

Examining research through a programmatic lens

10-11 June 2013 • Boston, Massachusetts

Meeting Report

Executive Summary

In recent years, the world has seen significant reductions in maternal mortality. However, much work remains to be done in order to make preventable maternal deaths a thing of the past. To achieve this goal, the global health and development communities must focus their efforts on the leading causes of maternal death around the world.

According to recent estimates from the London School of Hygiene and Tropical_Medicine (LSHTM), pregnant women living with HIV are eight times more likely to die than women without HIV. Additionally, approximately a quarter of deaths during pregnancy and the post-partum period in sub-Saharan Africa are attributable to HIV. Women and girls are increasingly and disproportionately affected by the HIV/AIDS epidemic and now comprise over half of those living with HIV. The feminization of the HIV and AIDS epidemic is a critical factor that is limiting progress in the reduction of maternal mortality.

As the global community discusses bold visions for new targets to reduce maternal mortality, researchers from both HIV and maternal health communities must come together to share knowledge and build a path to improved, women-centered, evidence-based programming. With this goal in mind, the Maternal Health Task Force (MHTF), the United States Agency for International Development (USAID), and the Centers for Disease Control and Prevention (CDC) jointly convened a technical meeting to lay the groundwork for ongoing collaboration between the HIV and maternal health communities—including a proposed dialogue on integrated programming and further discussion at global HIV and maternal health meetings and conferences later in 2013 and 2014.

This report summarizes the discussions, emerging themes, and next steps from the technical meeting <u>Maternal health, HIV, and AIDS: Examining research through a programmatic lens</u>. With support from the Bill & Melinda Gates Foundation (BMGF) and guidance from a steering committee (detailed in Appendix A), the MHTF, in collaboration with USAID and the CDC, convened the meeting in Boston, Massachusetts from June 10-11, 2013.

Meeting participants were invited based on their expertise and recent research in HIV and/or maternal and newborn health in varying geographic settings. Fifty-six people from developed and developing countries attended the meeting (Please see Appendix B for the complete list of participants and Appendix C for the meeting agenda.)

The meeting focused on sharing emerging research linking maternal health and HIV, identifying research gaps, considering programmatic implications, exploring opportunities for collaboration, and determining next steps for improving partnerships between the HIV and maternal health communities. While the intersection of maternal health and HIV is a critical issue around the world, this meeting focused on sub-Saharan Africa, where 90% of pregnant women with HIV reside.

Over the course of the meeting, six prominent themes arose as critical issues relating to the current state of maternal health, HIV, and AIDS in sub-Saharan Africa: 1) a need for better data and real numbers; 2) challenges with addressing comorbidities; 3) the importance of strengthening health systems; 4) the need to develop integrated approaches to maternal health and HIV services; 5) issues with equity and access to health services; and 6) major challenges with HIV stigma, discrimination, disrespect, and abuse.

List of Acronyms

AIDS acquired immunodeficiency syndrome

ANC antenatal care

ART antiretroviral therapy

CDC Centers for Disease Control and Prevention EGPAF Elizabeth Glaser Pediatric AIDS Foundation

HIV human immunodeficiency virus

LSHTM London School of Hygiene and Tropical Medicine

MHTF Maternal Health Task Force MMR maternal mortality ratio

MNCH maternal, newborn, and child health MTCT mother-to-child transmission (of HIV)

NIH National Institutes of Health

OGAC Office of the Global AIDS Coordinator

PCC preconception planning, counseling and care

PMTCT prevention of mother-to-child transmission (of HIV)

SSA sub-Saharan Africa

USAID United States Agency for International Development

WHO World Health Organization

1. Introduction

In recent years, the world has seen significant reductions in maternal mortality. However, much work remains to be done in order to make preventable maternal deaths a thing of the past. To achieve this goal, the global health and development communities must focus their efforts on the leading causes of maternal death around the world.

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In addition to this meeting and as part of the MHTF's recent work to foster dialogue between the maternal health and HIV communities, the MHTF also launched a <u>blog series</u> (on the MHTF Blog) with posts from experts working to address maternal health, HIV and AIDS throughout sub-Saharan Africa and around the world. Authors addressed topics such as lessons from specific countries, organizations, and projects; experiences managing HIV-related comorbidities and obstetric complications; approaches used in a specific country to integrate and improve maternal health and HIV prevention, treatment, or care; and analyses of persistent barriers to integrating and/or improving quality of maternal and HIV care for women.

The MHTF team utilized a number of online tools to share the meeting proceedings with the broader global health community in real-time and at the end of each day. The MHTF engaged colleagues around the world on Twitter (hashtag #MHHIV), posted daily updates from the meeting on the MHTF Blog, captured and shared photos in a Flickr photo gallery, and used Storify to publish daily summaries (Day 1 and Day 2) of the meeting discussions.

2. Meeting Objectives and Deliverables

The meeting objectives, developed in collaboration with the steering committee, were as follows:

- 1) Share findings of recent research on the linkages between HIV and maternal/pregnancy-related outcomes, including mortality
- 2) Identify and discuss research findings with important programmatic implications, including analysis of current models of HIV and maternal, newborn, and child health (MNCH) care throughout the pregnancy, delivery and postpartum periods
- 3) Develop conclusions and recommendations on research and practice, identify research gaps, and establish a forum for further collaboration

The meeting deliverables included:

- 1) Identify strategies for continued collaboration (i.e. a technical working group to be housed within an existing HIV organization, where sub-committees will continue specific pieces of work identified at the meeting)
- 2) Develop recommendations for translating research into enhanced programs for women living with HIV (with short, medium, and long-term goals)

3. Meeting Sessions

The first day-and-a-half of the meeting consisted of presentations and discussions by researchers working on maternal health, and/or HIV and AIDS programs throughout sub-Saharan Africa. Day one of the meeting focused on sharing current research around three broad themes: an overview of maternal health, HIV, and AIDS; HIV, AIDS, and comprehensive reproductive health care (including preconception, postpartum morbidity and mortality and nutritional management); and barriers to care.

Day two of the meeting revolved around new policy guidelines for antiretroviral treatment among pregnant women and the resource and programmatic challenges, ethical and medical issues, and relevant country experiences with implementing Option B+. (Please see Appendix D for summaries of the presentations from day one and two.)

In the afternoon of day two, meeting participants broke into small working groups to discuss knowledge gaps and next steps for improving the quality of maternal health and HIV services in sub-Saharan Africa. The groups focused on five main issues: 1) reproductive health services for women living with HIV (preconception counseling and postpartum contraception), 2) antenatal care, 3) intrapartum/postpartum care, 4) behavior change, and 5) measurement. Within each topic area, groups discussed which approaches and interventions have adequate evidence to implement now and which approaches and interventions require additional research. (Please see section 5 of this report for more information on the working groups.)

4. Major Themes

Over the course of the meeting, six prominent themes arose as critical issues relating to the current state of maternal health, HIV, and AIDS in sub-Saharan Africa:

1. Need for better data and real numbers

Significant knowledge gaps about the relationships between maternal mortality and morbidity and HIV remain. Better information is needed to inform clinical guidelines and for policy and programmatic decision-making in sub-Saharan Africa.

South Africa currently serves as an example for the region in terms of effective ways to implement data collection. The country has a long-standing and well-established system of Maternal Death Reviews. According to the World Health Organization, South Africa is one of only four African countries to have a strong civil registration and vital statistics system. In addition, South Africa has a wealth of data on maternal health and HIV due to the fact that most South African women deliver in hospitals, where data are routinely collected.

For other countries and the region as a whole, much of what is known about maternal health and HIV is based on estimates both in terms of the number of deaths and the cause of death. Further, the limited data and real numbers available often come from facility-based studies, which do not reflect the significant proportions of women who deliver at home in much of the region. Challenges with data quality and completeness also limit the accuracy of maternal death reporting, especially when using clinical records and verbal autopsies. Due to incomplete information about HIV status and failures to link women's serostatus with death records, it is often difficult to discern whether HIV might have contributed to a maternal death or maternal morbidity. Misclassification of maternal death may bias our understanding of the magnitude and causes of maternal death.

The WHO is currently implementing a new maternal death classification system that aims to facilitate more reliable comparisons between countries and regions. Ideally, it will also help to identify health system shortfalls that need to be addressed. However, given the data limitations mentioned above, this new system will not solve all of the challenges with data quality. There is an urgent need to validate new approaches to identifying causes of maternal mortality, possibly through the use of improved verbal autopsy questionnaires and algorithms as well as novel technologies such as a minimally invasive autopsy.

2. Challenges with addressing comorbidities

In settings with a high prevalence of HIV and AIDS, the global health community is now seeing a larger proportion of maternal deaths attributable to indirect causes of death (eg. infectious diseases including HIV, tuberculosis, malaria, pneumonia, etc.) as opposed to direct obstetric causes of maternal mortality. Malaria and tuberculosis have complicated and deleterious interactions with HIV and pregnancy. HIV infection increases the likelihood of reactivation of tuberculosis and tuberculosis-related mortality, and is a leading cause of maternal mortality among pregnant and postpartum women living with HIV. HIV coinfection with malaria also increases the prevalence and severity of malaria in pregnant women and has been associated with poor maternal and newborn health outcomes. HIV is also correlated with a threefold increase in women's risk of sepsis, including post-abortion

and post-caesarian sepsis. Comorbidities result in an increasing burden of maternal morbidity, too. While much is known about HIV-related comorbidities, questions remain about their relationship to maternal health outcomes. Screening and providing appropriate treatment for co-infections such as tuberculosis and malaria, as well as addressing sepsis and pneumonia among pregnant and post-partum women present both clinical and health systems challenges. In addition, research questions remain about drug interactions and fetal exposure during pregnancy.

Access to antiretroviral treatment for the benefit of the mother (in addition to reducing vertical HIV transmission) and the option of remaining on treatment for life after pregnancy (Option B+) are relatively recent developments for women in sub-Saharan Africa. While there are indications that expanded access to ART can reduce maternal mortality and morbidity, there are also data to suggest that women living with HIV may continue to experience higher complication rates, morbidities, and mortality even when on treatment. There is an urgent need to track and address the causes of maternal mortality and morbidity among women living with HIV as access to antiretroviral treatment is scaled up in sub-Saharan Africa, as well as to understand and address potentially adverse impacts of ART on maternal and infant health.

3. The importance of strengthening health systems

Addressing HIV and maternal health requires an integrated functioning health system, which requires looking beyond service delivery to address issues such as the health work force, information systems, community involvement, and procurement and distribution systems. The intersections of the feminized HIV pandemic and the maternal mortality epidemics in sub-Saharan Africa simultaneously demand more sophisticated responses and stretch existing resources to the breaking point. Research demonstrates that human resources are insufficient to carry out required tasks, affecting quality and coverage. Existing platforms for delivering health services (such as the antenatal care platform) are overburdened and have insufficient resources to carry out both maternal health and HIV services. While task-shifting and task-sharing are promising, there are frequently too few providers with whom to shift or share tasks. Health management information systems are frequently in need of strengthening and are not used to inform decision-making. Likewise supply chains for medications and other commodities face challenges across the continent. Seizing the opportunities to address the HIV pandemic and improve maternal health will require significant investments in health systems. For instance, discussions of provision of lifelong ART to women after pregnancy (Option B+), made abundantly clear the significant additional resources and multiple aspects of health system strengthening that are needed to successfully implement this program.

4. The need to develop integrated approaches to maternal health and HIV services

An integrated approach to service delivery, an approach that meets women's multiple health needs during the same visit and in the same health facility (and potentially by the same providers), could optimize women's contact with the health system and be an effective use of scarce human and financial resources. Areas where progress on integration is particularly crucial include the diagnosis and treatment of malaria and tuberculosis among pregnant and post-partum women and the provision of a full-range of

reproductive health services to women living with HIV, including pre-conception counseling and contraception. Significant health gains could be made by addressing malaria, tuberculosis, and HIV in an antenatal and postnatal care setting. Further, effective contraception continues to be under-utilized in many countries with high levels of maternal mortality and HIV, and women with HIV in sub-Saharan Africa report significant unmet need for family planning. As access to ART is scaled-up, fertility among women living with HIV may increase for both biological and behavioral reasons. Preventing unwanted pregnancy among women with HIV and offering the services necessary for women to make informed reproductive choices in MCH and HIV care is an effective way to prevent vertical HIV transmission and can contribute to preventing an array of issues including mortality.

The danger of integration is that adding additional services could prove to be an excessive burden on already under-resourced and over-burdened health systems throughout sub-Saharan Africa. Participants noted that more exploration into effective approaches to integration is needed.

5. <u>Issues with equity and access to health services</u>

The issue of equity is central to conversations about addressing maternal health and HIV challenges in sub-Saharan Africa. As mentioned earlier in this report, the burden of the intersecting epidemics of maternal mortality and HIV is greatest in sub-Saharan Africa. Improving the health of women in this region requires the global health community to focus on access and equity in efforts to tackle maternal mortality, HIV, and access to family planning. Equity also comes into play when considering the differences in access to care between pregnant (or recently pregnant) and non-pregnant women. Women living with HIV who have not been pregnant are more likely to die than women living with HIV who have had a recent pregnancy (probably due to the "healthy pregnancy effect"), which highlights the need to include all women in access to treatment initiatives, looking beyond the ANC platform. Finally, questions remain about balancing resource distribution between prevention and treatment programs—pointing to yet another question of equity.

6. Major challenges with HIV-related stigma, discrimination, disrespect, and abuse

While significant investments are being made in increasing access to ART, initiation and adherence for pregnant and post-partum women remain suboptimal. Identified barriers to seeking and remaining in care include gender-discrimination, HIV-related stigma and disrespect and abuse in maternal health services. Poor mental health status, including post-partum depression, and experiences of violence during pregnancy and in the post-partum period also negatively impact adherence to treatment, as well as other aspects of women's health.

Creating an enabling and respectful environment for pregnant and postpartum women to begin and remain in care will require a holistic approach. The approach will need to include: promotion of male engagement through family-centered HIV and maternal care; interventions that focus on reducing stigma; and programs that defend the health and human rights of all people living with HIV, including pregnant and post-partum women.

5. Recommendations for Translating Research into Enhanced Programs

On the final afternoon, participants broke out into small working groups. Based on the meeting's presentations and discussions, the groups identified critical interventions related to maternal health and HIV services. They then discussed whether the global health community has adequate experience implementing these interventions in various contexts and/or if additional research and evidence is needed for scale-up of these interventions. These discussions resulted in recommendations to translate research into enhanced programs to improve access to and the quality of maternal health and HIV services.

Watch the <u>video</u> of the small groups reporting on their discussions.

Group 1: Reproductive Health Services for Women living with HIV: Preconception Counseling and Postpartum Contraception: Programmatic Recommendations and Research Needs

Group 1 developed the following programmatic recommendations:

Recommendation	Suggestions	Comments/Notes
Improve service coverage and quality for all women of reproductive age	 Task shifting Using Job aids or checklists to incorporate pre-conception counseling into HIV care 	
Preconception Counseling for women living with HIV and their partners	 Conduct provider training Support disclosure of HIV status Expand HIV testing in community, ANC, FP, etc. Education about ART as prevention for safer conception (e.g. reduced viral load reduces transmission) 	
Provide RH Counseling and Services to women living with HIV	 Support informed decisions around fertility of women living with HIV Counseling on contraceptive methods Establish linkages with postpartum care Promote dual methods especially among women using DMPA Provide safe abortion and emergency contraception 	ART may increase fertility Increased HIV transmission risk with Depo-Provera (DMPA)
Engage men	 Provide family centered care Engage men to be supportive of partners and own health needs Promote HIV testing and disclosure 	

Group 1 identified the following research needs:

Theme	Research Questions	Next steps
Develop and test models of care for preconception counseling	 What do people living with HIV and HC providers know and communicate about serodiscordance and treatment as prevention? How will knowledge from preconception counseling impact reproductive desires and behaviors? What is the best way for providers to implement preconception counseling? How and for how long is it important to provide periconception preparation for serodiscordant partners? Questions around increased access to ART 	
Develop and test methods for effective family planning among women living with HIV	 How to effectively promote dual method use? How to address safe abortion services? 	
Engaging men in these processes	 How to involve and engage men in counseling and testing? How to involve and engage men in reproductive health services? 	

Group 2: Antenatal Care: Programmatic Recommendations and Research Needs

Group 2 developed the following programmatic recommendations:

Recommendation	Suggestions	Notes/Comments
Encourage ANC visits for all women		
Screen all women for HIV, TB, malaria (in endemic areas), anemia, and syphilis	Use Ward hemoglobin meterUse dual syphilis and HIV test	
Promote re-testing (and partner testing)		

Improve quality of ANC care	 Implement integrated ANC service models that address patient flow, 	
AIVC care	confidentiality, and adherence to	
	treatment	
	 Use clinical decision tools and job 	
	aids	

Group 2 identified the following research needs:

Theme	Research Questions	Next steps
Malaria in pregnancy and HIV	 What are the relative adverse and positive health outcomes of routine iron supplementation in malaria endemic areas? Do the costs/benefits change where endemic malaria co-exists with HIV? 	
TB screening	 What is the cost effectiveness of screening HIV-negative pregnant women for TB in areas with low HIV seroprevalence? 	
TB treatment and safety in pregnancy	 What is the safety and effectiveness of isoniazid during pregnancy? (NIAID study results in 2016) 	
TB treatment	 What are the best methods for excluding TB before initiating isoniazid prophylaxis in pregnant women? 	

${\it Group~3: Interpartum/Postpartum~Care: Programmatic~Recommendations~and~Research~Needs}$

Group 3 developed the following programmatic recommendations:

Recommendation	Suggestions	Notes/Comments
Strengthen health systems	 Ensure access to BEmONC within 2 hours of birth Support functional transport systems Strengthen HR staff and skills (including counseling) Promote monitoring and evaluation Promote quality assurance systems Ensure commodities and procurement systems Provide clinical updates and 	

Recommendation	Suggestions	Notes/Comments
	training	
Improve quality of intrapartum care	 Rapid HIV testing (if status unknown) Provide clean and safe birth – history taking, AMTSL, partograph, resuscitation, ENC, delayed cord clamping, etc) Increase length of stay after 	
	delivery Implement expanded differential diagnosis Utilize job aids Test HIV-exposed infant Provide PMTCT onsite	
Improve availability of intrapartum services	Increase availability of BEMONC services (24/7 coverage) and referral to CEMONC within 2 hours	
Improve availability of laboratory services	 Promote appropriate testing for women living with HIV (CD4, LFT, RPR, TB screening, etc.) 	
Improve pre- discharge counseling and care	 Targeted FP counseling and evaluation, including PAC services Support uptake of ART onsite (for woman and baby) Accompany woman to HIV care clinic Breastfeeding counseling Promote newborn circumcision 	
Improve postpartum care	 Home visit 48 hours after discharge Home visit on Day 7 for screening and referral Supportive supervision for community visits Facility visit at 2 weeks (post ART follow up) Facility visit at 6 weeks (linked with immunization) 	

Group 3 identified the following research needs:

Theme	Research Questions	Next steps
HIV and treatment status and clinical management for women and newborns in the intrapartum and postpartum period	 What are the causes of maternal/pregnancy-related deaths among women living with HIV and how should treatment be improved to address these causes? Should sepsis management practices be different for women living with HIV? Is elective cesarean section safe for women living with HIV who are not on ART? 	
HIV testing for newborns	 What is the optimal timing of cotrimoxazole prophylaxis for HIV- exposed infants? (4-6 weeks or earlier? Breastfeeing?) 	
Human resource needs	 What is the minimum number of providers needed to provide quality integrated care? What is the optimal mix of provider skills? Opportunities for task shifting? What are the outcomes of crosstraining CHWs in MCH and HIV? 	
Key interventions to support initiation of treatment, facilitate retention in care, and improve ART adherence	 How can we link HIV care to respectful maternity care and reduction of HIV-related stigma and discrimination most effectively? What are the most effective models for reducing disrespect and abuse in maternity care and reducing HIV-related stigma and discrimination? How do such interventions impact on the uptake of and retention in MCH and HIV services and health outcomes? 	
Linkages from MCH to HIV care	 Which integration MCH/HIV models are most effective to deliver HIV care (and initiation and retention of ART)? Does delaying discharge of women living with HIV diagnosed during labor and delivery improve update of HIV services and health outcomes? 	
Adolescents	 What are the specific health needs and outcomes for adolescents living with HIV in MCH, HIV, and FP care? 	

Group 4: Behavior Change: Programmatic Recommendations and Research Needs

Group 4 developed the following programmatic recommendations:

Recommendation	Suggestions	Notes/Comments
Peer-based and community social support for pregnant and postpartum women (living with HIV and HIV-)	 Mothers@mothers Peer mentors Mentor mothers Participatory women's groups 	More research needed for women's groups in HIV context
Participatory behavior change interventions focused on changing gender norms, empowering women, and decreasing intimate partner violence	 IMAGE study in South Africa Stepping Stones Couple HIV testing and counseling Sensitivity training for health workers 	More research on institutionalizing couple testing with safe disclosure (see below)

Group 4 identified the following research needs:

Theme	Research Questions	Notes/Comments
Couple testing	 What are innovative methods to implement and institutionalize couple testing that respect confidentiality and support safe disclosure? 	
SMS/Mobile Health	What is the evidence around mobile applications, technologies, or SMS and their impact on care seeking, reaching hard-to-reach populations and overcoming gender norms?	
Evaluation packages of interventions	What are the impacts of peer- based, participatory community- based interventions and structural interventions (e.g. microfinance) individually and in combination on maternal health outcomes in the context of HIV and how do we	

 measure those outcomes? Developing and evaluating the impact of interventions which target older, influential women and mothers-in-law and male partners as social supports for women of 	
 reproductive age Developing and evaluating the impact programs that target involving men and expectant fathers 	

Group 5: Measurement and Data: Programmatic Recommendations and Research Needs

Group 5 developed the following programmatic recommendations:

Recommendation	Suggestions	Next steps
Improve collection, review and use of data Improve collection of data at the	 Implement Maternal Death Surveillance and Response (MDSR). MDSR processes include engaging and community, facility and national levels, monthly review of data, use of consistent monitoring framework across sites, feedback loop Implement participatory community data collection and verbal autopsies 	
community level	·	
Harmonizing data collection platforms to have comparable data	Implement unique identifiers to track women across multiple registers	

Group 5 identified the following research needs:

Theme	Research Questions	Next steps
Improve quality of data	 How can we improve medical records, death certificates, and verbal autopsies to include a core set of key variables - cause of death, contributors (HIV, TB, malaria, etc.), pregnancy status, treatment status and regimen, timely and quality of BEmONC and 	

Theme	Research Questions	Next steps
	CEmONC received.	
Impact of information/data on service delivery	 How can a combination of approaches (MDSR, community data collection, etc.) be utilized to improve service delivery and health outcomes? What data sources have the best predictive power to identify causes of death? What information can be collected through routine systems as opposed to sentinel sites? 	
Improve verbal autopsies	 How can we improve verbal autopsies among women living with HIV, including validating existing tools as well as testing minimally invasive autopsies? 	

6. Conclusion and Next Steps

The meeting participants were in agreement that research findings call for service delivery paradigms that go beyond episodic care and siloed interventions toward a model of holistic care. These new paradigms will need to focus on the continuum of care and address women's health throughout the lifecycle, and not only as it relates to pregnancy and neonatal outcomes. Part of this more inclusive and holistic paradigm will be consideration of how best to innovate, evaluate, and scale-up models which link women (and other family and community members) to high quality, respectful health care services which may, in turn, assist in adherence to antiretroviral treatment. Obviously, the shared goal is to improve health outcomes and quality of life.

Theses ideas fed into a final plenary discussion led by David Stanton that resulted in a preliminary list of next steps. Participants shared numerous ideas for advancing the maternal health, HIV, and AIDS agenda:

- Include maternal health and HIV on the agenda of global leadership working groups like OGAC and UNAIDS
- Write a commentary to raise the profile of HIV and maternal health
- Develop a journal supplement on maternal health, HIV, and AIDS
- Convene a programmatic-oriented meeting for later this year
- Convene smaller, targeted meetings on the specific issues (stigma/respectful care, preconception care, etc)
- Convene in-country or regional meetings that bring the maternal health and HIV/AIDS communities together to discuss the issues and collaboration
- Invite leadership from country governments, civil society and networks of women living with HIV
- Organize webinars on these topics

A smaller group of meeting participants carried these ideas forward into a smaller discussion the next day, to identify priorities for a research and evaluation agenda on HIV and maternal health in sub-Saharan Africa.

Appendix A: Steering Committee Members

Jean Anderson (Johns Hopkins Center for Global Health, Jhpiego)
Stef Bertozzi (Bill & Melinda Gates Foundation)
Wafaie Fawzi (Harvard School of Public Health)
Adeodata Kekitiinwa-Rukyalekere (Baylor University)
Marge Koblinsky (USAID Office of Health, Infectious Disease, and Nutrition)
Carine Ronsmans (London School of Hygiene and Tropical Medicine)
David Stanton (USAID Office of HIV/AIDS)

Appendix B: Participant List

Jenny Albertini (USAID, Africa Bureau)

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Jean Anderson (Johns Hopkins Center for Global Health, Jhpiego)

Debbie Armbruster (USAID, Office of Health, Infectious Disease and Nutrition)

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Doris Chou (World Health Organization)

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Hoosen Coovadia (University of Witwatersrand)

Anna Coutsoudis (University of Kwazulu Natal)

Kelly Curran (Maternal and Child Health Integrated Program)

Isabella Danel (Centers for Disease Control and Prevention)

Margarett Davis (Centers for Disease Control and Prevention)

France Donnay (Bill & Melinda Gates Foundation)

Wafaa El-Sadr (Columbia University)

Wafaie Fawzi (Harvard School of Public Health)

Laura Fitzgerald (Jhpiego)

Karen Fogg (USAID, Office of Health, Infectious Disease and Nutrition)

Esiru Godfrey (Ministry of Health, Uganda)

Anja Giphart (Elizabeth Glaser Pediatric AIDS Foundation)

Kate Grindlay (Ibis Reproductive Health)

Edna Ionas (Management Sciences for Health)

Frank Kaharuza (School of Public Health, Makerere University)

Angela Kaida (Simon Fraser University)

Tamil Kendall (Maternal Health Task Force)

James Kiarie (University of Nairobi)

Karusa Kiragu (UNAIDS)

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Timothy Thomas (Harvard School of Public Health)
Janet Turan (University of Alabama at Birmingham)
Heather Watts (National Institutes of Health)
Mary Nell Wegner (Maternal Health Task Force)
Rebecca Zash (Beth Israel Deaconess Medical Center)

Appendix C: Meeting Agenda



Day 1 • June 10, 2013 • Kotzen Room • Simmons College

MORNING SESSION				
8:00-9:00	BREAKFAST			
9:00-9:30	OPENING/WELCOME	Ana Langer, David Stanton, and Isabella Danel		
9:30-10:00	Women at the crossroads: HIV, reproductive health, maternal mortality, and child health	Wafaa El-Sadr		
	Q and A			
10:00-10:30	COFFEE BREAK			
10:30-12:00	MATERNAL HEALTH, HIV, AND AIDS: WHERE ARE WE NOW?	Moderator: Marge Koblinsky		
	Contribution of HIV to pregnancy-related mortality	Clara Calvert		
	Causes of death and impact of treatment – what do we know?	Isabella Danel		
	Neglected causes of maternal mortality	Clara Menendez		
	Q and A			
12:00-1:00	LUNCH			
AFTERNOON SESSION				
1:00-2:30	HIV, AIDS, AND MATERNAL HEALTH CARE	Moderator: Diane Cooper		
	Safe conception and preconception planning, counseling, and care	Jean Anderson		
	HIV and postpartum morbidity/mortality	Tshidi Sebitloane		
	Nutritional management of HIV infected women of reproductive age	Wafaie Fawzi		
	Q and A			
2:30-3:00	COFFEE BREAK			
3:00-5:00	ENABLING RESOURCES AND BARRIERS TO CARE	Moderator: James Kiarie		
	Maternal health in the era of antiretroviral therapy (ART): A review of the literature	Edna Jonas		
	Stigma and discrimination as barriers to achievement of global PMTCT and maternal health goals	Janet Turan		
	Reproductive health decision-making among women living with HIV	Lisa Messersmith		
	Gender inequality and inequity as barriers to access maternal health care: a case of PMTCT service	Nomafrench Mbombo		
	Q and A and wrap up of day 1			
	CLOSE OF DAY 1			



Day 2 • June 11, 2013 • Kotzen Room • Simmons College

MORNING SESSION				
8:00-8:45	BREAKFAST			
8:45-9:00	RECAP OF DAY 1	Heather Watts		
9:00-9:30	New maternal mortality classification system Q and A	Doris Chou		
9:30-10:45	LIFELONG ART FOR PREGNANT WOMEN: BENEFITS, TRADE-OFFS, AND THE RESEARCH NEEDED TO OPTIMIZE MATERNAL, PERINATAL, AND COMMUNITY HEALTH OUTCOMES	Moderator: Tamil Kendall		
	Resource and programmatic considerations and issues	Karusa Kiragu		
	Ethical and medical considerations and issues	Anna Coutsoudis		
	Discussion and identification of key research questions	Hoosen Coovadia		
	Q and A			
10:45-11:15	COFFEE BREAK			
11:15-12:30	RELEVANT EXPERIENCES IMPLEMENTING B+	Moderator: Jenny Albertini		
	Rollout of option B+: A multi-country experience	Anja Giphart		
	Scientific and programmatic advances in PMTCT: To B or to B+	Roger Shapiro		
	New policy guidelines increase utilization of services for elimination of mother-to-child HIV transmission in Uganda	Esiru Godfrey		
	Q and A			
12:30-1:30	LUNCH			
AFTERNOON	SESSION			
1:30-3:00	Breakout groups	Allisyn Moran		
3:00-3:30	COFFEE BREAK			
3:30-4:30	Report out from small groups	Isabella Danel		
4:30-5:00	Next steps and close	Ana Langer and David Stanton		
	CLOSE OF MEETING			

Appendix D: Session Summaries

Day One

The first day of the meeting focused on sharing current research around three broad themes: an overview of maternal health, HIV, and AIDS; HIV, AIDS, and maternal health care; and enabling resources and barriers to care.

Ana Langer (MHTF) opened the meeting by describing the role of the Maternal Health Task Force, pointing out that one of our major roles is to bring together communities to address neglected issues. She also outlined the primary task for the day: Examine the existing research on maternal health and HIV and put it in the hands of those who need it most.

David Stanton (USAID) provided important context for the issue, noting that two-thirds of HIV infections occur in Africa, and two-thirds of those infected are women. Stanton also reminded participants to consider that HIV infections occur in a broader world with many variables. Sexual violence and access to contraception, among other factors, are also critical to this conversation.

Isabella Danel (CDC) offered a brief summary of what we know about the huge attributable risk of maternal mortality from HIV. She challenged meeting participants to think and identify the critical and remaining research gaps on this topic.

Wafaa El-Sadr (Columbia University) provided the keynote speech, titled "Women at the crossroads: HIV, reproductive health, maternal mortality, and child health." With women at the crossroads of the HIV epidemic, El-Sadr reminded participants that what we learn from HIV should inspire us to think differently about issues on which we have not made much progress. Participants should take this momentum, learn from HIV, and ask what they can do moving forward. El-Sadr organized her presentation around five main areas: the challenge of HIV, the HIV response, lessons learned, maternal and child health, and conclusions. She highlighted the disproportionate burden of HIV in sub-Saharan Africa, stating that the epidemic "rages on" with 34 million people living with HIV. El-Sadr explained that the HIV epidemic has motivated a transformation of the health system in sub-Saharan Africa and challenged the usual paradigm for delivering health care. While we have seen progress on improvements in maternal health, we would have seen even more maternal health progress had we had made more progress on HIV. Based on the lessons learned from HIV, new paradigms must go beyond episodic care and a single solution. The focus must be on the continuum of care. El-Sadr reminded the audience that when we talk about maternal health and HIV, we cannot escape issues of child and infant health and their relationship to this conversation. She also discussed lessons learned from HIV for the health system, noting that HIV has forced the global health community to think about the health system beyond service delivery to include the health work force, information systems, prevention, etc. In addition to thinking about the health system, issues of access and equity have been crucial for addressing HIV. El-Sadr said that the global health community should focus on access and equity when tackling maternal mortality and access to family planning. She concluded with a discussion on moving from discovery to scale up as it relates to maternal health and HIV. El-Sadr said that, sadly, many global health discoveries sit on bookshelves in medical journals. We need to move more efficiently from discovery to implementation.

Watch the <u>video</u> of El Sadr's presentation.

Marge Koblinsky (USAID) moderated the first panel titled, "Maternal health, HIV, and AIDS: Where are we now?" Speaking somewhat "off the record," Koblinsky said that she and others are shooting for setting a new goal of "50 by 2035." She reiterated several times that, in setting new goals like a major reduction in maternal mortality to a MMR of 50 by 2035, it will be important to be plausible yet aggressive. HIV/AIDS, tuberculosis, high fertility, and other global health issues are playing a role in slowing progress to reduce maternal deaths. Koblinsky encouraged panelists and meeting participants to consider how can we implement programs to reduce maternal mortality, taking in to consideration the various factors contributing to maternal mortality, and how we measure accountability at the country level.

Clara Calvert (LSHTM) presented the findings of her recent research that aims to better understand the "Contribution of HIV to pregnancy-related mortality." She posed three big questions to the audience: (1) What is the attributable risk of HIV; (2) Might HIV increase risk of obstetric complications (i.e. sepsis, malaria, anemia during pregnancy, etc.); and (3) Might pregnancy accelerate progression of HIV? Calvert's research found that women living with HIV have nearly 8 times the risk of death during pregnancy compared to women without HIV. In West Africa, 6 % of maternal deaths are attributable to HIV, whereas 17 % of maternal deaths in East Africa are attributable to HIV and 53% of maternal deaths in Southern Africa are attributable to HIV. Calvert's research suggests that HIV increases a women's risk of sepsis by 3 times. Direct obstetric complications likely comprise a small fraction of excess HIV-related mortality among pregnant women. Big questions remain as do implications for understanding and thinking about how to address HIV among pregnant women.

Watch the <u>video</u> of Calvert's presentation.

Isabella Danel (CDC) reviewed "Causes of death and impact of treatment - what do we know?" Like Calvert, Danel raised three main questions at the start of her presentation: (1) What do we know about the major causes of death among women with HIV during pregnancy and postpartum; (2) Do we know if pregnancy worsens HIV progression; and (3) What do we know about the impact of treatment? Danel explained that much of what we know about maternal health and HIV is based on estimates. We need better data and real numbers. The challenge with most studies on maternal health and HIV is that they are institution-based studies. What about women who deliver at home? Danel spoke in detail about the role of indirect infectious deaths, noting that co-infection with tuberculosis is a leading cause of maternal mortality in settings with a high HIV burden. HIV infection increases the reactivation of tuberculosis and tuberculosis-related mortality. Co-infection with malaria is also common among individuals with HIV, as HIV increases the prevalence and severity of malaria. Mental health and violence are also critical in these discussions, as they have a big impact on adherence to treatment. Furthermore, Danel noted that there appears to be an increased risk of puerperal sepsis (especially after cesarean section) and abortion related sepsis. Though it is still unclear how much ART will improve maternal health outcomes, there is a need for more ART and sooner. Remaining issues include challenges with data quality and completeness, a need for integrated antenatal care, and a need for screening for depression. Danel concluded that pregnancy does not appear to accelerate HIV disease progression, and there is no evidence of increased risk of death from AIDS in pregnant women living with HIV versus non-pregnant women living with HIV.

Watch the <u>video</u> of Danel's presentation.

Clara Menendez (University of Barcelona) spoke about "Neglected causes of maternal mortality" and explained that a big barrier to achieving MDG 5 in Africa has been that interventions have not

been evidence-based. She said that the main sources of data on cause of death come from clinical records and verbal autopsies, both of which come with big limitations. Menendez's recent work in Mozambique showed that many maternal deaths resulted form malaria despite malaria not being typically considered a major contributor to maternal mortality in Africa. The same study found a majority of indirect maternal deaths were attributable to HIV/AIDS, bronchiopneumonia, and malaria. Menendez noted the prevalence of major diagnostic errors by pathology at autopsy. While the gold standard is a complete diagnostic autopsy, there is an urgent need to validate to newer approaches. Menendez discussed work underway for a minimally invasive autopsy that could be performed or guided by low-cost ultrasound machines (or possibly even without these machines).

Watch the <u>video</u> of this Menendez's presentation.

Watch the <u>video</u> of the Q/A from the previous sessions.

Doris Chou (World Health Organization) via Skype, presented, "The WHO Application of ICD-10 to deaths during pregnancy, childbirth, and puerperium: ICD-MM" which looked at section 5a of the Millennium Development Goals. She warned that even the coding rules of ICD-10 are inconsistent, and how misclassification and loss of number of and cause of maternal deaths may hinder our grasp on the actual magnitude surrounding maternal deaths. Misclassification is most seen with deaths associated with cardiovascular, CNS disorders, injuries and indirect conditions. She emphasized the importance of filling out MCCD forms properly and completely so that data is accurate and full. With classifications, it should be noted that there should be only one underlying cause of death, and that cause should be exclusive of all other associating conditions. She noted that obstructed labor, anemia, suicide, and HIV are no longer 'causes' of death, as they are tied to many other factors which are actual causes of death. Chou concluded by suggesting that the maternal death classification system should be used by all countries so that data can be compared amongst countries and regions, and can help identify pitfalls in the health care system of those areas that better need to address maternal mortalities. The full document relating to this presentation can be found here.

Watch the <u>video</u> of Chou's presentation.

Jean Anderson (Johns Hopkins Center for Global Health, JHPIEGO) began the second panel, "HIV, AIDS, and Maternal Health Care," with a presentation on "Safe Conception and Pre Conception Planning, Counseling and Care." She discussed the rationale for preconception planning, counseling and care (PCC) around HIV; PCC interventions that may improve or promote maternal health of women with HIV; and the need to identify research gaps in this area. PCCs goals include to prevent unintended pregnancy, promote appropriate birth spacing, optimize maternal health before pregnancy, optimize maternal and fetal health during pregnancy, prevent MTCT, and reduce risk of transmission to a woman's uninfected partner. Preconception planning is important for many reasons, especially given the high rates of unintended pregnancy among women living with HIV. Additional reasons include high rates of HIV serodiscordance, fertility desires and intentions of women with HIV, high rates of comorbidities, and advances in HIV care and prevention of perinatal transmission. Anderson also discussed the adverse effect on fertility of HIV and potential improvement in fertility with use of ART. It is possible that ART might inadvertently increase rates of unintended pregnancy. Effective contraception is under-used in many places with high levels of maternal mortality and HIV, and emergency contraception should be considered in such settings. Anderson also pointed out that high rates of comorbidities are potentially affecting maternal and/or fetal health. She called on participants to think about violence, depression, human papilloma virus, tuberculosis, anemia, and other comorbidities. Anderson concluded by sharing the following areas for further research: how to motivate uptake and sustained use of longer acting,

less user-dependent contraception for women who do not desire pregnancy; how to implement and integrate PCC interventions into HIV care; the role of pre-exposure prophylaxis/ART in safe conception implementation and supporting adherence; and outcomes research regarding PCC effectiveness for maternal health.

Watch the video of Anderson's presentation.

Tshidi Hannah Sebitloane (University of Kwazulu Natal) covered "HIV and postpartum morbidity/mortality." She opened her presentation by thanking the organizers for including experts from sub-Saharan Africa, saying "Nothing about us, without us... When you talk about us, we need to be here." Sebitloane described the burden of maternal mortality, noting that the biggest problems are in sub-Saharan Africa and Southern Asia. She pointed out that, according to the WHO, 18% of all maternal deaths are attributable to HIV. The effect of HIV infection on maternal mortality is best documented in South Africa for two reasons: (1) South Africa is the country with the highest number of people living with HIV; and (2) the availability of detailed data on maternal deaths that occurred in South Africa since 1995. Since most South African women deliver in hospitals, where data is routinely collected, South Africa has a wealth of data on maternal health and HIV. Sebitloane discussed institutional MMRs for women living with HIV versus women without HIV and said that the MMR for women living with HIV was 6 times higher. Women with HIV also experienced many cases of sepsis. In addition to maternal mortality, Sebitloane also described the major problem of maternal morbidity: For every maternal death, there is 5-6 times more maternal morbidity. She noted five main things that need to be done to address maternal health and HIV: (1) prevention; (2) early identification and initiation of treatment; (3) use of regimens that are safe during pregnancy; (4) screening for tuberculosis and prophylaxis; and (5) prevention of unwanted pregnancies (that will also help to prevent many septic abortions).

Watch the <u>video</u> of Sebitloane's presentation.

Wafaie Fawzi (HSPH) spoke about "Nutrition management of HIV infected women of reproductive age." In addition to discussing the "vicious cycle" of micronutrient deficiencies and HIV pathogenesis, Fawzi explained the interaction between HIV and nutrition, with HIV impairing nutrition and poor nutrition exacerbating HIV. Fawzi shared recent research from South Africa, Thailand, Tanzania, and Zimbabwe that showed that showed a link between vitamin B and longer time to AIDS disease progression death.

He discussed the effects of multivitamins on postpartum wasting, hemoglobin concentrations, disease progression, and risk of infection during breastfeeding. Fawzi said that it is important to think about women's health (and nutrition) before, during, and after pregnancy. He closed by highlighting the importance of an integrated approach and said that we must think about this issue (and the work that still needs to be done) in terms of the discovery side as well as the translational side.

Watch the <u>video</u> of Fawzi's presentation.

Watch the <u>video</u> of the Q/A from the previous session.

Edna Jonas (MSH) began the panel on "Enabling Resources and Barriers to Care" by presenting African Strategies for Health's literature review on "Maternal health in the era of antiretroviral therapy." She began by explaining why this topic was proposed by USAID and highlighted the review's three main questions: (1) What are the most effective interventions for reducing mortality among women living with HIV during pregnancy and up to one year postpartum?; (2) What are the

demand side factors and how do they influence a women's initiation and adherence to ART during pregnancy and up to one year postpartum?; and (3) What are the operational factors/health systems factors and how do they affect women's initiation and adherence to ART during pregnancy and up to one year postpartum? ART was the only intervention found to directly reduce excess risk of mortality, but there was very little evidence on other interventions. The review acknowledged that many gaps remain. There is a lack of evidence about non-clinical and clinical interventions other than ART and a lack of information about women who do not use services. Insufficient information impedes the design of effective interventions to address the needs of women living with HIV and support them in accessing and using services. The question of why women on ART continue to experience an increased risk of mortality from tuberculosis remains unanswered. Neither consistent definitions of adherence vs. retention nor indicators to measure adherence exist. There is insufficient evidence about effects of ART on birth outcomes and its long-term effects on women. Despite these gaps, the review acknowledged that opportunities also exist. Option B+ for PMTCT, for example, offers opportunities to test more women/mother-centered and integrated models of care to improve initiation, adherence, and long-term retention.

Watch the video of Jonas' presentation.

Janet Turan (University of Alabama, Birmingham) discussed "Stigma and discrimination as barriers to achievement of global PMTCT and maternal health goals." She began her presentation by providing an overview of the possible pathways for the effects of HIV on maternal health. HIV increases a woman's susceptibility to HIV-related infections, advancing HIV infection, and pregnancy complications. HIV-related stigma and discrimination have adverse effects on utilization and quality of maternity services not only for women living with HIV but also for all women. After asking participants how stigma might effect utilization and quality of HIV services for women, Turan provided a diagram explaining the effects of stigma on maternal, neonatal, and child health showing the connections between psycho-social effects, behavioral consequences, and effects on health. She shared data that showed very high rates of anticipated HIV-related stigma. Given that women might be declining HIV tests for fear of stigma, this topic may be a big barrier to reaching maternal health and HIV goals. Turan also shared examples of actual experiences of stigma from women in multiple countries, noting how widespread and far reaching this issue is. The existing academic and programmatic literature details how stigma and discrimination affect each step in the "PMTCT cascade." Fear of stigma and unwanted disclosure of HIV status might lead to more home births. Helping women to figure out approaches to safe disclosure may increase utilization of health services. Turan reinforced that reducing stigma is an essential piece of delivering care for all women, men, and children; if we ignore these issues, we will not meet our goals.

Watch the video of Turan's presentation.

Lisa Messersmith (Boston University School of Public Health) spoke about "Reproductive Health Decision-Making Among Women Living with HIV." She framed reproductive health decision-making along a continuum: desire for children → sexual and reproductive rights → major challenges (e.g. testing, retention in care, ART initiation and adherence). HIV status is one of multiple factors that contribute to a woman's decision to have children. Additional factors that influence reproductive health decision-making include the availability of ART for PMTCT as well as long-term treatment; the death of a child from HIV-related causes; the HIV status of partner; stigma (from family, friends, health providers, etc.); intimate partner violence and abandonment due to disclosure; fear of infecting a partner or child; and fear of orphaning a child. Messersmith raised important questions about reproductive health programs and policies and discussed the issue of reproductive health decision-making for women living with HIV in the context of several

international treaties and conventions. She talked about "contested domains" for women living with HIV, such as the right to live a healthy sexual life, the right to decide to have/not to have children, access to ART for PMTCT, access to contraception and safe abortion, the right to health, and ART for long-term treatment and prevention between discordant couples. She then outlined a number of sexual and reproductive health and rights violations of women living with HIV, including coerced abortion, coerced sterilization, and withholding information and services related to safe conception. Messersmith concluded by outlining numerous social and behavioral as well as structural and health systems barriers to retention and adherence. Behavioral facilitators for retention in care and adherence include accessing accurate information; witnessing improved health among those on ART; feeling better; having hope for living longer; and receiving support from partners, friends, and family. Structural facilitators include family-focused care, counseling, peer support, point-of-care CD4 testing, linkages to long-term care, escorting women between ART and ANC services, and testing for ART eligibility and initiation.

Watch the <u>video</u> of Messersmith's presentation.

Nomafrench Mbombo (University of Western Cape) concluded the final panel of the day with a presentation on "Gender inequality and inequity as barriers to access maternal health care: A case of PMTCT service." She discussed gender concepts, gender as a barrier to PMTCT, and approaches to overcoming gender barriers in order to promote access to MCH programs. Mbombo discussed the practical and strategic needs of women, noting that we must go beyond the practical needs to address the strategic needs. Gender can influence various factors within the three delays model. Gender can also result in HIV impacting women differently than men. She challenged meeting participants by asking them three questions: (1) Does the program take into account men and women's different roles and responsibilities and their differential access to and control of resources?; (2) Does the program challenge existing gender and social relations?; and (3) Have you considered the potentially different impacts of the program on both men and women? It is crucial to incorporate gender into maternal health and specifically HIV/AIDS programming. Programs must take into account the specific needs of men, women, girls and boys with respect to both biological/sex differences and sociocultural gender differences. The design, implementation, monitoring, and evaluation of programs at all levels should benefit both women and men equally and promote inequities. Programs should also promote both gender equality and equity and should be grounded in a rights-based approach. She reminded participants that we must challenge harmful sociocultural norms and stereotypes related to masculinity and femininity, specifically sexuality. Gender mainstreaming is a strategy for making women's as well as men's concerns and experiences an integral dimension of the program.

Watch the <u>video</u> of Mbombo's presentation.

Watch the <u>video</u> of the Q/A from the previous session.

Day Two

The second day of the meeting focused on sharing current research around lifelong ART for pregnant women, including resource and programmatic challenges, ethical and medical issues, relevant experiences implementing Option B+, and new policy guidelines.

Heather Watts (National Institutes of Health) started the morning off with a helpful <u>recap of day one</u>.

Karusa Kiragu (UNAIDS) presented "Lifelong ART for pregnant women: Benefits, trade-offs, and the research needed to optimize maternal, perinatal, and community health outcomes. Resource and Programmatic Considerations." She noted that it is important to remember that over half of the women who are eligible for HIV treatment are not receiving it. Children even less so with only 26% of those eligible receive HIV treatment. She also stated that HIV increases mortality in general, even among those with higher CD4 counts. She mentioned the five pillars of 'Treatment 2.0': 1. Optimize drug regimens 2. Simplify monitoring 3. Reduce costs 4. Adapt delivery systems 5. Mobilize communities. Ms. Kiragu noted that due to advocacy, the price of life-long ART has dropped, from \$364 in 2012 to \$110 in 2013 for a 12-month supply. Unfortunately, there is still a concern that many of countries rely on outside funding to support ART treatments. She noted that life-long treatment beginning during pregnancy has many benefits including: treatment benefits for women, simpler regimens (1 pill 1x a day), simpler messages (treatment for life), simpler eligibility guidelines (only voluntary and confidential HCT), prevention benefits for child and partner, simpler supply chain, and a better opportunity for integration of other health services and health needs. Problems associated with rolling out Option B+ include: infrastructure, human resources reorganization, supply chain changes, changes for community systems, decentralization of primary services, integration (MNCH clinics to ART clinics), service integration, monitoring and evaluation for toxicity and resistance, QA, client retention, and adherence. She noted that the B+ Option is implemented in Malawi and Uganda, and has been MOH approved by Namibia, Tanzania, Angola, Mozambique, Zambia, Ethiopia, Lesotho, Zimbabwe, and DRC. She suggests going to the Global Plan and **IATT** websites for more information.

Watch the <u>video</u> of Kiragu's presentation.

Anna Coutsoudis (University of Kwazulu Natal) started her presentation on "Ethical and Medical Considerations and Issues" by noting that from the programmers perspective Option B+ is easier to implement because it is a one-pill regimen, may reduce mother-to-child transmission of HIV, and may be more cost-effective. In settings without access to CD4 testing and very high fertility rates, it may make sense for women to take lifelong antiretroviral treatment independent of their immune status. However, Coutsoudis warned that there are still many questions to be answered about the B+ Option, and both medical and ethical issues to be addressed. First, it doesn not seem that Option B+ is more effective at reducing vertical transmission than option B or Option A. Further, most vertical transmission occurs among women who have CD4 counts below 350 copies, and thus will not be affected by the B+ recommendation as they are already receiving triple therapy with Option A. Second, while it is accepted that ARV treatment offers significant benefits for individuals with CD4 counts under <350 copies, it is undetermined how much those with CD4s between 350 and 500 copies will benefit, and unknown if there are benefits of ARV treatment for individuals with CD4 > 500. Given that the rather scarce available data is from the general population of men and women with HIV, Coutsoudis asked if it is relevant to extrapolate the assumption of benefit to pregnant women. She stated that we must look at the side effects of ARV treatment in the long term (eg. renal failure), during pregnancy (eg. preterm births, small gestational age, stillbirth, along with the associated economic and societal costs of these outcomes), and post-pregnancy (eg. toxicity through breast milk, bone density problems, and anemia). The development of antiretroviral resistance is a significant concern with Option B+, including the possibility of sexually and vertically transmitted resistance. In turn, development of resistance will be a significant financial challenge as health systems are called upon to provide second and third line drug regimens. She warned that

decisions about resource allocation—and the programs that will be scaled back—to implement B+ and also which populations will be able to access treatment (pregnant women vs. non-pregnant individuals with a greater immediate need for treatment) raise ethical dilemmas. Coutsoudis questioned whether Option B+ is the best intervention, pointing out that it might result in women receiving insufficient information about treatment, feeling coerced into taking treatment, and not developing other skills to deal with their HIV-positive status—which in turn will impact on adherence and quality of life. She concluded by stating that more research is needed on a variety of issues related to B+: analyses A vs, B vs B+ options, and M&E for those already using B and B+.

Watch the video of Coutsoudis' presentation.

Hoosen Coovadia (University of Witwatersrand) then joined via Skype as a discussant. He clarified that in his view the main issues to be addressed with regards to the choice between offering Option B and Option B+ were: safety, adherence, retention and drug resistance. Dr. Coovadia questioned the ethics of privileging pregnant mothers over other populations as a concern and argued that Option B+ will not directly address leading causes of maternal mortality directly, post-neonatal mortality or under 5 mortality rates that are attributed to other causes. In South Africa, Coovadia notee that child mortality and maternal mortality rates have reduced in past years due to targeted interventions which directly address causes of maternal and child death. He recommended privileging direct, evidence-based interventions to target leading causes of maternal and child mortality.

Watch the <u>video</u> of Coovadia's presentation.

Anja Giphart (Elizabeth Glaser Pediatric AIDS Foundation) presented, "Rollout of option B+: A multi-country experience." Drawing on case studies from Malawi, Zimbabwe, and Rwanda, Giphart discussed best practices and challenges associated with implementing Option B+. Roll-out is most advanced in Malawi. Giphart emphasized the significant financial resources from international sources, staff training, planning, and ongoing monitoring and evaluation from the national level necessary to successfully roll-out B+--as well as the associated rewards. Adoption of B+ and provision of PMTCT services at ALL ANC sites in the country resulted in a doubling of PMTCT coverage within 12 months. Retention remained at 84% of pregnant women still on treatment at 6 months, and 79% at 12 months. However, some women did not return after the ART initiation visit and women who started treatment during breastfeeding had better retention rates than women who started during pregnancy. Option B+ in Zimbabwe, showed is an association between early treatment initiation and prevention of transmission, which showed the rates of women presenting late in pregnancy a challenge. There was also a significant loss to follow up of exposed infants either because parents are not returning for follow-up visits or because data management systems are unable to track exposed infants. In Rwanda, where B+ has been implemented, they have started a "One Stop" model where women can access ARV while attending immunization for the child—in integrated services 79% got their ARVs on the same day as they went to the infant immunization, as opposed to 16% in non-integrated services. Similarly, integrated services increased same-day infant HIV testing—86% in integrated vs. 58% in non-integrated services. The integrated model had benefits for both women—reducing the time spent at the clinic—but also for clinic staff who reported less overwhelmed by fewer visits. Giphart noted that Option B+ implies significant planning and additional resources, does not overcome all of the current bottlenecks, that less attention is being given to pediatric care and treatment, and that sustaining quality services and promoting adherence and retention is a significant challenge. Giphart concluded by saying that we

need "keep eyes on the prize" of a generation free of HIV. To do this well, ongoing implementation research will be key.

Watch the <u>video</u> of Giphart's presentation.

Roger Shapiro (Harvard Medical School) presented, "Scientific and programmatic advances in PMTCT: To B or not to B+" which started with a review of the history of PMTCT. He noted that the information in the future from the PROMISE study will help to answer some of our questions surrounding the comparison of different treatment regimens, but as that study is not yet finished, we will have to look at other data. Shapiro stated, from Europe and Africa, the evidence suggests that ARV use during pregnancy causes higher rates of stillbirths, preterm births, and low birth weight. The US data is mixed and not conclusive. Shapiro presented research from Botswana that looked at birth outcomes from nearly 33,500 deliveries from 6 different district hospitals from May 2009 to April 2011; 29% of the sample was HIV-positive. Shapiro noted that in all categories HIVexposed children had poorer outcomes (stillbirth, small for gestational age, preterm births, and neonatal deaths) babies from mothers living with HIV fared worse. He also found that HAART treatment in mothers, particularly taking HAART before pregnancy, was associated with higher rates of preterm delivery, smaller for gestational age, and stillbirths. Shapiro's group also did an autopsy sub-study on 99 placentas of women who experienced stillbirth which associated HAART with a higher likelihood of pathology consistent with chronic hypertensive damage, as compared to those that took only ZDV or no ARVs while pregnant. Shapiro raised several outstanding questions to be answered about Option B+: What about EFV teratogenicity? Is there less long-term resistance? Is there a mortality advantage compared with B? Is this a case of treatment as prevention? Is it cost effective? However, despite these outstanding questions, Shapiro endorsed Option B+ as a crucial opportunity to meaningfully scale-up access to PMTCT.

Watch the <u>video</u> of Shapiro's presentation.

Esiru Godfrey (Uganda Ministry of Health) presented, "New policy guidelines increase utilization of services for elimination of mother-to-child HIV transmission in Uganda." Uganda began to implement Option B+ in September of 2012. Some of the supply chain innovations included: a single warehouse for ART and PMTCT regimens, homogenization of order forms and master lists for PMTCT and HIV clinics, providing an initial stock of two-months of ARV to each site, and the creation of a web-based system for ordering ART. Uganda has also implemented several innovations to improve healthworker training, mentorship and accreditation and has been actively involving the community and people living with HIV, using family, community and peer support models, encouraging male involvement, and mobile phone technology for adherence reminders and appreciation of women who participate in the program. A new monitoring and evaluation system with online and SMS reporting has also been implemented. Knowledge gaps include more effective models of care and integration of PMTCT and ARV, stigma and disclosure, and human resource needs.

Watch the video of Godfrey's presentation.

Watch the <u>video</u> of the Q/A from the previous session.