is still much to be learned about effectiveness and real-life implementation, as well as cost-effectiveness.³²

So what advice can be given to the serodiscordant couple with regard to PrEP? While the results among MSM are promising, and it is likely that PrEP may offer some protection (although whether this will be the case in heterosexual HIV transmission is unknown today), unprotected intercourse with an HIV infected person is never ‘no-risk’, even if PrEP is partially effective.

TABLE IV. PREP RESEARCH IN PROGRESS³²

Location	Population	Expected completion date
Thailand (CDC)	2 400 injecting drug users	2012
South Africa, Uganda, Zimbabwe (VOICE)	5 000 heterosexual women	2013
Kenya, Uganda (Partners for Prevention)	4 700 serodiscordant heterosexual couples	2013

6. CASE STUDIES

Case study 1

LM is a 33-year-old woman initiated on EFV, stavudine and lamivudine in May 2005. She responded well to treatment and is currently receiving treatment and care at a down-referral primary health clinic. Her most recent viral load, May 2009, was lower than the detectable limit and her CD4 cell count in January 2010 was 797 cells/ μ l. She has two children, both over 12 years old, but has no children with her current partner of several years, to whom she has disclosed her status. He is HIV negative.

Initially the patient said that she had no desire to have more children. However, over time she indicated that she and her partner wanted to have a child together. Aside from her ART regimen, she was a good candidate for a safe conception. Upon indicating her intention to conceive, she was referred by study staff for a regimen change. She was told by clinic nurses that a referral was useless as she would need to be up-referred to her initiation site for a regimen change and that up-referrals for regimen changes were not being accepted for planned pregnancies; she should request a regimen change only after conceiving. At a subsequent visit on 3 June 2010, the patient had a positive pregnancy test and the same day was up-referred by the primary health centre to her ART initiation site for a regimen change. Upon presenting at the up-referral site with her referral letter, the clinic chose not

to accept her back, saying that her current living address was outside their jurisdiction, and referred her elsewhere. The second clinic was willing to receive her, but would not change her regimen or provide an explanation for refusing a regimen change. After 10 weeks of going between clinics the patient was clearly distressed about potential harm that might have been caused to the baby by her current regimen, and after one more failed attempt to receive a regimen change she booked to terminate her planned pregnancy. She had a termination of pregnancy on 25 August, without seeking counselling and discussing her concerns with health care providers or study staff, who might have been able to assuage her fears about the EFV-related risks posed to the baby.

This situation would have been avoided if the patient had: (i) received a regimen change when she initially indicated that she was trying to conceive; or (ii) failing this, been received by the clinic she was referred to and given an immediate regimen change, as was the expected protocol. Furthermore, had any counselling been provided to her about the actual level of risk associated with EFV-based conceptions, the outcome would probably have been different.²⁵

It is important to note that EFV poses a risk to fetal neural tube development. Neural tube formation occurs at approximately 4 weeks' gestation. The practical point is that unless planned prior to conception, most women on EFV will present after this sensitive time period, making regimen changes both unnecessary and unhelpful. The alternative regimens may be more problematic, e.g. in the case of nevirapine in women with higher CD4 counts (>250 cells/µl), and much more difficult to adhere to in the case of lopinavir/ritonavir (Kaletra). A rule of thumb is not to change unless a pregnant woman on EFV presents at <12 weeks' gestation (first trimester), although one could argue that change is necessary in the case of presentation at >6 weeks.

Case study 2

A nulliparous, 33-year-old HIV-positive woman seeks counselling around safe conception. She had first tested positive for HIV 3 years previously and had been participating in wellness care as her CD4 cell count was still >200 cells/µl. Her partner is HIV positive and on ART. In 2009, the patient's CD4 count was 420 cells/µl. Her most recent CD4 count (June 2010) was 318 cells/µl; a viral load had not been done. The patient desperately wants to conceive, but is worried about MTCT as she is not on ART.

This woman's case is challenging, as she is not indicated to start ART under the national treatment guidelines until her CD4 count drops to 200 cells/µl. However, she is relatively healthy and it may be another year or more before she becomes eligible for ART. The patient understands that as her CD4 count decreases her viral load is rising, and she is worried about a large spike in her viral load around the time of pregnancy if she were to conceive now. On the other hand, if she were to conceive, under the new guidelines she would immediately be eligible to start ART as a pregnant woman, since her CD4 count is <350 cells/µl.

What is the best plan of action for this woman if she cannot get started on ART? She can wait for a year or so for her CD4 count to drop and her viral load to spike, start ART and

then wait again for another 6 months to achieve virological suppression. At this point she will be 35 and potentially have lowered fertility due to the disease progression and increasing age. Alternatively, she can conceive before ART initiation, with a sub-optimal CD4 cell count and a rising viral load. In this situation she would hope to diagnose the pregnancy as soon as possible, and be initiated onto ART sooner rather than later. The second option allows her to maximise her fertility, particularly now while she is still relatively healthy, but may increase the risk of MTCT and infant mortality, the primary concerns for many HIV-positive women planning to conceive.^{14,15} In a resource-intensive setting, the patient would be offered antiretrovirals immediately. There is a potential risk for hypersensitivity and/or hepatotoxicity with nevirapine at a CD4 count of 318 cells/ μ l. However, EFV is also contraindicated in the first trimester. In South Africa, it would be an option to commence treatment with a boosted PI such as lopinavir or atazanavir. It must be confirmed that both partners are virally suppressed before conception.

WHAT ART IS APPROPRIATE TO USE IN THIS SETTING?

Any woman with reproductive intent who has a CD4 count <250 cells/ μ l should commence with nevirapine and tenofovir plus lamivudine or FTC. If she is already pregnant and on EFV and presenting in the first trimester, consider changing EFV. If the CD4 count is <250, opt for nevirapine; if >250, opt for a PI, e.g. atazanavir or lopinavir. Note, however, the greater pill burden and possibly greater nausea and vomiting with the latter, especially in the first trimester. If necessary and for simplicity the PI can be changed to EFV in the second or third trimester.

Case study 3

A 24-year-old woman who had been on nevirapine, stavudine and lamivudine since January 2009 indicated that she did not currently want to have any more children. She had a CD4 count of 265 cells/ μ l and a history of irregular menstrual cycles since HIV diagnosis; she had not menstruated since giving birth 9 months previously. She had a positive pregnancy test during a routine clinic visit in November 2009. She was not prepared for another child and chose to terminate the pregnancy. During her subsequent visit she was encouraged to start family planning, as she indicated that she has difficulty negotiating condom use with her partner. In May 2010, she was diagnosed with a second pregnancy. At this point she went for a second termination of pregnancy in 6 months and was strongly counselled by medical staff to begin using family planning. At her next clinic visit she was still amenorrhoeic. She had a pregnancy test and was given the negative result to present to the clinic nurses in order to initiate an injectable method of family planning. However, she was refused family planning because she was not menstruating. She had a third pregnancy in September 2010.

Amenorrhoea is not uncommon in women, and prolonged amenorrhoea may be more prevalent among HIV-positive women, particularly those with lower CD4 cell counts.¹⁶ Research also suggests that HIV-positive women may be more likely to be ovulating

APPENDIX. VAGINAL ARTIFICIAL SELF-INSEMINATION INSTRUCTIONS

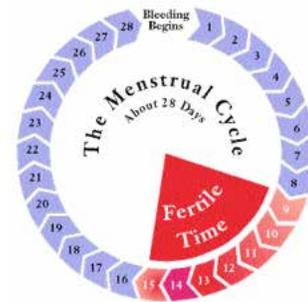
Vaginal artificial self-insemination is the process of placing sperm into your vagina without your partner's penis going inside you. This gives you the chance to get pregnant without the risk of passing HIV on to your partner.

Two important things will give you the best opportunity to get pregnant. Firstly, do the artificial insemination at the time of the month when you are the most fertile, and secondly do not wait too long to place his sperm inside you.

How do you know when it is your most fertile time?

The most fertile time in your menstruation cycle is 2 weeks before you get your period, or around day 14 of your cycle.

Other signs to look out for are an increase in your body temperature (if you have a thermometer) or changes in your vaginal discharge. The mucus will become more clear and sticky – you can pull it into strings if you rub it between your fingers.



What you need to do when the time is right.

The first thing to do is to get a sample of sperm from your partner. You can do this in two ways. You can have sex with a condom (don't use one with spermicide) and use the semen that is captured in the end of the condom. The other way is to get your partner to ejaculate into a clean container you can get from the clinic for this purpose. He can do this with your help or on his own.

Once you have the semen sample, don't wait too long. As soon as possible you need to draw the semen into a 5 millilitre (ml) clean plastic syringe without a needle or a bulb pipette (your local clinic can provide you with one). The next thing to do is to get yourself in the right position. Lie on your back with your knees bent. Place a cushion under your hips to get your back flat and your pelvis tipped up.

Make sure you have got all the extra air out of the pipette or syringe and place it into your vagina, a bit like you would a tampon. Don't push it up too far. (This should NOT be painful. If it is, stop what you are doing and report to your clinic.) Then slowly push the semen out of the syringe or pipette backwards into your vagina.

If possible try to stay in this position for an hour. The chance that you will get pregnant might be a bit better if you masturbate and bring yourself to orgasm while you are lying there, although this is not required if you are not used to it.



Realistically, the possibility that you will get pregnant is around 5 - 10%. You can try this technique 2 - 4 times during your fertile time. The more often you try, the greater your chance of success.

If you have any questions ask your counsellor or health care provider.

while amenorrhoeic than their HIV-negative counterparts.¹⁷ Policies, whether formally written or just informally followed, to initiate family planning only on the first day of a woman's menstrual cycle are inconvenient for women and result in lower contraceptive uptake and increased rates of unplanned pregnancies. These policies also do not take into consideration HIV-related health concerns, such as an increased risk of amenorrhoea, specific to HIV-positive women. Clear guidelines must be in place to address fertility concerns related to family planning for HIV-positive women.

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APPENDIX B

SPECIFIC DRUG INTERACTIONS WITH COMBINED ORAL CONTRACEPTIVES

DATABASE OF ANTIRETROVIRAL DRUG INTERACTIONS

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INTERACTIONS BETWEEN HORMONAL AGENTS AND ANTIRETROVIRAL DRUGS

Interactions with ethinyl estradiol/norethindrone acetate

Antiretroviral (ARV)	Dose of ARV	Dose of ethinyl estradiol/norethindrone acetate	Effect on ARV levels	Effect on ethinyl estradiol/norethindrone acetate levels	Potential clinical effects	Mechanism of interaction	Management
Amprenavir ⁶⁰ (Agenerase)	1200 mg BID x 28 days	0.035 mg ethinyl estradiol/1 mg norethindrone x 1 cycle	Amprenavir AUC: decreased 22%; Cmin: decreased 20%	Ethinyl estradiol Cmin: increased 32%; Norethindrone AUC: increased 18%; Cmin: increased 45%	Unknown effect on birth control	Not established	Dose adjustment not established; may need to use alternative method of birth control Alternative Agents: Barrier devices, condoms
Atazanavir, (ATV) (Reyataz)	400 mg QD x 14 days	1 tab QD (7/7/7)	Not studied	Norethindrone Cmax: increased 67%; AUC: increased 110%; Cmin: increased 262%; Ethinyl estradiol AUC: increased 48%; Cmax: no significant change; Cmin: increased 91%	Increased norethindrone and ethinyl estradiol effects	Inhibition of UGT 1A1 by atazanavir	No dose adjustment necessary

INTERACTIONS BETWEEN HORMONAL AGENTS AND ANTIRETROVIRAL DRUGS

Interactions with ethinyl estradiol/norethindrone acetate (continued)

Antiretroviral (ARV)	Dose of ARV	Dose of ethinyl estradiol/norethindrone acetate	Effect on ARV levels	Effect on ethinyl estradiol/norethindrone acetate levels	Potential clinical effects	Mechanism of interaction	Management
Darunavir ^{161, 365} (DRV) (Prezista)	600 mg BID with ritonavir 100 mg BID	Ethinyl estradiol 35 mcg/ Norethindrone 1.0 mg QD x 21 days	No significant effect	Ethinyl estradiol AUC: decreased 44%; Cmax: decreased 32%; Cmin: decreased 62%; Norethindrone AUC: no significant change; Cmax: no significant change; Cmin: decreased 30%	Decreased ethinyl estradiol and norethindrone effects (e.g., contraceptive failure)	Induction of CYP450 3A4 by ritonavir	Use alternative contraceptive method Alternative Agents: Barrier devices, condoms
Efavirenz ⁹⁰ (EFV)(Sustiva)	400 mg x 10 days	Ethinyl estradiol 50 mcg x 1 dose	No significant change	No significant change	—	—	No dose adjustment necessary
Etravirine ⁴⁰⁵ (ETR)(Intelece)	—	0.035 mg ethinyl estradiol/1 mg norethindrone QD	—	Ethinyl estradiol AUC: increased 22%; Cmax: increased 33%; Norethindrone Cmin: decreased 22%	—	—	No dose adjustment necessary
Indinavir ^{16, 254} (IDV)(Crixivan)	800 mg Q8H x 1 week	0.035 mcg ethinyl estradiol/1 mg norethindrone QD x 1 week	Not studied	Ethinyl estradiol AUC: increased 24%; norethindrone AUC: increased 26%	—	—	No dose adjustment necessary
Lopinavir/ritonavir ¹⁸ (LPV/r)(Kaletra)	400 mg/100 mg BID x 14 days	Ethinyl estradiol 35 mcg QD x 21 days	—	Ethinyl estradiol AUC: decreased 42%; Cmax: decreased 41%; Cmin: decreased 58%	Decreased ethinyl estradiol effects (eg, contraceptive failure)	Induction of CYP450 3A4 by ritonavir	Use alternative contraceptive method Alternative Agents: Barrier devices, condoms

INTERACTIONS BETWEEN HORMONAL AGENTS AND ANTIRETROVIRAL DRUGS

Interactions with ethinyl estradiol/norethindrone acetate (continued)

Antiretroviral (ARV)	Dose of ARV	Dose of ethinyl estradiol/norethindrone acetate	Effect on ARV levels	Effect on ethinyl estradiol/norethindrone acetate levels	Potential clinical effects	Mechanism of interaction	Management
Lopinavir/ritonavir ⁷⁸ (LPV/r)(Kaletra)	400 mg/100 mg BID x 14 days	Norethindrone 1 mg QD x 21 days	—	Norethindrone AUC: decreased 17%; Cmax: decreased 16%; Cmin: decreased 32%	Decreased norethindrone effects (eg, contraceptive failure)	Induction of CYP450 3A4 by ritonavir	Use alternative contraceptive method Alternative Agents: Barrier devices Condoms
Nelfinavir ^{254, 24} (NFV)(Viracept)	750 mg Q8H x 7 days	Ethinyl estradiol (EE) 35 mcg/ Norethindrone (N) 0.4 mg QD x 15 days	—	Ethinyl estradiol AUC: decreased 47%; Cmax: decreased 28%; Norethindrone AUC: decreased 18%; Cmax: no significant change	Contraceptive failure	Induction of glucuronyl transferase by nelfinavir; inhibition of CYP450 3A4 by nelfinavir	Use alternative method of birth control Alternative Agents: Condoms; barrier methods
Nevirapine ³⁷⁰ (NVP)(Viramune)	200 mg BID x 30 days	Ethinyl estradiol 0.035 mg/ Norethindrone 1 mg QD x 30 days	No significant change	Ethinyl estradiol: AUC decreased 23%; half-life: decreased 44%; Norethindrone: AUC decreased 18%; half-life: decreased 15%	Possible contraceptive failure	Induction of CYP450 3A4 by nevirapine	Avoid coadministration; additional contraceptive measures may be needed
Nevirapine ^{369, 95} (NVP)(Viramune)	200 mg QD x 2 weeks then 200 mg BID	Ethinyl estradiol 0.035 mg/ Norethindrone 1 mg x 1 dose	No significant change	Ethinyl estradiol AUC: decreased 19%; Cmax: no significant change Norethindrone AUC: decreased 18%	Possible contraceptive failure	Induction of CYP450 3A4 by nevirapine	Use alternative contraceptive method Alternative Agents: Barrier devices; Condoms

INTERACTIONS BETWEEN HORMONAL AGENTS AND ANTIRETROVIRAL DRUGS

Interactions with ethinyl estradiol/norethindrone acetate (continued)

Antiretroviral (ARV)	Dose of ARV	Dose of ethinyl estradiol/norethindrone acetate	Effect on ARV levels	Effect on ethinyl estradiol/norethindrone acetate levels	Potential clinical effects	Mechanism of interaction	Management
Rilpivirine ⁵⁶⁷ (RPV)(Edurant)	25 mg QD	0.035 mg QD ethinyl estradiol with 1 mg norethindrone QD	No significant change	Ethinyl estradiol Cmax: increased 17%; Norethindrone: no significant change	—	—	No dose adjustment necessary
Ritonavir ^{368, 55} (RTV)(Norvir)	500 mg Q12H	50 mcg x 2 doses	—	Ethinyl estradiol Cmax: decreased 32%; AUC: decreased 41%	Decreased oral contraceptive effectiveness	Induction CYP450 3A4 by ritonavir	Use alternative contraceptive method Alternative Agents: Barrier devices; Condoms
Saquinavir ³⁶⁶ (SQV)(Fortovase, Invirase)	600 mg saquinavir hard gel caps on days 1 and 22	0.03 mg ethinyl estradiol/0.075 mg gestodene QD on days 4-22	No significant change	No significant change	—	—	No dose adjustment necessary
Tenofovir ³⁶⁷ (TDF)(Viread)	300 mg QD	1 tab QD	No significant change	No significant change	—	—	No dose adjustment necessary

INTERACTIONS BETWEEN HORMONAL AGENTS AND ANTIRETROVIRAL DRUGS

Interactions with ethinyl estradiol/norethindrone acetate (continued)

Antiretroviral (ARV)	Dose of ARV	Dose of ethinyl estradiol/norethindrone acetate	Effect on ARV levels	Effect on ethinyl estradiol/norethindrone acetate levels	Potential clinical effects	Mechanism of interaction	Management
Tipranavir ¹⁵⁴ (TPV)(Aptivus)	500 mg BID with 100 mg ritonavir BID x 12 days	0.035 mg/1 mg x 1 dose on day 1 and day 15	Tipranavir Cmin: decreased 26%; Ritonavir AUC: decreased 22%; Cmax: decreased 26%; Cmin: decreased 41%	Ethinyl estradiol AUC: decreased 48%; Cmax: decreased 48%	Decreased ethinyl estradiol/norethindrone effects	Possible induction of CYP450 3A4 by tipranavir	Dose adjustment not established; backup contraceptive method recommended
Tipranavir ¹⁵⁴ (TPV)(Aptivus)	750 mg BID with 200 mg ritonavir BID x 12 days	0.035 mg/1 mg x 1 dose on day 1 and day 15	Ritonavir Cmin: decreased 20%;	Ethinyl estradiol AUC: decreased 42%; Cmax: decreased 51%; Norethindrone AUC: increased 26%	Decreased ethinyl estradiol/norethindrone effects	Possible induction of CYP450 3A4 by tipranavir	Dose adjustment not established; backup contraceptive method recommended

“—” indicates that there are no data available

INTERACTIONS BETWEEN HORMONAL AGENTS AND ANTIRETROVIRAL DRUGS

Interactions with ethinyl estradiol/norgestimate

Antiretroviral (ARV)	Dose of ARV	Dose of ethinyl estradiol/norgestimate	Effect on ARV levels	Effect on ethinyl estradiol/norgestimate levels	Potential clinical effects	Mechanism of interaction	Management
Atazanavir (ATV)(Reyataz)	300 mg QD with 100 mg atazanavir QD	—	—	Ethinyl estradiol AUC: decreased 19%; Cmax: decreased 16%; Cmin: decreased 37% 17-deacetyl norgestimate AUC: increased 85%; Cmax: increased 68%; Cmin: increased 102%	—	—	—
Dolutegravir ⁴¹ (Tivicay)	50 mg BID	0.035 mg ethinyl estradiol	—	No significant change	—	—	No dose adjustment necessary
Efavirenz ⁴¹ (EFV)(Sustiva)	600 mg QHS	0.025 mg ethinyl estradiol/0.25 mg norgestimate	—	Ethinyl estradiol: no significant change; Norgestromin AUC: decreased 64%; Cmax: decreased 46%; Cmin: decreased 82%	Decreased effects of ethinyl estradiol and norgestimate	Induction of CYP450 3A4 by efavirenz	Do not coadminister; use other forms of birth control
Elvitegravir/cobicistat ²³ (Stribild)	150/150 mg	0.18/0.215/0.250 mcg norgestimate	—	Norgestimate AUC: increased 126%; Cmin: increased 167%; Ethinyl estradiol AUC: decreased 25%; Cmin: decreased 44%	Increased norgestimate effects; decreased ethinyl estradiol effects	—	Use with caution; alternate form of contraception recommended
Tenofovir ³⁰ (TDF)(Viread)	300 mg QD	1 tab QD	—	Ethinyl estradiol: no significant effect; Deacetyl norgestimate: no significant effect	—	—	No dose adjustment necessary

“—” indicates that there are no data available

INTERACTIONS BETWEEN HORMONAL AGENTS AND ANTIRETROVIRAL DRUGS

Interactions with levonorgestrel

Antiretroviral (ARV)	Dose of ARV	Dose of levonorgestrel	Effect on ARV levels	Effect on levonorgestrel levels	Potential clinical effects	Mechanism of interaction	Management
Efavirenz ⁴⁴⁹ (EFV)(Sustiva)	600 mg QHS	0.75 mg x 1	Not studied	Levonorgestrel AUC: decreased 58%; Cmax: decreased 45%; Cmin: decreased 71%; half-life: decreased 47%	Decreased levonorgestrel effects	Induction of levonorgestrel metabolism by efavirenz	Use backup form of birth control (e.g. barrier)

Interactions with medroxyprogesterone acetate

Antiretroviral (ARV)	Dose of ARV	Dose of medroxyprogesterone acetate	Effect on ARV levels	Effect on medroxyprogesterone acetate levels	Potential clinical effects	Mechanism of interaction	Management
Efavirenz ³⁹³ (EFV)(Sustiva)	—	150 mg	Efavirenz AUC: no significant change	Progesterone levels: no significant change	—	—	No dose adjustment necessary
Nelfinavir ³⁹³ (NFV)(Viracept)	—	150 mg	Nelfinavir AUC: no significant change; M8 AUC: no significant change	Progesterone levels: no significant change	—	—	No dose adjustment necessary
Nevirapine ³⁹³ (NVP)(Viramune)	—	150 mg	Nevirapine AUC: no significant change	Progesterone levels: no significant change	—	—	No dose adjustment necessary

“—” indicates that there are no data available

INTERACTIONS BETWEEN HORMONAL AGENTS AND ANTIRETROVIRAL DRUGS

Interactions with norethindrone							
Antiretroviral (ARV)	Dose of ARV	Dose of norethindrone	Effect on ARV levels	Effect on norethindrone levels	Potential clinical effects	Mechanism of interaction	Management
Nelfinavir ⁴⁰² (NFV)(Viracept)	750 mg Q8H x 7 days	0.4 mg QD x 15 days	—	Norethindrone AUC; decreased 18%	—	—	Use alternative method of birth control
Tipranavir ¹⁵⁴ (TPV)(Aptivus)	500 mg BID with 100 mg ritonavir BID	1 mg x 1 dose	—	No significant change	—	—	No dose adjustment necessary
Tipranavir ¹⁵⁴ (TPV)(Aptivus)	750 mg BID with 200 mg ritonavir BID x 21 doses	1 mg x 1 dose	—	Norethindrone AUC; increased 27%	—	—	No dose adjustment necessary
Interactions with norgestromin							
Antiretroviral (ARV)	Dose of ARV	Dose of Norgestromin	Effect on ARV levels	Effect on Norgestromin Levels	Potential clinical effects	Mechanism of interaction	Management
Dolutegravir ⁴⁴¹ (Trivicya)	50 mg BID	0.25 mg	—	No significant change	—	—	No dose adjustment necessary

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APPENDIX C

ILLUSTRATIVE INDICATORS

TABLE 1: SAFER CONCEPTION: EXAMPLES OF STRATEGIES, INTERVENTIONS, AND INDICATORS FOR M&E OF INTEGRATED FP-ART INITIATIVES

Desired Outcome: If conception is desired by an HIV-positive client, the woman has been informed of considerations to reduce the likelihood of perinatal transmission and of transmission to her sexual partner, if uninfected

ILLUSTRATIVE INTERVENTIONS

ILLUSTRATIVE INDICATORS: ALL CLIENT DATA SHOULD BE DISAGGREGATED BY SEX AND SEROSTATUS

Process indicator

Output indicator

1. Development of policies, service delivery guidelines, norms, and protocols for managing ART and desired conception

- Establish system-wide protocols and norms for counseling and managing clients desiring pregnancy
- Improve clinic infrastructure to provide private, confidential space for consultations
- Modify supervisory tools to reflect integrated FP-ART services, including those relating to counseling and managing HIV-positive clients desiring pregnancy
- Strengthen multisectoral collaboration with other community-based services as part of routine protocols

- No. of health units supported by the intervention [“Support” usually includes at least one of the following: trained providers deployed to site; supportive supervision or clinical monitoring; provision of equipment/supplies/ expendables; quality assurance or advocacy training]
- No. of health units implementing system-wide protocols, policies, and service norms for clients desiring pregnancy
- No. of health units with space to ensure clients’ privacy/ confidentiality
- No. of facilities with a formalized relationship to which clients might be referred
- No. of multisectoral and community-based stakeholder meetings held to promote collaboration to facilitate ongoing service integration

- % of health units that have documented and adopted a protocol for the counseling and management of clients desiring pregnancy
- % of health units with at least one provider trained to counsel and manage those desiring pregnancy
- % of health units with IEC materials for counseling HIV-positive clients desiring pregnancy
- % of ART units with integrated FP-ART service supervisory tools
- % of ART units showing use of supervisory tools for integrated FP-ART services

2. Training of service providers

- Strengthen health care providers’ ability to counsel and manage HIV-positive clients desiring pregnancy

- No. of providers trained to assess and document reproductive intentions
- No. of providers trained to counsel and manage HIV-positive clients desiring pregnancy

- % of providers who say that PLHIV have the right to bear children

TABLE 1: SAFER CONCEPTION: EXAMPLES OF STRATEGIES, INTERVENTIONS, AND INDICATORS FOR M&E OF INTEGRATED FP-ART INITIATIVES (CONTINUED)

ILLUSTRATIVE INTERVENTIONS	ILLUSTRATIVE INDICATORS: ALL CLIENT DATA SHOULD BE DISAGGREGATED BY SEX AND SEROSTATUS	
	Process indicator	Output indicator
<ul style="list-style-type: none"> • Train providers to initiate discussion of reproductive intentions and to respond to clients' questions about ARVs, pregnancy, and related concerns • Conduct training among providers at established community-based referral networks of care and social services to inform HIV-positive women/couples about how to reduce their risk of HIV transmission while achieving pregnancy 	<ul style="list-style-type: none"> • No. of referral sites supported to inform HIV-positive women/couples how to reduce their risk of HIV transmission while achieving pregnancy 	<ul style="list-style-type: none"> • % of providers who demonstrate competency during observed counseling session (e.g., correctly and consistently use appropriate screening protocols for reproductive intentions; provide appropriate counseling and management of clients desiring pregnancy; offer nonjudgmental counseling respectful of the right of PLHIV to bear children)
3. Routine screening for reproductive intentions (for couples who are serodiscordant, reducing the likelihood of HIV acquisition)		
<ul style="list-style-type: none"> • Train provider to: <ul style="list-style-type: none"> ◦ Routinely screen women in ART services for their reproductive intentions and refer them for FP methods, if needed ◦ Ensure that women living with HIV can share their experiences and receive adherence support from the provider ◦ Ensure quality of care during screening ◦ Discuss whether the client feels confident she can safely disclose her HIV-positive status 	<ul style="list-style-type: none"> • No. of providers who screen women for their reproductive intentions • No. of women/couples provided instruction/guidance about safer conception during ART services • No. of providers who demonstrate ability to advise about HIV disclosure 	<ul style="list-style-type: none"> • % of women living with HIV who state their reproductive intentions • % of HIV-positive women who report discussing their reproductive intentions and contraceptive needs during a visit with their ART provider • % of women who report that the screening was done in private, not during the clinical exam, and in a sensitive and respectful manner
4. Dissemination of materials and information during counseling		
<ul style="list-style-type: none"> • Train provider to: <ul style="list-style-type: none"> ◦ Inform all clients of ways to reduce the risk of HIV transmission while achieving a healthy pregnancy outcome 	<ul style="list-style-type: none"> • No. of brochures or IEC materials produced in local language that cover guidance for safer conception, delivery, and postpartum contraception 	<ul style="list-style-type: none"> • % of providers who consistently explore reproductive intentions of women living with HIV in a nonjudgmental manner

TABLE 1: SAFER CONCEPTION: EXAMPLES OF STRATEGIES, INTERVENTIONS, AND INDICATORS FOR M&E OF INTEGRATED FP-ART INITIATIVES (CONTINUED)

ILLUSTRATIVE INTERVENTIONS	ILLUSTRATIVE INDICATORS: ALL CLIENT DATA SHOULD BE DISAGGREGATED BY SEX AND SEROSTATUS	
	Process indicator	Output indicator
4. Dissemination of materials and information during counseling (cont.)		
<ul style="list-style-type: none"> ◦ Discuss condom negotiation ◦ Explore disclosure of HIV status ◦ Counsel for safer conception ◦ Conduct confidential community outreach for follow-up using personal digital assistants (PDAs) and mobile sites linked to clinic 	<ul style="list-style-type: none"> • No. of provider job aids available at unit that cover HIV disclosure, condom negotiation, etc. (taking gender dynamics into account) • No. of messages produced and disseminated via PDAs, mobile devices, and mobile sites 	<ul style="list-style-type: none"> • % of clients who have received information on reducing the risk of HIV transmission while becoming pregnant, both verbally and (if desired) in pamphlet form • % of clients who received information on all nationally available FP methods (for when the woman/couple may need it) • % of clients who state that they have received a health message via mobile device or mobile outreach site
5. Supervision		
<ul style="list-style-type: none"> • Train supervisor to: <ul style="list-style-type: none"> ◦ Support staff knowledge and skills through coaching and other mechanisms, such as supportive supervision ◦ Facilitate use of new commodity logistics system to ensure reliable supply of IEC materials, other supplies (e.g., materials for preexposure prophylaxis, clean vials for ejaculate, cycle beads for timing intercourse, locally appropriate sperm collection with self-insemination at time of ovulation, while avoiding spermicide-containing condoms) (Bekker et al., 2011) ◦ Use modified supervisory tools to ensure quality counseling for integrated services ◦ Advocate for service site's needs to ensure adequate staffing and infrastructure support for integrated services 	<ul style="list-style-type: none"> • No. of sites supported by the intervention • No. of FP-integrated ART supervisory tools developed or revised • No. of supervisors trained to support integrated services • No. of staff supported by their supervisor to provide safer conception information and services as part of integrated package of services • No. of supervisors using quality monitoring results to advocate for needed staff, equipment, and supplies 	<ul style="list-style-type: none"> • % of supervisors using FP-integrated ART supervisory tools to support and monitor the quality of integrated services • % of providers who state that their supervisor has coached them in counseling and managing clients on ART who desire pregnancy • % of staff accurately reporting commodity use • % of supervisors using quality monitoring results to advocate for needed staff, equipment, and supplies • % of sites with adequate numbers of trained staff to provide integrated services

TABLE 1: SAFER CONCEPTION: EXAMPLES OF STRATEGIES, INTERVENTIONS, AND INDICATORS FOR M&E OF INTEGRATED FP-ART INITIATIVES (CONTINUED)

ILLUSTRATIVE INTERVENTIONS	ILLUSTRATIVE INDICATORS: ALL CLIENT DATA SHOULD BE DISAGGREGATED BY SEX AND SEROSTATUS	
	Process indicator	Output indicator
6. Commodity logistics (Please refer to: WHO, 2011b)		
<ul style="list-style-type: none"> • Strengthen staff capacity to correctly use the commodity logistics systems to ensure a supply of FP equipment and supplies (contraceptives and supplies required for provision consistent with level of integration being implemented), ARVs, medications for OI, and other service supplies (e.g., materials for preexposure prophylaxis, clean vials for ejaculate, cycle beads for timing intercourse, locally appropriate sperm collection with self-insemination at time of ovulation, while avoiding spermicide-containing condoms) (Bekker et al., 2011) 	<ul style="list-style-type: none"> • No. of supported sites using new/ expanded commodity requisition system • No. of staff trained to correctly administer logistics for FP-ART integrated services 	<ul style="list-style-type: none"> • % of facilities using modified commodity requisition forms • % of facilities that submit commodity request forms in a timely fashion • % of facilities with commodities and supplies necessary (see column 1) to provide FP-integrated ART services on day of visit • % of facilities reporting stock-outs (in specified time period) • % of facilities that maintain appropriate storage conditions
7. Record keeping		
<ul style="list-style-type: none"> • Strengthen providers' ability to: <ul style="list-style-type: none"> ◦ Maintain documentation of service activities ◦ Maintain accurate and consistent records of client data in a secure/confidential setting ◦ Periodically document (at least every six months for ages 15–49) reproductive intentions, as well as ART tolerance, side effects, and/or complications ◦ Document follow-up via facility- and community-based personnel ◦ Use mobile phone technology for patient follow-up, where feasible 	<ul style="list-style-type: none"> • Existence of client record-keeping system tracking number of clients receiving FP-integrated ART services, including screening for reproductive intentions • No. of sites demonstrating secure/confidential filing • No. of ART providers trained to accurately complete integrated service records • No. of client records with documented discussion of reproductive intentions • No. of documented follow-up visits and/or calls 	<ul style="list-style-type: none"> • % of client records that are accurate/up to date • % of client records that are filed in a secure/confidential manner • % of client records with documented discussion of reproductive intent • % of patients who know the number of tablets per dose, the amount of each dose to be taken, and the timing of each dose to be taken • % of clients receiving a follow-up visit(s), call, or message, according to standard protocol

TABLE 1: SAFER CONCEPTION: EXAMPLES OF STRATEGIES, INTERVENTIONS, AND INDICATORS FOR M&E OF INTEGRATED FP-ART INITIATIVES (CONTINUED)

ILLUSTRATIVE INTERVENTIONS	ILLUSTRATIVE INDICATORS: ALL CLIENT DATA SHOULD BE DISAGGREGATED BY SEX AND SEROSTATUS	
	Process indicator	Output indicator
8. Referral		
<ul style="list-style-type: none"> • Ensure health care staff ability to: <ul style="list-style-type: none"> ◦ Provide information and services for safer conception at the lowest system level where services can be provided (i.e., if possible, at the community level; if not, at the primary level; at secondary level, etc.) ◦ If services cannot be provided at the lowest system level, ensure referral to next level of care ◦ Maintain list of sites within X km and contact information on updated referral sheet 	<ul style="list-style-type: none"> • No. of sites with updated referral information sheet outlining location of referral site, directions, transport options, hours of service, etc. • No. of clients referred (for safer conception information and services) • No. of sites receiving feedback from the referral site/no. of referral sites providing feedback 	<ul style="list-style-type: none"> • % of facilities with updated referral sheet outlining location of referral site, directions, transport options, hours of service, etc. • % of clients who were referred (plus reason) • % of clients who received the needed services at X level (lowest level) of the health care system • % of sites receiving feedback from the referral site/% of referral sites providing feedback

TABLE 2: DESIRE TO AVOID PREGNANCY: EXAMPLES OF STRATEGIES, INTERVENTIONS, AND INDICATORS FOR M&E OF INTEGRATED FP-ART INITIATIVES

Desired outcome: If an HIV-positive client wishes to delay, space, or avoid a pregnancy, the woman has been informed of the full range of FP methods and can access and effectively use her method of choice

ILLUSTRATIVE INTERVENTIONS

ILLUSTRATIVE INDICATORS: ALL CLIENT DATA SHOULD BE DISAGGREGATED BY SEX AND SEROSTATUS

Process indicator

Output indicator

1. Development of policies, service delivery guidelines, norms, and protocols for managing ART and FP clients		
<ul style="list-style-type: none"> Establish system-wide protocols and norms that integrate provision of contraceptive options within ART services Improve implementation of system-wide protocols, policies, and norms for managing FP-integrated ART services Improve clinic infrastructure to provide private, confidential space for consultations Modify supervisory tools to reflect integrated FP-ART services Strengthen multisectoral collaboration with other community-based services as part of routine protocols 	<ul style="list-style-type: none"> No. of health units supported by the intervention ["Support" usually includes at least one of the following: trained providers deployed to the site; supportive supervision or clinical monitoring; provision of equipment/supplies/expendables; quality assurance or advocacy training] No. of health units implementing system-wide protocols for integrating FP and ART services No. of health units that have done a readiness assessment for the delivery of integrated FP-ART services No. of facilities with a formalized relationship to facilities where clients might be referred No. of multisectoral and community-based stakeholder meetings held to promote collaboration to facilitate ongoing service integration 	<ul style="list-style-type: none"> % of health units that have documented and adopted a protocol for counseling and management of ART clients desiring FP % of health units with at least one provider trained to provide FP counseling within ART services % of health units with IEC materials tailored toward FP and HIV % of ART units with integrated FP-ART services supervisory tools % of women accessing services who indicate they received appropriate, nonjudgmental comprehensive care for ART and FP
2. Training of service providers		
<ul style="list-style-type: none"> Ensure that providers correctly follow reproductive intention screening protocols Strengthen health care providers' ability to offer FP methods consistent with HIV-positive woman's/couple's reproductive intentions 	<ul style="list-style-type: none"> No. of HIV service providers trained to assess and document the reproductive intentions of ART clients No. of HIV providers trained to offer FP counseling No. of HIV providers trained to supply FP or refer for a method 	<ul style="list-style-type: none"> % of HIV-positive women who report discussing their reproductive intentions and contraceptive needs during a visit with their provider

TABLE 2: DESIRE TO AVOID PREGNANCY: EXAMPLES OF STRATEGIES, INTERVENTIONS, AND INDICATORS FOR M&E OF INTEGRATED FP-ART INITIATIVES (CONTINUED)

ILLUSTRATIVE INTERVENTIONS	ILLUSTRATIVE INDICATORS: ALL CLIENT DATA SHOULD BE DISAGGREGATED BY SEX AND SEROSTATUS	
	Process indicator	Output indicator
2. Training of service providers (cont.)		
<ul style="list-style-type: none"> • Ensure that providers initiate discussions and respond to clients’ questions about FP and ARV interactions • Conduct training among providers at community-based referral networks and social services to advise HIV-positive women/couples how to reduce their risk of transmission and to avoid pregnancy • Address stigmatizing norms and attitudes within service settings to help PLHIV meet their reproductive intentions 	<ul style="list-style-type: none"> • No. of providers offering clients the full range of contraceptive options tailored to reproductive intentions • No. of providers at referral sites supported to advise HIV-positive women/couples on dual protection and provide the desired method(s) 	<ul style="list-style-type: none"> • % of trained providers who demonstrate competency during observed counseling session (e.g., correctly and consistently use appropriate screening protocols for reproductive intentions; provide appropriate counseling and management of clients; and offer nonjudgmental counseling respectful of the right of PLHIV to use their chosen method of FP) • % of health units with at least one ART provider trained to offer FP • % of trained providers providing preferred FP methods to ART users • % of providers who state that they feel comfortable asking clients about reproductive intentions and sexuality in ART services • % of trained providers correctly responding to client questions about FP and ARVs
3. Routine screening for reproductive intentions (for couples who are serodiscordant, reducing the likelihood of HIV acquisition via dual protection)		
<ul style="list-style-type: none"> • Train providers to: <ul style="list-style-type: none"> ◦ Routinely explore women’s/ men’s/couple’s reproductive intention(s) within ART services ◦ Supply clients with the full range of contraceptive options tailored to their reproductive intentions ◦ Refer for FP methods, if needed 	<ul style="list-style-type: none"> • No. of providers who screen women for their reproductive intentions • No. of providers who offer clients the full range of contraceptive options tailored to their fertility intentions (or refer them) • No. of providers who demonstrate competency during observed counseling session 	<ul style="list-style-type: none"> • % of providers who consistently explore reproductive intentions of women living with HIV • % of HIV-positive women who report discussing their reproductive intentions and contraceptive needs during a visit with their ART provider • % of women who report that screening was done in private, not during the clinical exam, and in a sensitive and respectful manner

TABLE 2: DESIRE TO AVOID PREGNANCY: EXAMPLES OF STRATEGIES, INTERVENTIONS, AND INDICATORS FOR M&E OF INTEGRATED FP-ART INITIATIVES (CONTINUED)

ILLUSTRATIVE INTERVENTIONS	ILLUSTRATIVE INDICATORS: ALL CLIENT DATA SHOULD BE DISAGGREGATED BY SEX AND SEROSTATUS	
	Process indicator	Output indicator
<ul style="list-style-type: none"> ◦ Ensure quality of care during screening ◦ Ensure that women who live with HIV can share their experiences with their provider and receive adherence support ◦ Discuss whether client feels confident she can safely disclose her HIV-positive status 	<ul style="list-style-type: none"> • No. of women/couples provided with instruction/guidance about FP within ART services • No. of providers who demonstrate ability to advise about HIV disclosure 	<ul style="list-style-type: none"> • % of women who report that they were referred if a desired FP method was not available on-site
4. Dissemination of materials and information during counseling		
<ul style="list-style-type: none"> • Train provider to: <ul style="list-style-type: none"> ◦ Counsel for contraception by intention (delay [postpone first birth], space [interval between pregnancies], limit [completion of childbearing]) ◦ Confirm clients' contraceptive needs ◦ Discuss full range of available methods, tailored to reproductive intention, using appropriate visual aids and client materials ◦ Discuss dual protection, including dual method use ◦ Discuss condom negotiation ◦ Conduct confidential community outreach for follow-up using personal digital assistants (PDAs) and mobile sites linked to clinic ◦ Link clients with FP-informed HIV peer support groups 	<ul style="list-style-type: none"> • No. of brochures or IEC materials produced in local language that cover comprehensive FP information • No. of health units that have FP-integrated IEC materials available to distribute to clients • No. of clients who say they have received FP-integrated IEC materials • No. of client-provider encounters covering contraception and ARVs • No. of provider job aids that cover HIV disclosure, condom negotiation, etc. (taking gender dynamics into account) • No. of messages produced and disseminated via PDAs, mobile devices, and mobile sites • No. of clients who receive HIV-positive peer support that includes support for FP • No. of clients referred to HIV peer support groups where FP could be discussed 	<ul style="list-style-type: none"> • % of clients who received information, verbally and/or in pamphlet form, on all nationally available FP methods • % of clients who received FP-integrated IEC material • % of providers who discuss full range of FP methods tailored to clients' reproductive intentions, regardless of HIV status • % of clients who state that they received a message about FP/ARV use via mobile device or mobile outreach site • % of clients who receive HIV-positive peer support that includes support for FP

TABLE 2: DESIRE TO AVOID PREGNANCY: EXAMPLES OF STRATEGIES, INTERVENTIONS, AND INDICATORS FOR M&E OF INTEGRATED FP-ART INITIATIVES (CONTINUED)

ILLUSTRATIVE INTERVENTIONS	ILLUSTRATIVE INDICATORS: ALL CLIENT DATA SHOULD BE DISAGGREGATED BY SEX AND SEROSTATUS	
	Process indicator	Output indicator
5. Supervision		
<ul style="list-style-type: none"> • Train supervisors to: <ul style="list-style-type: none"> ◦ Support staff knowledge and new skills through coaching and other mechanisms (such as supportive supervision) ◦ Facilitate use of new commodity logistics system to ensure reliable supply of integrated IEC materials and FP supplies ◦ Use modified supervisory tools to ensure quality FP counseling within an integrated service environment ◦ Advocate for service site's needs, to ensure adequate staffing and infrastructure support for integrated services 	<ul style="list-style-type: none"> • No. of sites supported by the intervention • No. of supervisors trained to support FP-integrated HIV services (including maintenance of a reliable supply of listed FP commodities) • No. of providers who state that their supervisor coaches them in FP counseling, method provision, and side effects management • No. of FP-integrated ART supervisory tools developed or revised • No. of supervisors using quality monitoring results to advocate for needed staff, equipment, and supplies 	<ul style="list-style-type: none"> • % of supervisors using FP-integrated ART supervisory tools to support and monitor the quality of integrated services • % of providers who state that their supervisor has coached them in counseling and managing clients on ART and FP • % of staff accurately reporting commodity use • % of supervisors using quality monitoring results to advocate for needed staff, equipment, and supplies • % of sites with adequate numbers of FP-trained staff to provide integrated services
6. Commodity logistics (Please refer to: WHO, 2011b)		
<ul style="list-style-type: none"> • Strengthen capacity of staff to correctly use the commodity logistics systems to ensure a supply of FP equipment and supplies (contraceptives and supplies required for provision consistent with level of integration being implemented), ARVs, medications for opportunistic infections, and other service supplies 	<ul style="list-style-type: none"> • No. of health units that have ART and FP commodities • No. of supported sites using new/expanded commodity requisition system • No. of staff trained to correctly administer logistics for FP-ART integrated services 	<ul style="list-style-type: none"> • % of facilities using modified commodity requisition forms • % of facilities that submit commodity request forms in a timely fashion • % of facilities with commodities and supplies necessary to provide FP-integrated ART services on the day of visit • % of facilities reporting stock-outs (in specified time period) • % of facilities that maintain appropriate storage conditions

TABLE 2: DESIRE TO AVOID PREGNANCY: EXAMPLES OF STRATEGIES, INTERVENTIONS, AND INDICATORS FOR M&E OF INTEGRATED FP-ART INITIATIVES (CONTINUED)

ILLUSTRATIVE INTERVENTIONS	ILLUSTRATIVE INDICATORS: ALL CLIENT DATA SHOULD BE DISAGGREGATED BY SEX AND SEROSTATUS	
	Process indicator	Output indicator
7. Record keeping		
<ul style="list-style-type: none"> • Strengthen health care providers' ability to: <ul style="list-style-type: none"> ◦ Maintain documentation of service activities ◦ Maintain accurate and consistent records of client data in a secure/confidential setting ◦ Periodically document (at least every six months for ages 15–49 and younger in some settings) ART tolerance, side effects, and/or complications of FP method and ART ◦ Document follow-up via facility- and community-based personnel ◦ Use mobile phone technology for client follow-up, where feasible 	<ul style="list-style-type: none"> • Existence of client record-keeping system tracking number of clients receiving FP-integrated ART services, including screening for reproductive intentions • No. of sites demonstrating secure/confidential filing • No. of ART providers trained to accurately complete integrated service records • No. of client records with documented discussion of reproductive intentions • No. of documented follow-up visits and/or calls 	<ul style="list-style-type: none"> • % of client records that are accurate/up-to-date • % of client records that are filed in a secure/confidential manner • % of clients records with documented discussion of reproductive intent • % of clients who know the number of tablets per dose, the amount of each dose to be taken, and the timing of each dose to be taken • % of clients who report correctly and consistently using their chosen FP method • % of clients receiving a follow-up visit(s) or call, according to standard protocols
8. Referral		
<ul style="list-style-type: none"> • Ensure health care staff's ability to: <ul style="list-style-type: none"> ◦ Provide contraceptive information and services at the lowest system level where services can be provided (i.e., if possible, at the community level; if not, at the primary level; at the secondary level, etc.) ◦ If services cannot be provided at the lowest system level, ensure referral to the next level of care ◦ Maintain a list of sites within X km and contact information on updated referral sheet 	<ul style="list-style-type: none"> • No. of sites with updated referral information/sheet outlining location of referral site, directions, transport options, hours of services, etc. • No. of clients referred (for FP information and services) • No. of sites receiving feedback from the referral site/no. of referral sites providing feedback 	<ul style="list-style-type: none"> • % of facilities with an updated referral sheet outlining location of referral site, directions, transport options, hours of service, etc. • % of client who were referred (plus reason) • % of clients who received the needed services at X level (lowest level) of the health care system • % of sites receiving feedback from the referral site/% of referral sites providing feedback

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