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Critical issues for integrating SRH and HIV/AIDS services to provide dual protection against unintended pregnancy and HIV/STI acquisition

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SYMPOSIUM REPORT

December 2011

In response to the programmatic and policy issues arising from the conflicting evidence concerning interactions between hormonal contraception and HIV acquisition, Population Council and Marie Stopes International convened a symposium to review and discuss the critical and emerging issues around integrating SRH and HIV and AIDS services, to enable dual protection.

Critical issues for integrating SRH and HIV/AIDS services to provide dual protection against unintended pregnancy and HIV/STI acquisition

The **STEP UP (Strengthening Evidence for Programming on Unintended Pregnancy) Research Program Consortium** generates policy-relevant research to promote an evidence-based approach for improving access to family planning and safe abortion in Bangladesh, Ghana, India, Kenya, and Senegal. STEP UP is coordinated by the Population Council in partnership with the African Population and Health Research Center; ICDDR,B; the London School of Hygiene and Tropical Medicine; Marie Stopes International; and Partners in Population on Development. STEP UP is funded by UKaid from the Department for International Development. www.stepup.popcouncil.org



Marie Stopes International is a not-for-profit sexual and reproductive health organisation that uses modern business methods to achieve the social goal of preventing unintended pregnancies and unwanted births in countries worldwide. www.mariestopes.org



The Population Council confronts critical health and development issues—from stopping the spread of HIV to improving reproductive health and ensuring that young people lead full and productive lives. Through biomedical, social science, and public health research in 50 countries, we work with our partners to deliver solutions that lead to more effective policies, programs, and technologies that improve lives around the world. Established in 1952 and headquartered in New York, the Council is a nongovernmental, nonprofit organization governed by an international board of trustees. www.popcouncil.org

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BACKGROUND AND MEETING OBJECTIVES

- To provide a framework for thinking about policy development, implementation guidance and development of innovative interventions to strengthen dual/multiple protection strategies
- To present an overview of evidence around HIV acquisition and hormonal contraception to frame policy considerations to be discussed at the WHO technical consultation

Engendering linkages between sexual and reproductive health (SRH) and HIV and AIDS, especially through integrating services, has received strong support and political commitment globally. Over the past decade, strategies have been developed to integrate various HIV and AIDS prevention and treatment services with a variety of SRH services, notably maternal health and family planning services. However, the evidence base available to guide programming remains limited. Strategies for enabling women and couples to protect themselves against both an unintended pregnancy and a sexually transmitted infection received considerable attention immediately after the 1994 Cairo International Conference on Population and Development and early in the HIV epidemic, but the development of dual protection strategies has not progressed much beyond promoting consistent condom use.

The objectives of this one-day symposium were to review and discuss critical and emerging issues around integrating SRH and HIV and AIDS services to enable dual protection, including new directions in dual protection technology and behaviour change interventions. The meeting also provided an opportunity to discuss the programmatic and policy issues arising from the conflicting evidence concerning interactions between hormonal contraception and HIV acquisition. Overview presentations were given by **John Townsend** (Vice President for Reproductive Health, Population Council), **Ian Askew** (Co-Director, Strengthening Evidence for Programming on Unintended Pregnancy [STEP UP] Research Consortium, Population Council) and **Heidi Quinn** (Technical Adviser, Strengthening International Family Planning Organisations Programme, Marie Stopes International) to set the scene for discussions, providing a framework for thinking about policy development and implementation guidance to strengthen dual/multiple protection. Lunch time guest presentations were made by **Susannah Mayhew** and **Kathryn Church** (London School of Hygiene and Tropical Medicine) that presented key findings from a large-scale operations research programme that is testing and evaluating alternative models for integrating SRH and HIV services.

SESSION ONE: THE NET CONTRIBUTION OF HORMONAL CONTRACEPTION: UNINTENDED PREGNANCIES AND THE RISK OF HIV TRANSMISSION

Body of evidence on hormonal contraception and HIV, biological mechanisms, and trade-offs of withdrawing DMPA and HIV infection, unintended pregnancies, maternal mortality, delivery options for hormonal contraception

John Townsend from **Population Council** delivered a presentation entitled “**Competing risks of unintended pregnancy and HIV acquisition**”. Looking at the Heffron et al. (2011) study, “*Use of hormonal contraceptives and risk of HIV-1 transmission: a prospective cohort study*”, Townsend discussed possible mechanisms for HIV acquisition (male to female) with hormonal contraception. These included:

1. Transfer across intact or disrupted vaginal or cervical epithelium (direct infection), including through abrasions
2. Modification of the epithelial “barrier” by hormones
3. Upward transfer in cervical mucus
4. Increased risk of transfer during bleeding
5. Disturbed vaginal and cervical immunology
6. Acquisition of other STIs increasing risk.

The limitations of studies generating this evidence include co-infections, change in immunology and changes over the menstrual cycle. While there is evidence of increased viral shedding, this is still difficult to understand. The possibility of selection bias was mentioned, as was the fact that the hormonal contraception dosage was undisclosed. In summary, the biomedical mechanisms through which use of hormonal contraception would increase the risk of HIV acquisition remain unproven because of inconclusive evidence. Townsend presented the difficult choices faced by service users for dual protection goals (against infectious disease and unwanted pregnancy), and challenges faced by policy makers in determining programming and funding interventions.

The conclusive message remains the additional use of condoms with all other forms of contraception for dual protection.

Choices for Individuals:

- Sterilization, IUD, and implants better than DMPA;
- DMPA better than oral, condom, or no method

Public Policy Options:

- Withdrawal of DMPA not warranted;
- Randomised controlled trial neither feasible nor ethical;
- Need to repeat analyses for other contexts

The presentation ended with the following key questions:

1. Does it make sense to change WHO Medical Eligibility Criteria for hormonal products?
2. Should procurement and counselling policies be reviewed, in what contexts?
3. How should international organisations engage in this debate?

The plenary discussion began with the question of the HIV transmission mechanism. While there may be potential for increased transmission due to hormonal contraception use, there has not been enough evidence to determine how this might occur. The focus so far has been on cases that have a much larger impact, for example, abrasions. More robust measures and analysis of condom use are needed.

The need for improved messaging around dual protection from a policy perspective was emphasised. Discordant couples may receive more counselling, or orientation, which may lead to a higher reported dual use. It was agreed that there is very little evidence relating to our understanding of the acceptability of dual protection and related behaviours. It was noted that dual protection is a service provision “mantra”, but that there is no clarity over what this actually means. The possibility of a randomised control trial was discussed; however, due to the likely costs its feasibility is in doubt.

The issue of counselling was discussed extensively, focussed not on communicating how hormonal contraception may affect HIV transmission, but rather on how to ensure that couples know who is positive and counsel accordingly.

WHO's Medical Eligibility Criteria were discussed with the conclusion, subsequently confirmed at the WHO meeting, that they are not changing, but have added an addendum. Extra advice would be more around programming and counselling – towards method mix, dual protection, risk assessment, and country profile.

SESSION 2A: WHAT CAN WE DO RIGHT NOW TO ENHANCE DUAL PROTECTION?

Proven approaches to program integration: Focus on reproductive rights, balanced counselling, improved availability of more methods, re-position condom

Ian Askew from Population Council delivered a presentation on **Dual Protection**. Askew began by presenting the UK government perspective – one that is supportive of greater integration and linkage between SRH and HIV. The rationale for linking the two focuses on the evidence that the majority of HIV infections in developing countries are sexually transmitted or associated with pregnancy, childbirth and breastfeeding.

Some common determinants of unintended pregnancy and vulnerability to infection cited were:

- Poverty
- Gender inequality
- Gender-based violence
- Human rights violations
- Marginalisation of key populations
- Stigma and discrimination.

A greater push is needed to develop stronger linkages between SRH and HIV. However, there are concerns around the potential cost of such strategies, and the potential diversion of resources into less effective interventions. There are also concerns regarding stigmatisation and reduced service quality.

Issues around linkage include the lack of systematic documentation on intervention effectiveness and integration and the lack of evidence on resource requirements. Overall there is a lack of rigorous research and intervention evaluations.

A rights-based approach is essential, and any dual protection strategy has to be determined by individual rights and needs. Each situation has a different frame of reference for the individual women and a desired impact for the service delivery model trying to meet her needs.

It is important to remember that while condoms are a technology, they require a *behaviour* in order to be effective. It is necessary to move away from a focus on a purely technological “fix” and towards behavioural considerations in technology use, as even a highly effective technology can fail without the correct behaviour. It was agreed that job aides can be useful, helping providers to overcome bias. Providing information and services simultaneously is usually preferred, although referrals can work and in some situations are preferable.

Questions around reaching those clients outside the formal health system were raised, and the importance of looking at alternatives from a programming point of view emphasised. The presentation concluded with the following discussion points:

- 1. How to ensure that girls and women can access and benefit from the new technologies?**
- 2. How to maximise and sustain their effectiveness when used or implemented?**

SESSION 2B: EXPERIENCES FROM SERVICE DELIVERY

Integrating services and choices: The MSI experience

Heidi Quinn from **MSI** delivered the next presentation, addressing the **programmatic challenges of integrating HIV and SRH services**, and the re-integration of HIV into SRH care. Quinn suggested that MSI has been more effective with delivering FP services, but less so with HIV services. MSI country programmes are dependent not only on policies and support from headquarters, but also on the interest and expertise of the individual MSI country programmes, and on donor funding and policy support and resources available.

Implications for MSI from the Heffron et al. study:

The international community response was viewed as relatively balanced. MSI sent advice and guidance to partner programmes following national media coverage of the study in several countries, emphasising the need to maintain a comprehensive family planning method mix and emphasizing dual protection. This message was also communicated with external MSI partners and donors. Anecdotally, at a programme level there appears to be no decrease in demand for injectables and very few client-led enquiries into the issue.

MSI is currently assessing and re-emphasising integration in its service delivery programmes. MSI has looked at the best way of bundling services together depending on the setting. For example, in South Africa this may be VCT with safe abortion, in Kenya STI screening is offered for male circumcision and family planning clients and in Vietnam it is cervical screening. MSI has also targeted male circumcision programmes in Zambia and Malawi, with the aim of linking the entry point of men into SRH, family planning and HIV testing.

MSI is also developing a new Management Information System (MIS) which will enable better linkage of the client and the services they receive in order to be able to look at the integration of services and an improved ability to include consideration of the profile of its clients. MSI's USAID-funded Strengthening International Family Planning Organizations (SIFPO) project is working with Population Council, HIV/AIDS Alliance, EngenderHealth and the International Centre for Research on Women on appropriate integration of services with family planning, and for special groups such as youth and PLWHA.

Through an "HIV-SRH integration tool" developed by the HIV/AIDS Alliance, MSI Partners will be able to examine the level and quality of their integration. As part of the tool there will be a recommendation of a minimum level of integration that all MSI partners should be offering; what they could be offering above this will depend on the prevalence and drivers of the epidemic. Whether MSI's partners should aim to serve the general population with comprehensive integrated services or offer targeted services to most-at-risk groups will depend on the national situation.

Future improvements will include ensuring measurement of integration in a logical way. Implications of the Heffron et al. study on service provision will depend on whether WHO changes its guidance, but MSI would like to train providers to better discuss and assess risk with clients to inform their SRH choices. The ability of the provider to discuss health issues is critical for the assessment of individual needs. However, multiple variables may affect the client's disclosure of HIV status, reproductive desires and lifestyle, while the national health environment and services also affect clients' risk factors. Rural clients and providers, where the choice of methods and services may not be optimal, must be taken into account when making a policy assessment and must be advised accordingly. Key challenges for MSI include the location of integration services and commodity security.

The plenary session began with the challenge of reform. Some of the biggest obstacles to service delivery include the discussion regarding full or partial integration. A significant concern is the present lack of female condoms being on the agenda and the poor promotion of dual protection.

The importance of rigorous evidence, including through systematic reviews of the effectiveness of integration interventions, was stressed, while acknowledging that determinants outside the health system are also critical. It was suggested that the evidence base around structural determinants of HIV is weak and there is little information regarding social determinants of dual protection.

Counselling was an issue that arose consistently, with the point made that there have been very few interventions aimed at increasing dual protection.

- The question of access was raised in terms of where clients can access stigma-free client-friendly services. Vulnerable clients may not always want to be referred as they would often rather have a one-stop shop.

LUNCH AND GUEST PRESENTATIONS

INTEGRA: A LARGE-SCALE STUDY TO DETERMINE THE IMPACT OF SRH-HIV INTERVENTIONS

Assessing integrated SRH and HIV services in Kenya, Swaziland and Malawi

Susannah Mayhew introduced the INTEGRA project, a collaboration between International Planned Parenthood Federation, London School of Hygiene and Tropical Medicine and Population Council in Kenya, Swaziland and Malawi, with the objectives of determining the benefits from different integrated models, the impact of different integrated services on HIV risk and fertility behaviours, the efficiency of different operational models, and utilization of the research findings by policy and program decision makers. Mayhew discussed the characteristics of the four integration models being piloted in Kenya and Swaziland and the range of research methods associated with the evaluations, including facility assessments, community surveys, cohort surveys, cross-sectional surveys and economic analyses.

Challenges include the complex implementation environment in all countries and marrying the rigorous multi-method evaluation research approach with the 'reality' of large-scale delivery of integrated HIV and SRH services.

Measuring unmet need for dual protection in Kenya: An analysis of community survey and family planning client cohort datasets

Kathryn Church delivered the second presentation from INTEGRA. Church presented the background to the study, discussing the current lack of standardised methods for measuring unmet need for dual protection. Church explained the methodology and discussed the definitions of the terms 'unmet need for FP' and 'unmet need for HIV prevention'. Those 'at risk' include clients who have attended STI services within the past 12 months, and/or those who have attended HIV care, or their partner has in the past 12 months, or those with more than one current sexual partner, or those who have never had an HIV test or do not know their status.

Church then discussed the 'risk profile' and determinants of unmet needs (for family planning and prevention). A 'risk profile summary' identified those with increased odds of unmet needs. Findings include the fact that a high proportion of women are at risk for unmet need for FP, with a lower proportion at risk for STIs, while the proportion at risk for both is lower still. More specifically:

Those at risk for unmet need for FP include those with the following characteristics: younger, not married, have secondary education, not the main earner, never had HIV test.

Those at risk for unmet need for prevention include those with the following characteristics: older, married, lower SES, nulliparous, have more sex partners, not been for FP services in past year

Church also looked at the characteristics of those FP clients with an unmet need for prevention. These include: married, lower education, Christian, manual workers, medium income, different fertility desires to partner, have more children, are HIV-negative or unknown status.

Limitations to the study include the crude estimates of unmet need due to weaknesses in measuring type of contraception used and consistency of condom use. Differences in indicator variables across surveys also make direct comparisons challenging. Further analysis is required to tease out potential effect modification.

SESSION 3: FUTURE INVESTMENTS IN IMPROVING DUAL PROTECTION INTERVENTIONS

Dual protection products and technology (Naomi Rutenberg)

In **Naomi Rutenberg's** absence, **John Townsend** delivered a presentation on **future investments in improving dual protection interventions**. Beginning with summarising the magnitude of the need for dual protection, the scope of dual protection technologies with regards to reducing risks of unintended pregnancy and HIV acquisition was considered in terms of technical feasibility, safety and acceptability.

Townsend noted the ARV-based products currently in development for HIV prevention, and then explained what is in the pipeline for dual protection. These include USAID-supported initiatives:

- 90-day combination vaginal ring with TFV and LNG (CONRAD)
- 60-day combination vaginal ring with a hormonal contraceptive (tbd) and dapivirine (IPM)
- Pericoital vaginal gel with MIV-150, Zn-acetate, carrageenan and LNG (Population Council)
- SILCS diaphragm with TFV gel –barrier device + drug (CONRAD, PATH).

And others including:

- Ferrous gluconate with AZT IVR (Weil MC, Cornell)
- Praneem polyherbal tablet (NARI, India)
- New versions of male and female condoms.

The non-hormonal contraceptive options were then discussed, and the question arose as to whether they can be paired with HIV prevention strategies. Barrier drug combinations and other options were looked at. Safety issues for both contraceptive products and HIV prevention options were examined next. While ARV-based HIV prevention strategies have raised concern over the emergence of resistance, specific ARV-based strategies have known safety side effects, including effects on bone density and kidneys. Technical feasibility options and challenges were discussed, although the regulatory path remains unknown.

Discussion questions began with the main acceptability and compatibility challenges. Questions included the compatibility of dual protection products with current service delivery strategies for family planning. Also raised was the issue of how routine HIV testing might be incorporated into family planning service provision. Final thoughts focused on what it would take to introduce the proposed formulations/delivery systems to users and providers in Sub Saharan Africa.

CONCLUDING GROUP DISCUSSION

What actions and investments are needed in research, policy guidance and implementation programming?

Tania Boler opened by summarising the Symposium recommendations. First, to look at the implications from the consensus body of evidence around hormonal contraception and HIV acquisition, with the recommendation of no policy change. For key populations, the recommendation would be to manage the provision and correct, consistent use of condoms. As one of a series of studies reporting the relationship between hormonal contraception and HIV acquisition, the Heffron et al. study must be put into context given the conflicting findings.

The issue of counselling is not clear-cut, in particular for frontline providers around combining advice and guidance on HIV prevention and avoiding unintended pregnancy, in particular the capacity to understand and communicate the nuanced risk and complex tradeoffs. Future investments include those around structure, technology and behaviour. New ways of providing the counselling were debated, and solutions included social marketing, media, and information dissemination. The issue of provider bias was raised. The importance of tools allowing a provider to assess risk quickly was emphasised. Text messaging through eHealth and mHealth can be an effective method of communication and assessment.

Further points discussed were focussed around operations research, and the need for qualitative research to better understand the behaviour of those regularly using dual protection. The changing landscape of HIV prevention, with male circumcision now a factor, was also raised. Finally, the group discussed the cost efficiency of integrated programming and the potential for undertaking research to look at cost efficiencies.

PARTICIPANT LIST

Participant	Organisation
Ian Askew	Population Council
John Townsend	Population Council
Patricia Atkinson	Marie Stopes International (MSI)
Tania Boler	MSI
Adrienne Testa	MSI
Heidi Quinn	MSI
Kate Worsley	MSI
Emma Simpson	MSI
Divya Bajpai	International HIV/AIDS Alliance
Felicia Wong	International HIV/AIDS Alliance
Veronique Filippi	London School of Hygiene and Tropical Medicine (LSHTM)
Joanna Busza	LSHTM
Suzanna Carter Francis	LSHTM
Susannah Mayhew	LSHTM
Isolde Birdthistle	LSHTM
Kathryn Church	LSHTM
Rebecca French	LSHTM
Rudiger Pittrof	LSHTM
Anna Guthrie	DFID
Jane Hobson	DFID
Andy Guise	IPPF
Karen Newman	Population and Sustainability Network

AGENDA

Objectives:

1. Provide a framework for thinking about policy development, implementation guidance and development of innovative interventions to strengthen dual/multiple protection strategies
2. Present an overview of evidence around HIV acquisition and hormonal contraception to frame policy considerations to be discussed at the WHO technical consultation
3. Generate recommendations for research and evidence strengthening

Time	Title	Presenter
10.30 – 11.00	Introduction and overview	Michael Holscher and Patricia Atkinson
11.00 – 12.00 (moderated discussion)	Session 1: The net contribution of hormonal contraception: unintended pregnancies and the risk of HIV transmission Body of evidence on hormonal contraception and HIV, biological mechanisms, and trade-offs of withdrawing DMPA and HIV infection, unintended pregnancies, maternal mortality, delivery options for hormonal contraception	John Townsend
12.00 – 13.00	Session 2a: What we can do right now to enhance dual protection? Proven approaches to program integration: Focus on reproductive rights, balanced counselling, improved availability of more methods, re-position condom Session 2b: Experiences from service delivery Integrating Services & Choices: The MSI Experience	Ian Askew Heidi Quinn
13.00 – 13.30	Lunch and guest presentation: INTEGRA: A large-scale study to determine the impact of FP-HIV interventions	Susannah Mayhew and Kathryn Church (LSHTM)
13.30 – 14.30 (moderated discussion)	Session 3: Future investments in improving dual protection interventions Dual protection products and technology	Naomi Rutenberg
14.30 – 15.00	Concluding group discussion: What actions and investments are needed in research, policy guidance and implementation programming?	Tania Boler

Symposium moderator: Emma Simpson