Expert Consultation on

Operations Research on the prevention of mother-to-child transmission of HIV and pediatric HIV care, support & treatment

September 9-11, 2009
Washington, D.C.

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Please note: PowerPoint presentations referred to herein can all be found in a separate document that should accompany this summary report.

I. Acronyms

ANC	Antenatal Clinic
ART	Antiretroviral therapy
ARV	Antiretroviral
AZT	Zidovudine
CST	Care, Support, and Treatment
CDC	Centers for Disease Control and Prevention
EID	Early Infant Diagnosis
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
EPI	Expanded Program on Immunization
FP	Family Planning
GWU SPHHS	The George Washington University School of Public Health and Health Services
IAS/ILF	International AIDS Society/Industry Liaison Forum
IATT	Inter-Agency Task Team
MOH	Ministry of Health
MOHSW	Ministry of Health and Social Welfare
M&E	Monitoring and Evaluation
MNCH	Maternal, Newborn, and Child Health
NGO	Non-Governmental Organization
NIH	National Institutes of Health
NVP	Nevirapine
OR	Operations Research
PBF	Performance-Based Financing
PEPFAR	President's Emergency Plan for AIDS Relief
PITC	Provider-Initiated Counseling and Testing
PLHIV	People Living with HIV
PMTCT	Prevention of Mother-to-Child Transmission
QI	Quality Improvement
RCH	Reproductive and Child Health
STI	Sexually Transmitted Infections
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

II. EXECUTIVE SUMMARY

UNICEF, WHO, and UNAIDS, in collaboration with the George Washington University (GWU) and the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), held a technical consultation on operations research (OR) related to the prevention of mother-to-child HIV transmission (PMTCT) and pediatric HIV/AIDS care, support, and treatment (CST) on September 9 – 11, 2009 in Washington, D.C. Approximately 70 representatives from international and donor organizations, government, selected highly impacted countries, implementing organizations, foundations, and academic institutions participated.

The primary goal of the consultation was to define the highest priority operations research questions that need to be addressed to promote the rapid national scale-up of PMTCT and pediatric HIV CST programs.

There has been great progress scientifically in the knowledge about how to prevent mother-to-child HIV transmission and treat pediatric HIV infection. The challenge is in the implementation at scale and optimization of PMTCT and CST programs in settings with limited resources. Implementation science is critical in order to provide strong evidence-based, scalable interventions that address current barriers to effective PMTCT/CST programs and achieve the goal of global elimination of pediatric HIV and AIDS. Successful operations research studies are those with results that change policy and practice and/or improve program and health system performance. The realization of the importance of OR has come to the forefront as programs for PMTCT and pediatric CST are scaled up worldwide in areas with limited resources and infrastructure that require effective and efficient use of resources.

The experts in the field of PMTCT, pediatric care and treatment, policy, research, and program implementation attending the meeting were charged with identifying the top 20 priority OR questions across four key strategic areas. The top 5 research questions identified by each of the 4 work groups are listed below, in the order of priority chosen by the group.

Work group 1: Maximizing PMTCT effectiveness

1. What are effective strategies for provision and monitoring of CD4 testing and antiretroviral treatment for eligible pregnant and breastfeeding women?
2. For postpartum prophylaxis during breastfeeding:
   a. What are effective strategies for implementation?
   b. What is the comparative effectiveness of infant versus maternal prophylaxis?
3. What are feasible and valid methods to measure PMTCT effectiveness for both maternal and infant outcomes at both the program and population levels?
4. What are the community strategies to effectively increase PMTCT uptake?
5. How can family and male partner involvement be increased? Does family and male partner involvement increase PMTCT uptake and successful completion of the cascade?

Work group 2: Pediatric HIV and AIDS care, support, and treatment

1. What is the optimal model for delivery of comprehensive care and treatment for HIV-infected infants and children?
2. What are the best models to provide care and support services to exposed infants?
3. What are the interventions at the program, facility, community, and household levels that have greatest impact on retention in care, especially in the first 12 months of life?
4. What are the best interventions to support implementation and uptake of infant feeding recommendations?
5. How can the maximum number of HIV-infected infants and children be identified early?

Work group 3: Integration of HIV programs within broader Maternal, Newborn and Child Health (MNCH) programs

1. What is the feasibility and impact of integrating PITC services and care for HIV-exposed infants into routine MNCH services?
2. What is the feasibility and impact of providing ART for eligible pregnant women in ANC?
3. What is the appropriate timing, content, and setting within MNCH services to ensure the integration and provision of FP services to HIV-positive women?
4. How can community health workers and peers increase utilization of MNCH and HIV/AIDS services?
5. What are the benefits, challenges, cost-effectiveness, and effects on service utilization of integrating PITC into EPI services for children under five?

Work group 4: Health systems in the context of PMTCT and pediatricCST

1. Task shifting: What is the effect and impact of task shifting on PMTCT and pediatric CST scale-up in various settings, at various levels of the health care system and among different cadres of health workers?
2. Data: What is the effect of different approaches to data collection on data quality and data use at all levels of the health care system?
3. Governance: What is the effect of innovative approaches for improving sub-national planning and management of health services, using PMTCT and Pediatric CST as tracer interventions?
4. Financial accountability and management: What are cost-efficient models for delivering PMTCT and Pediatric CST within the broader context of MNCH services?
5. Logistics: What is the impact of various approaches to supply chain management on PMTCT services / scale-up (availability …. outcome)?

In health and disease control programs: "any research producing practically-usable knowledge (evidence, findings, information, etc) which can improve program implementation (e.g. effectiveness, efficiency, quality, access, scale-up, sustainability) regardless of the type of research (design, methodology, approach) falls within the boundaries of **operations research**" (*Global Fund, USAID, WHO, Special Programme for Research and Training in Tropical Diseases, UNAIDS, World Bank)*

After individual scoring of all the 20 combined priority questions from all the 4 groups to get the overall highest priority questions, the top five questions across all the groups in priority order were:

1. What are effective strategies for provision and monitoring of CD4 testing and antiretroviral treatment, if eligible, for pregnant and breastfeeding women? (Group 1)
2. For postpartum prophylaxis during breastfeeding:
   a. What are effective strategies for implementation?
   b. What is the comparative effectiveness of infant versus maternal prophylaxis? (Group 1)
3. What is the feasibility and impact of providing ART for eligible pregnant women in ANC? (Group 3)
4. Task shifting: What is the effect and impact of task shifting on PMTCT and pediatric CST scale-up in various settings, at various levels of the health care system and among different cadres of health workers? (Group 4)
5. What are the interventions at the program, facility, community, and household levels that have greatest impact on retention in care, especially in the first 12 months of life? (Group 2)

There has been remarkable global progress in PMTCT and CST programs in the last few years, but there is still a long way to go to reach all women and children in resource-limited settings with these services. This meeting illustrated the need to set a priority research agenda to guide countries and programs, advocate with donors around the importance of funding OR, and identify mechanisms for sharing OR results quickly to enhance program design and implementation. National programs must focus their efforts, personnel, and resources on developing comprehensive PMTCT and pediatric CST scale-up strategies that include OR to better inform efforts to achieve the goal of the elimination of pediatric HIV and AIDS.

III. BACKGROUND

Recent data have shown notable progress in coverage of PMTCT services, especially of antiretroviral (ARV) regimens for MTCT prevention and pediatric antiretroviral therapy (ART) since 2004. The proportion of HIV-positive pregnant women who received ARVs for PMTCT in low- and middle-income countries increased from 10% in 2004 to 45% in 2008. As of December 2008, approximately 275,700 children were receiving ART, up from 75,000 by the end of 2005, with more than a 250% increase.[1]

In the framework of global support to national PMTCT and pediatric CST programs, especially in low- and middle-income countries, two types of knowledge are of critical importance:

- Emerging scientific evidence that informs the design of evidence-based interventions to reduce HIV vertical transmission, especially the use of ARVs and safer infant feeding practices; and
- Real-world program experience, especially in the context of weak health systems with substantial human and financial resource limitations

The body of evidence on implementation of known interventions in non-research settings is still weak, partly because of the lack of formal channels to facilitate the sharing of experiences or systematic analysis of existing field data, and the lack of global mechanisms to identify priorities and set up the global agenda for operations research.

National programs are increasingly asking for more guidance on how global guidelines could be implemented while taking into consideration the local context. In line with this need, the Inter-Agency Task Team (IATT) on prevention of HIV in pregnant women, mothers, and children has identified operations research as a priority in setting the global agenda for PMTCT and HIV care for children. In the guidance for global scale-up of PMTCT, IATT partners call on global partners and national governments to support evidence-based strategic information collection to track progress, improve programming and guide policies. More specifically, partners are expected to support national programs carry out operations research (OR) and to adopt *learning-by-doing* approaches to inform policy, advocacy, and programming. This support should include:

- Defining priorities and mobilizing resources for PMTCT and pediatric HIV-related research, including operations research, and
- Documentation and dissemination of best practices and successful models

Most resource-limited countries are now in the process of moving from limited projects and initiatives toward national PMTCT and pediatric HIV CST programs and programs that address the majority of women and their partners and children in need. This includes phasing in more efficacious ARV regimens for the prevention of HIV infection from an infected pregnant woman to her infant. This transitional process is challenged by various political, structural, and programmatic bottlenecks. There are knowledge gaps in achieving full effectiveness of known PMTCT and pediatric HIV CST interventions in settings with different epidemic typologies and health systems of varying strength.

Despite recent progress and lessons learned from programs, there are critical implementation knowledge gaps; more evidence is still needed in various program areas to further expand PMTCT and pediatric HIV CST services through existing primary care systems. In fact, various initiatives are being undertaken to generate evidence on how existing guidance, guidelines, and recommendations can effectively be operationalized at scale in resource-limited settings. These efforts however, have not been systematic and there are no well-defined channels or mechanisms through which lessons learned could be shared at

[1]Towards Universal Access: *Scaling up priority HIV/AIDS interventions in the health sector: Progress Report 2009* (UNAIDS, WHO, UNICEF)

all levels. Furthermore, there is no global agenda on OR around PMTCT and pediatric HIV CST based on identified gaps and defined priorities.

1. Rationale for Consultation

To fill these gaps and provide further evidence-based guidance to national programs, UNICEF, in collaboration with WHO, UNAIDS, and the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), planned a technical consultation on OR related to PMTCT and pediatric HIV CST (refer to the concept note in Annex 1). This initiative supports WHO's primary global role in the area of norms and standards; it also complements the expanded IATT's mission, with its specific focus on global strategies, resource mobilization and allocation, progress tracking, and support for implementation and country program scale-up.

In preparation for this consultation, a Steering Committee was formed to determine the agenda and invitees for the consultation, the focus and composition of the Work Groups that would articulate OR priorities during the consultation and the next steps after the consultation. George Washington University (GWU) and EGPAF were selected to serve as the Consultation Secretariat. The Secretariat organized and recorded the proceedings of the Steering Committee meetings; conducted an extensive literature review prior to the consultation to identify gaps in the OR literature; organized the logistics of the consultation; moderated and took minutes at the consultation; and wrote this final consultation report. Representatives from UNICEF, WHO, UNAIDS, NIH, EGPAF, USAID, CDC, and IAS also served on the Steering Committee. A list of Steering Committee members can be found in Annex 2.

The main objectives of the consultation were to:

1. Review operations bottlenecks to scaling up PMTCT and pediatric HIV CST in resource-limited settings and identify innovative approaches that have been used by national programs to address these bottlenecks;
2. Map out key ongoing and planned operations research projects on PMTCT and pediatric HIV CST, including geographic regions, areas of assessment, methodological approaches, time of project and institution/agency supporting the project;
3. Identify gaps and national programs' needs in PMTCT and pediatric HIV CST-related operations research in the broader framework of maternal, newborn and child health (MNCH);
4. Define priorities for an operations research agenda aiming at responding to needs felt at the country-level

This consultation was coordinated with a parallel International AIDS Society – Industry Liaison Forum (IAS-ILF) initiative, which involved a comprehensive research review and consensus-building consultation to identify recommendations for an HIV clinical and OR agenda for women and children in resource-limited settings.

2. Participants' Representation and Expertise

Participants were selected for their expertise in PMTCT and pediatric HIV CST, as well as their role as leaders in the international global health arena. The list of participants from international organizations, U.S. Government agencies, research institutions, universities**,** implementing agencies, foundations, and country representatives can be found in Annex 3. Some organizations invited to attend were not able to send representatives to the consultation.

3. Overview of Consultation Activities

In preparation for the meeting, the GWU Secretariat and EGPAF created an Access database of published literature, abstracts and ongoing and planned OR studies in the areas of PMTCT, pediatric CST, integration within MNCH services, and health systems. A summary of an extensive OR literature review of nearly 300 peer-reviewed manuscripts and over 100 abstracts was included in the database, summarized, and presented at the consultation to identify gaps in knowledge that the consultation attendees could address. In addition, a survey of a wide range of implementing partners, research organizations, funding agencies and others was conducted to gather information on research in these areas that was either ongoing or planned.

There were four broad areas of focus for the consultation around which the literature review, presentations, work groups, and meeting outcomes were structured. These areas included maximizing PMTCT effectiveness, pediatric HIV CST, integration of HIV programs within broader MNCH programs, and health systems strengthening in the context of PMTCT and pediatric HIV CST.

On the first day of the meeting, key presentations provided the background for the work of the consultation attendees by reviewing the importance of operations research in scaling up PMTCT and pediatric HIV CST programs; the link between PMTCT and health systems strengthening; an update on the new science in the field of PMTCT and pediatric HIV CST; and OR priorities in the context of changing WHO guidelines. The afternoon sessions consisted of a review of PEPFAR-identified priority areas for research, a summary of the IAS-ILF mapping exercise and consensus on priority research areas for women and children, and presentations of the summaries of the literature review in the four defined topic areas.

The second day of the consultation was devoted to Work Group activities, where members of the consultation were divided into four work groups based on the key priority areas defined above: maximizing PMTCT effectiveness; pediatric HIV CST; integration of HIV programs within broader MNCH programs; and health systems strengthening in the context of PMTCT and pediatric HIV CST. With the literature review as a background for identifying gaps in knowledge, each work group discussed the OR questions relevant to the group's topic area and determined the five questions that the group felt were *most crucial* to addressing key gaps in the assigned area. For each of the priority research questions identified, work groups also discussed potential OR study designs or interventions to address them. Criteria for consideration as research questions were being prioritized included answerability, usefulness in filling an important knowledge gap, and potential impact on disease burden reduction.

After the four groups presented and discussed their top five priority research questions, each meeting participant was asked to score each of the 20 merged questions on the three criteria (answerability, usefulness, impact) using the following scale:

1 = not likely to fulfill the criteria
2 = may possibly fulfill the criteria
3 = will quite likely fulfill the criteria
4 = will almost certainly fulfill the criteria

The scores were tallied and presented to the group at the beginning of Day 3. The remainder of Day 3 focused on a discussion of the way forward after the consultation, including a presentation from country representatives from India and Africa on operational research needs from a country perspective. The closing was delivered by UNICEF.

IV. DAY 1:

KEY HIGHLIGHTS FROM PRESENTATIONS AND KEY POINTS FROM DISCUSSION

Opening Remarks by GWU, EGPAF, and Sponsoring UN Agencies (UNICEF, WHO, and UNAIDS)

Brief introductory remarks and words of welcome to the sponsors and participants were offered by Dr. Josef Reum, the Interim Dean at GWU's School of Public Health and Health Services, and Ms. Pam Barnes, the President and CEO of the Elizabeth Glaser Pediatric AIDS Foundation.

Additional opening remarks were then given by the sponsoring and attending UN agencies: UNICEF, WHO, and UNAIDS. Dr. Chewe Luo, the Team Leader for Programme Scale-up in the HIV Section at UNICEF, began by recognizing that the field has come a long way since the early days of the epidemic. She said that there is now knowledge as to what interventions are proven to work as the result of trials, such as the HIVNet 012; and efforts are currently ongoing to increase program impact by addressing bottlenecks and enhancing the efficacy of these interventions. Dr. Luo reminded the consultation participants that PMTCT is a child survival intervention just like immunizations, and even with immunizations, children are still dying of vaccine preventable diseases.

Dr. Yves Souteyrand, the Strategic Information and Research Coordinator in the HIV/AIDS Department at WHO, noted that as PMTCT is one of the key areas of the health sector response, health systems issues must be addressed, including data collection and analysis and weak infrastructure. He also urged the participants to assist WHO in identifying OR priorities and proposing a process for moving forward.

Dr. Karusa Kiragu, the Senior Prevention Advisor of the UNAIDS Secretariat, told the consultation participants that UNAIDS is in the process of operationalizing priorities for the UNAIDS family for 2011-2015, of which PMTCT is one. This meeting was considered important to identify technical gaps, capacity gaps (personnel), and leverage political capital. Participants were also requested to bear in mind all four prongs of the UN strategy, particularly primary prevention of HIV among pregnant women, throughout the meeting.

Dr. Rene Ekpini, Senior Advisor of the Health Section of the Programme Division at UNICEF, then presented the meeting objectives (see section on background and rationale for the meeting).

Plenary Presentations and Discussions

1. Health System Research within the Context of MNCH and HIV Service Delivery

Dr. Ekpini presented the first plenary on *Health System Research within the Context of MNCH and HIV Service Delivery.* Please refer to his slide presentation in the accompanying document.

Health System Research Discussion

Participants raised several important and varied issues, including

- The need to address the role and contributions of the community (the "demand side") in a health systems approach, including the greater use of community workers in a task shifting approach
- The perception that some interventions and support are disruptive to general health systems, such as some of the proposed solutions in human resources
- The need to examine what is already happening in successful program models
- The need for greater precision in defining health systems strengthening, desired outcomes, and outcome measurement
- Better utilization of program data to help shape new programs

2. Operations Research to Address Barriers to HIV Prevention, Care and Treatment Scale-up in Resource-limited Settings

Dr. Laura Guay, the Vice President of Research at EGPAF and Research Professor at GWU, gave the next plenary on *Operations Research to Address Barriers to HIV Prevention, Care and Treatment Scale-up in Resource Limited Settings*. Please refer to her slide presentation in the accompanying document.

Operations Research Discussion

It was noted that academic institutions have been conducting OR for some time, but that historically they were not necessarily involved in implementation. However, this is changing and many universities have now become implementers as well. The focus has shifted from the research itself to the results that influence program implementation. (Please note: additional discussion on this topic can be found in the following section.)

3. PMTCT and Pediatric Care and Treatment Update and Programmatic and Policy Implications

The third presentation of Day 1, *Update on the New Evidence on PMTCT and Pediatric Care and Treatment,* was given by Dr. Lynne Mofenson, Chief of the Pediatric, Adolescent, and Maternal AIDS Branch, Center for Research for Mothers and Children, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health. This presentation was followed by *PMTCT and Pediatric CST OR in the Context of Changing PMTCT Guidelines: Programmatic and Policy Implications* by Dr. Nathan Shaffer, the PMTCT Team Leader in the HIV/AIDS Department at WHO. Please refer to their slide presentations in the accompanying document.

PMTCT and Pediatric Care and Treatment Update and Implications Discussion

An important question was raised about how to link the results of OR with countries' programming and ensure that the results are fed back into countries for scale-up purposes. In addition, it was suggested that the PMTCT cascade should include HIV prevention services, outreach to women, and a better understanding of the social context in different countries (e.g., women who would prefer not to know their status, couples issues, etc.). It was agreed that standardized approaches were needed in these areas.

Participants discussed the implementation of the 2006 WHO Guidelines for ARV regimens at length. WHO has data on those countries that have fully implemented the guidelines, but more information is needed on the barriers to their implementation and how further support and information can be provided to countries, particularly in light of the newly revised guidelines. Regional WHO offices can serve to guide regional strategies to support the dissemination, adoption, and implementation of the new guidelines. Country programs should also be encouraged to share their best practices.

One participant noted that reporting compliance with WHO guidelines and having national policy guidelines does not necessarily translate into services or uptake of those services. The importance of anthropology, social science research, and a greater focus at the community level and outside the facility setting was stressed throughout this discussion, and was illustrated with an example related to ARV regimens. In one investigation of the experience of people living with HIV (PLHIV), it was found that fear and paranoia of taking ARVs and the mothers' practice of taking medication themselves instead of providing them to their children are barriers to completing the cascade. Other health systems challenges to implementing the ARV guidelines were noted; they include issues related to stock-outs, health worker salaries, transportation, and road infrastructure.

The mental health of HIV-infected children and the documentation of the benefits and negative consequences of PMTCT for women were noted as general PMTCT OR gaps.

It was recommended that a list of the OR priorities should be available to the international community shortly after this consultation, particularly to the Global Fund as OR is a high priority area for them.

4. PEPFAR Perspective

Dr. RJ Simonds, the Deputy Director of the Global AIDS Program at CDC, gave the plenary on the *PEPFAR Perspective on Priorities for PMTCT and Pediatric CST OR, Current and Future Plans.* Please refer to his slide presentation in the accompanying document.

PEPFAR Perspectives Discussion

The response of the participants to the PEPFAR presentation involved a brief discussion on the balance of collecting enough data so that the impact of programs can be evaluated, but that is not too burdensome or of poor quality. PEPFAR is also in the process of conducting random data quality audits, which has been a source of tension for programs, but has also revealed important problems. It was explained that part of the challenge is that the basic ownership of data belongs to the ministries. Data for special projects are in the process of being collected, but there is not a central clearinghouse for PEPFAR data other than the annual reports that are submitted by implementers. The increasing interest in endpoint data (e.g., two year HIV-free survival) was also mentioned.

5. IAS/ILF Update

The next presentation, *Summary of the IAS/ILF Meeting on Building Consensus on Research Priorities for Women and Children,* by Dr. Shirin Heidari, the Senior Manager of Programmes and Initiatives at International AIDS Society immediately followed. Please refer to her slide presentation in the accompanying document.

IAS/ILF Update Discussion

In addition to other endeavors, the IAS Industry Liaison Forum developed an overview of OR and clinical research involving women and children. PMTCT OR was originally part of this review, but upon learning of UNICEF's activities, they agreed to incorporate the findings from the GWU/EGPAF literature review for the PMTCT portion. The IAS/ILF consultation was held in July in conjunction with the 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention and resulted in 15 recommendations. The environmental scan and meeting report can be found at www.iasociety.org/ilf.aspx.

Participants had several questions regarding the structure and function of the IAS/ILF. The summarized points are below:

- IAS/ILF encourages OR by stimulating new research projects, not capacity building, and works primarily on advocacy and policy at the international level rather than within countries
- Representatives of the forum are pharmaceutical companies as well as independent investigators and representatives from international agencies and NGOs
- The Journal of the International AIDS Society (JIAS) encourages submissions in the field of OR. All articles on the IAS journal website are processed fairly quickly. All abstracts from the AIDS and IAS conferences are available on the JIAS website
- There is a need to explore additional publication outlets specifically focused on OR which fast track the publication of OR studies

5. OR Literature Review and Findings on PMTCT and Pediatric HIV CST

The final sessions of Day 1 included the findings on the review of published and ongoing OR in the following areas: PMTCT, pediatric HIV CST, integration of services within MNCH, and health systems. Dr. Guay presented an overview of the literature review process and the first two topics. Her presentation was entitled, *Published and ongoing studies in PMTCT and pediatric HIV CST: Key Knowledge and Gaps in the Field.* Please refer to her slide presentation in the accompanying document.

OR Literature Review and Findings on PMTCT and Pediatric HIV CST Discussion

Participants were told that the findings of the literature review as well as the database that contains the review of articles would be available for their group work the following day.

Participants first raised questions regarding the methodology of the literature search and review. The review began with published articles and abstracts. Published articles were from 2004 to 2009 and abstracts were included from the relevant scientific conferences of 2008 and 2009. Given the short timeframe and the challenge of locating sources of gray literature and white papers, few of these were included. The review did include ongoing and planned OR studies, but there was a very small response rate from organizations that were contacted as a part of this process. Participants were encouraged to submit these types of publications, which the GWU/EGPAF team will continue to collect.

It was explained that the original plan was to collect only data from research studies; however, to examine barriers, it was also necessary to review program descriptions and challenges. The level of confidence in the evidence and data was not graded as a part of this review given the limited time frame, but is a critical issue and should be considered when groups are developing their priorities. Some of the health systems articles were from other areas (TB, family planning, etc), but most of what was included in the health systems research was focused on publications related to pediatric PMTCT and HIV CST. This topic is discussed in-depth below as part of the presentation and discussion that followed. It was also noted that the limited review of research on adolescence was purposeful since the difference in issues experienced by younger patients differ vastly from those of adolescents and there was simply not enough time to adequately address this important topic.

Although the information was presented according to subject area and in anticipation of the work in small groups, the database was structured so that users could conduct searches by a number of study characteristics, including study design, analysis type, and location.

This discussion on the process highlighted a number of issues. One is the need to have a new kind of communication to move past the traditional journal format and to disseminate OR information more quickly. Secondly, the review illustrated that there were few studies that tested new interventions; a significant number of articles simply identified and described existing programs and challenges. In other words, “true” OR studies in the published literature were limited. Thirdly, evaluation should be integral to the structure of any program and not considered ad hoc.

Recommendations and ideas for further intelligence gathering were also volunteered during the discussion:

- There could be lessons learned from research and interventions conducted in the U.S. earlier in the epidemic that could be applied to the international stage, including those interventions addressing highly mobile urban populations and the private versus public sector approaches.
- The work of the Cochrane Foundation should be explored, which involves a similar project and utilizing a systematic approach to reviewing and cataloging research.

- Participants were made aware of the NIH-supported meeting in March 2010 on implementation research dissemination, with a focus on methodologies and attempting to address the capacity building needs and gaps that were further illustrated in this review. The conference website can be found at http://conferences.thehillgroup.com/obssr/di2010/index.html.

6. OR Literature Review and Findings on Integration of Services with MNCH and Health Systems

The second part of the literature review, *Published and Ongoing Studies on the Integration of PMTCT and Pediatric Care and Treatment within MNCH Services and Health Systems: Key Knowledge and Gaps in the Field,* was presented by Dr. Christian Pitter, the Director of the Global Technical Policy Unit at EGPAF. Please refer to his slide presentation in the accompanying document.

OR Literature Review and Findings on Integration of Services with MNCH and Health Systems Discussion

Compared to the amount of published literature in PMTCT and HIV care and treatment, the research is relatively limited in these areas. While the work groups were charged with identifying the priorities, there are still many knowledge gaps, particularly in health systems. Since health systems research is poorly characterized and has consequently produced limited evidence, it was concluded that there is a need to focus on formative or exploratory research in addition to OR.

Participants asked if additional documents, other than published articles, abstracts, and a small number of descriptions from ongoing studies, were included in this analysis, such as the evaluation of aspects of systems management within countries, including poverty reduction strategy papers, Sector-wide Approaches (SWAps), or country-level documents from ministries (e.g., annual performance reports). Although important, the review of country-specific documents was not the focus of this literature review.

There were many sub-topics addressed during the discussion under the broad heading of health systems: health care workforce, health information systems, program governance, program financing, logistics, drug procurement, and supply management. For example, the issue of how to answer questions regarding stock-outs was raised, and some participants offered that qualitative and quantitative information on stock-outs is captured in the International Treatment Preparedness Coalition (ITPC) listserv and WHO systems. In terms of cost-effectiveness, most studies in this review focused on Prong 3 and the cost-effectiveness of integrating the services reflected in the four prongs was not represented.

The importance of quality improvement (QI) was also discussed. The research in the literature review suggested that QI is effective and perhaps more investment should be made in this area. UNICEF is working in a number of countries on QI, in order to help countries improve their data collection, utilization, and feedback processes to enhance program performance. One participant noted that QI is a natural overlap with OR and helps to identify bottlenecks and systemic ways to reach solutions, however QI in PMTCT is more difficult because the data collection system is fragmented.

In regard to the research on integration within MNCH services, some gaps revealed in the review include follow-up for children in need of HIV care and treatment and community services to reach those that do not seek care at facilities. Most of the studies were focused on integrating PMTCT with reproductive health services. In anticipation of the group work, the point was made that there would be considerable overlap in the two groups addressing integration and health systems. Initiatives to strengthen health systems can help improve the quality of care, in areas such as PMTCT logistics, IT, and the health care workforce. Participants also learned that there is some work being done in this area on linkages among HIV, PMTCT, and sexually transmitted infections (STIs) by WHO, International Planned Parenthood Federation, and UNAIDS collaborators. This group has produced a tool to be used at country level and analysis is ongoing in a number of countries.

Lastly, it was noted that there is a need for OR that addresses both the micro and macro levels of the challenges and bottlenecks that occur in implementation, and an awareness that best practices must always be tested and adapted in the dynamic settings in which the consultation participants work.

7. Work Group Assignments and Objectives

At the end of Day 1, the group had the opportunity to discuss their ideas for the remaining work in the upcoming two days and the best ways to move forward.

It was felt that developing the 20 highest priority OR questions would be an important accomplishment in its own right and useful to country programs. In addition to prioritizing questions, a concern was also raised that donor fatigue surrounding HIV/AIDS responses and concerns about these efforts worsening health systems in general was growing. There is now an urgency to implement creative and effective strategies within HIV prevention, care, and treatment as part of the overall health system structure.

The moderators of the session clarified that the participants' role was to develop and prioritize the questions that are going to have the biggest impact globally. An identification of the key gaps in the groups' respective focus areas was important and necessary, but how to address them with research questions and strategies was the ultimate goal of the consultation. Groups were encouraged to be flexible and practical throughout the process.

The relevance of the chosen questions to countries and the linkages to funding, such as through the Global Fund, were integral to this discussion. It was suggested that a similar prioritization process could be repeated in-country, and noted that countries may not have the same priorities. An important next step was identified: to provide capacity building and technical assistance to countries and help them conduct the research themselves. Country ownership and involvement were said to be crucial to moving this process forward.

V. DAY 2:

OUTCOME OF GROUP DISCUSSIONS

Focus Areas

Day 2 of the consultation was devoted to work group activities. Members of the consultation worked in groups based on the four key areas presented in the review of the literature. The purpose of these work groups was to discuss the operations research questions relevant to each topic area and to determine those questions that are *most crucial* to addressing key gaps. Groups were asked to identify five priority research questions, provide a rationale for each question, and to discuss potential OR study designs or interventions to address them.

The four focus areas are listed below. Each group was also given specific sub-topics to consider to minimize duplication due to the overlap in these areas. A more detailed explanation of the group work can be found in the Work Group Guidance in Annex 5.

1) **Maximizing PMTCT effectiveness**
   a. Program scale-up, coverage, and access of services
   b. PMTCT regimens, including ART for eligible women and breastfeeding prophylaxis
   c. Cascade adherence, including HIV testing and counseling, ARV receipt, drug adherence, infant dosing, etc.
   d. Transmission through breastfeeding
   e. Family and community engagement
   f. Assessment of PMTCT effectiveness
2) **Pediatric HIV CST**
   a. Care and prophylaxis for HIV-exposed infants
   b. Identification of HIV-infected infants and children
   c. Retention and adherence to medication and postnatal follow-up
   d. Links to comprehensive HIV care and treatment for those infected (and their families)
   e. Infant feeding
   f. Community engagement
   g. Pediatric psychosocial support and counseling
3) **Integration of HIV programs within broader MNCH programs**
   a. Linkages with other maternal services such as ANC, delivery care, postnatal care (PNC), reproductive health, family planning, STI programs, malaria, and TB
   b. Linkages with other pediatric services such as immunizations and nutrition
4) **Health systems in the context of PMTCT and pediatric HIV CST**
   a. Healthcare workforce
   b. Health information systems
   c. Program governance (e.g., district-based approach, decentralization, management and accountability)
   d. Program financing (e.g., performance-based financing, district, community-based organizations)
   e. Logistics, drugs procurement, and supply management

Group Composition

Consultation participants were assigned into one of the four above groups based on their areas of expertise by the GWU Secretariat and approved by the Steering Committee in advance of the meeting. Groups ranged from 13 to 16 participants. For a list of each work group's members, please refer to Annex 6.

Each group had a leader, two resource persons, a rapporteur and a note-taker. The work group leader was responsible for ensuring that the discussion remained focused on achieving consensus on the priority research questions, that each member adhered to group ground rules, and that the conclusions of the group were reflected in the rapporteur's summary presentation. The rapporteur was responsible for providing a technical summary of the work group's discussion that was used for documenting the conclusions of the work group, and presenting on behalf of the work group to the whole consultation. Additional resource persons, consisting of members from UNICEF/WHO and country representatives, were positioned in each work group to assist the group in achieving the desired session outcomes. These resource persons supported the group leader in ensuring that the work group addressed the consultation objectives; and an in-country representative was placed in each group to ensure that the discussion and prioritization were relevant, feasible, and addressed the needs of local governments/implementers. A note-taker was also assigned to each group to document the work group discussions and conclusions.

Group Guidance and Methodology

Participants spent the Day 2 morning session of the expert consultation in their respective work groups. Groups reported back to the entire consultation in the afternoon session. Each group made a 15-20 minute presentation on the consensus of the work group using a PowerPoint template that was provided.

Groups were instructed to decide among themselves how they would come to consensus on the top five priority research questions, whether done by voting, scoring, or discussion. However, they were asked to consider the following criteria for each question during the group prioritization:

- **Answerability**
  - Can the question be answered through well designed and conducted OR?
  - Would the OR study needed to answer the question be feasible within the current ethical, population and financial environment (logistically, financially, timely)?
- **Usefulness in filling an important knowledge gap**
  - Will answering the research question add significantly to the PMTCT and pediatric HIV CST knowledge base?
  - Will the answers to the research question be relevant, useful, and generalizable to the global efforts to scale up PMTCT and pediatric HIV CST services?
- **Potential impact on disease burden reduction**
  - Will answering the OR question have a large impact on the epidemic and/or the survival of the HIV infected population?
  - Will it be feasible to rapidly and widely implement the results of the OR study needed to address the research question (logistically, financially, timely)?

In the group guidance provided, one suggested option for prioritization was to rate their questions according to a scale utilizing these criteria, as this would be the process for the entire consultation group's prioritization of the 20 questions. Each question should be assigned a score from 1 to 4 for each criterion. Therefore, one could assign a maximum score of 12 for each question, using the following scale:

1 = not likely to fulfill the criteria
2 = may possibly fulfill the criteria
3 = will likely fulfill the criteria
4 = will almost certainly fulfill the criteria

The following are summaries of the work group discussions, their decision-making processes, and the top five priority questions selected by each group. Although the above criteria were considered, groups developed their own means for determining the highest priority questions. Groups varied in the extent that they were able to develop suggested research strategies for addressing the proposed questions. Please refer to the groups' slide presentations in the accompanying document

Group 1: Maximizing PMTCT Effectiveness

The group leader began the session by having each member voluntarily talk about what they see in the field and what they perceive as key areas or problems. This initial phase of discussion generated intense discussion with each key area or problem that was mentioned. The topics discussed during this phase included continuity of care and community engagement. However, these two topics generated considerable debate and this general form of open discussion was determined not to be optimal for decision-making. Following the mention of issues existing at each level of the PMTCT cascade, the group leader decided to change the format of the discussion.

In an effort to produce more structured discussion, the leader requested that the group identify the points along the cascade and then discuss the specific key problems at each level. The group used a flip chart paper to create an outline. They divided the cascade into two main parts: "pregnant woman" and "baby." As the group moved through the cascade, priority issues emerged as the members found themselves returning to key themes or spending more time on certain topics. The group created the following outline as they discussed the progression of the cascade and the issues at various points along the cascade. (Please note that this was for brainstorming purposes only and is not meant to be an exhaustive list):

Pregnant woman

- She has to seek antenatal care
- She has to disclose her status
- If need testing – then testing cascade
- If HIV-positive then need to do women's care, including CD4 count, referral
- Initiate prophylaxis or ART
- Monitoring, follow up, baby package
- Adherence to therapy
- Delivery
  - Institutional deliveries
  - How can those with non-facility deliveries be supported?
- Make assessment of mother's status following delivery
- Reassessment of mother's status?

Baby

- Exposure status
- Infant feeding
- Drug or treatment of some sort
- Reinforce to the family that there is testing at six weeks (This is another chance for mother care and treatment)
- Determine final status

Key questions emerging from this exercise for decision making were the following:

- Are there ways to address multiple questions on the cascade with one intervention?
- Where is the biggest "bang for our buck"?
- Where does the cascade begin and end?

Once the cascade was completed, a general consensus was reached around seven questions as priorities. Through further discussion the list was shortened to the main five priority questions. Following the determination of the five priority questions, discussion on suggested interventions ensued, however the time remaining was limited.

Top five priority OR questions

1. What are effective strategies for provision and monitoring of CD4 testing and antiretroviral treatment, if eligible, for pregnant and breastfeeding women?
2. For postpartum prophylaxis during breastfeeding:
   a. What are effective strategies for implementation?
   b. What is the comparative effectiveness of infant versus maternal prophylaxis?
3. What are feasible and valid methods to measure PMTCT effectiveness for both maternal and infant outcomes at both the program and population levels?
4. What are the community strategies to effectively increase PMTCT uptake?
5. How can family and male partner involvement be increased? Does family and male partner involvement increase PMTCT uptake and successful completion of the cascade?

The following are highlights from the discussion following Group 1's presentation to the entire consultation:

- One participant noted that the UN Prongs 1 (primary prevention) and 2 (provision of appropriate reproductive health counseling) were not reflected in these questions; Group 1 felt that these important issues should be addressed in another forum and deserve attention in their own right; the mandate for this particular task was to focus on PMTCT programs for HIV-positive pregnant and post-partum women in clinics
- In light of the revised WHO Guidelines, another comment was made that the focus on Prong 3 needs to be expanded to outcomes for the mother and her baby, not just on the prevention of MTCT
- It was also noted that the first challenge is to increase access; participants suggested strengthening community engagement and working more closely with demographers and epidemiologists to expand coverage and scale up programs to reach greater numbers of women
- Group 1 explained that Question #1 was selected because it could prove to have the biggest and broadest impact, though there were health systems issues raised in the larger discussion, including health care worker shortages and the most appropriate model for delivering care

Group 2: Pediatric HIV Care, Support, and Treatment

Group members began the process of prioritizing the top five OR questions in the field of pediatric HIV care and treatment with an open forum discussion. First, group members individually suggested topics for OR research, which were recorded on a flip chart by the group leader. Initially the group worked to decide if certain research questions that were suggested were too broad or too narrowly focused. Through discussion, the participants decided that it was best to initially identify the broad categories and then develop the specifics of those deemed as the five most important OR priorities.

After a lengthy period of general suggestions, it was proposed that the group's discussion should focus on the broad research sub-topics that were provided in the work group guidance (see above). Group members discussed the relative importance of these sub-topics and debated whether or not to group certain categories together or to remove some of the categories from their discussion entirely. Ultimately they decided to develop several important research questions within each sub-topic then narrow those

down to their top five OR priorities. In reviewing this list, group members suggested specific questions for OR research within each broad topic. The participants worked together to refine the wording of research questions and to either combine several different suggested questions or separate out larger-scale questions into smaller research topics as appropriate. The group considered the answerability of the proposed research questions in this process. Certain research topics, such as reproductive counseling for adolescents, were considered but determined to be outside the scope of the group's focus area.

The group used a modified Delphi technique to individually rank the top five OR questions in priority order. Using secret ballots, each group member awarded five points to their top priority question; four points to their second highest priority question; three points to the third, two points to the fourth, and one point to the fifth. Total scores were computed for each of the 12 research questions to determine the group's OR priorities. The group then went through each of the top five questions to describe the rationale for its selection as an OR priority. Finally, the group discussed each of the top five OR priorities at length to determine suggestions for study designs, interventions that could be used, and outcomes of interest. The group maintained a focus on identifying any potential harms of the suggested interventions and evaluated each intervention in the context of overall child health, not just HIV and AIDS care.

Top five priority OR questions

1. What is the optimal model for delivery of comprehensive care and treatment for HIV-infected infants and children?
2. What are the best models to provide care and support services to exposed infants?
3. What are the interventions at the program, facility, community, and household levels that have the greatest impact on retention in care, especially in the first 12 months of life?
4. What are the best interventions to support implementation and uptake of infant feeding recommendations?
5. How can the maximum number of HIV-infected infants and children be identified early?

The following are highlights from the discussion following Group 2's presentation to the entire consultation:

- Group 2 noted that the crux of the debate within their group was the relative importance of identification versus treatment of HIV-infected children; the latter was not included in the final list but was discussed at length
- Group 2 clarified that the determination of optimal models for children should be setting and population specific
- It was recommended that family-centered approaches in particular should be studied further
- To avoid new infections in children, it was noted by the larger group that primary prevention in children/adolescents should be addressed; Group 2 felt that this was outside of its scope but sexual health and primary prevention in this population was discussed
- Participants stressed other important issues related to children to consider outside of ART, including special considerations for orphans, education, nutrition, more general health outcomes, etc.

Group 3: Integration of HIV Programs within Broader MNCH Programs

The group discussion began with introductions, including a brief summary of their professional background and skills. This provided a good platform for understanding the group's knowledge and skill set.

Next the group had a brief discussion of what "integration within MNCH" entailed. The group discussed what services are currently offered within most MNCH programs and which of those services should be

the focus of the group's discussion. One of the main issues that emerged was how to integrate the facility into the community setting.

The discussion centered on the different elements that would need to be integrated into the community (care, policy, NGOs, etc) and the different levels in which to address integration. The group spent considerable time discussing all of the different areas of focus and determining which area would have the most impact. After discussing many different ideas, one participant grouped all of the questions (approximately 20) into five thematic areas. These areas were the following:

1) Integrating EID into pediatric services
2) Family planning
3) Nutrition and infant feeding
4) Community involvement/demand generation
5) Integrate ART into MNCH services

Next the group went through each of these topics and discussed them in depth. Their criteria for prioritization are listed below:

- Where is the "biggest bang for our buck?"
- What services will save the most lives?
- Will answering this OR question have a large impact on the epidemic?

The group also considered the cost-effectiveness of the different measures. There was also discussion on focusing on "how" to integrate rather than "where" to integrate. When considering integration the group also felt that it was important to consider what the desired outcome is and setting minimal standards of coverage and quality of service.

For each priority question identified, the group developed a rationale and identified possible study designs.

Top five priority OR questions

1. What is the feasibility and impact of integrating PITC services and care for HIV-exposed infants into routine MNCH services?
2. What is the feasibility and impact of providing ART for eligible pregnant women in ANC?
3. What is the appropriate timing, content, and setting within MNCH services to ensure the integration and provision of FP services to HIV-positive women?
4. How can community health workers and peers increase utilization of MNCH and HIV/AIDS services?
5. What are the benefits, challenges, cost-effectiveness, and effects on service utilization of integrating PITC into EPI services for children under five?

The following are highlights from the discussion following Group 3's presentation to the entire consultation:

- Group 3 explained their reasoning for their OR prioritization and said integration of all services into MNCH was discussed; taking the minimum package of services and integrating it into the MNCH services was also considered
- In response to comments, Group 3 also explained that integration based on feasibility and the use of models to predict outcomes and the numbers of women and children needed to reach to have an impact were also topics included in their group's discussion
- Clear connections with health systems strengthening were raised by the larger group, as programs cannot be built up in isolation; however one participant noted that donors are not going to pay for restructuring entire health systems

Group 4: Health Systems in the Context of PMTCT and pediatric HIV CST

The group began by discussing the issues that they felt were important to include in the research questions; scale-up, efficiency, and community were the first issues addressed in the discussion. The group commented that the work group guidance omitted community issues, but they did use the sub-topic list to guide their discussion. The members recognized the importance of answerability and timeliness in determining their priority OR questions.

The group decided to make a list of OR questions throughout the discussion. When discussing where to begin, they decided to use the findings of the GWU/EGPAF literature review and determine what research should be done based upon the gaps identified in the review. Human resources were discussed in-depth, as well as the possibility of a task shifting solution in PMTCT. The group also recognized the importance of these questions as they relate to policy (i.e., "is this research question going to change policy?"). The issues of quality, ART, PMTCT, political resistance, and impact on other health outcomes were raised in relation to task shifting and added to the initial list.

Program governance and the types of feasibility studies needed in order for the government to develop policy were discussed. Because one or two governance issues that were the most important to address could not be identified, it was determined that OR should be focused on identifying those issues as a first step. The research question "can PMTCT be used as an indicator to guide better governance?" evolved into "evaluating innovative approaches for improving sub-national planning and management of health services using PMTCT/ CST as tracer interventions."

Moving into program financing issues and logistics, the group raised the issues of accountability, service delivery models, weighing the cost of action versus inaction, linking resources to results, sustainability, and performance-based financing (PBF). Members of the group suggested forgoing logistics/supply chain management altogether because the issue can be dense and problematic. Instead, the group decided to narrow down the focus to the impact of logistics on PMTCT stock-outs. It was agreed upon that the objective could be to find a logistical system that does work well, and attach PMTCT to it as a tracer.

Other topics discussed included training and skills development integration, better use of data in PMTCT, and funding for PMTCT activities.

Narrowing this large discussion down to five OR questions was accomplished through a listing of all of the questions posed throughout their discussion, and a ranking of the questions. Study designs were also discussed and decided upon by the group. The group recognized that the review needs to be more systematic, that there was not adequate time to explore all of the possible OR questions.

Top five priority OR questions

1. Task shifting: What is the effect and impact of task shifting on PMTCT and pediatric CST scale-up in various settings, at various levels of the health care system and amongst different cadres of health workers?
2. Data: What is the effect of different approaches/models to data collection on data quality and data use at all levels of the health care system?
3. Governance: What is the effect of innovative approaches for improving sub-national planning and management of health services, using PMTCT and pediatric CST as tracer interventions?
4. Financial accountability and management: What are cost-efficient models for delivering PMTCT and pediatric CST within the broader context of MNCH services?
5. Logistics: What is the impact of various approaches to supply chain management on PMTCT services / scale-up (availability …. outcome)?

The following are highlights from the discussion following Group 4's presentation to the entire consultation:

- Group 4 explained that the questions were not designed to focus on planning or programming, but on scaling up
- In their discussion on financing, Group 4 focused on providing for some flexibility in financing programs by putting a system in place that allows the sub-national level to innovate
- Participants felt the question on data was an important one, but that Question #2 was broad and raised several other issues surrounding data:
    - How to evaluate the data currently being collected and the validity and relevance of the indicators?
    - How to promote better data use at district and facility levels?
    - What is the future role of longitudinal patient-level data and electronic medical records?
- One participant noted that rather than supply chain management, other activities could be addressed through OR; Group 4 felt that this is a weak and sensitive area and although difficult to address, the question could be narrowed down to what is appropriate for PMTCT.

OR Prioritization Process

After each group had the opportunity to present their top five priority questions and the other participants were able to ask questions and provide input, all participants were provided with a spreadsheet and asked to rate the merged questions from each group (20 in total) according to the criteria and scale defined above (refer to page 16): answerability, usefulness in filling an important knowledge gap, and potential impact on disease burden reduction. Each question received a maximum score of twelve points based on the extent to which the question was able to fulfill these criteria. The scores were entered into an Excel database, tallied, quality checked, and the questions were ranked according to the highest score.

VI. DAY 3:

KEY HIGHLIGHTS FROM DISCUSSION

Highest Priority Questions and Discussion

The 20 highest priority questions in ranked order were presented to the group on the morning of Day 3. Those receiving the highest scores are listed below, which includes at least one question from each group. The complete ranking of all questions by total score and by each criterion can be found in Annexes 7 and 8.

> #1: What are effective strategies for provision and monitoring of CD4 testing and antiretroviral treatment, if eligible, for pregnant and breastfeeding women?
>
> #2: For postpartum prophylaxis during breastfeeding: What are effective strategies for implementation; and what is the comparative effectiveness of infant versus maternal prophylaxis?
>
> #3: What is the feasibility and impact of providing ART for eligible pregnant women in ANC?
>
> #4: Task shifting: The effect and impact of task shifting on PMTCT and pediatric CST scale-up in various settings, at various levels of the health care system and amongst different cadres of health workers.
>
> #5: What are the interventions at the program, facility, community and household levels that have greatest impact on retention in care, especially in the first 12 months of life?

After participants received the ranking of questions, discussion ensued on the methodology and implications of these results. Participants acknowledged that all questions posed in the list are important and should be considered as next steps are discussed. Some also raised the issue that these questions should be viewed within their own thematic area, as partners and funders will have different priorities when it comes to addressing pediatric HIV CST, PMTCT, or health systems and require potential projects to be specific and targeted. Moreover, participants stressed that while the highest ranked questions were identified through this process, all 20 OR questions should be considered important and priority questions to be addressed. It was also noted that of the three criteria, answerability may have affected participants' decision-making more than the other two. In other words, certain questions may have scored high on potential impact and usefulness, but participants may have felt that they were too difficult to answer. An important observation was also made that the questions focus mainly on Prongs Three and Four of the UN strategy to approach prevention of HIV infection in infants and young children. Finally, it was noted that OR should not be mistaken for programmatic priorities, such as quality improvement and the quality of data collection systems.

The development of the priority list is one step; the OR studies that move forward will largely depend on the will, resources, and capacities of the countries and donors.

Presentation: High Priority Research Questions- Considerations
Anirban Chatterjee, UNICEF

Dr. Chatterjee presented on the considerations of these priority questions, which are outlined briefly below. Please refer to his slide presentation in the accompanying document.

- Priority setting in a local context: What are the policy implications at country and facility levels?
- Forging partnerships: What are the different levels of engagement of organizations involved in OR, including funding, researching, and implementing?

- Country program coordination mechanisms: What are their roles in defining priorities and moving from research findings to policy to practice?
- Use of existing national level program data: Should OR be a separate process or work within national data collection systems?
- Capacity building for OR at the national level: How do we optimize experts in the various regions and what role can they have?

Presentation: Country Perspectives

Participants representing NGOs, hospitals, and ministries in select countries (Zimbabwe, Uganda, India, and Zambia) met prior to the Day 3 session to discuss their perspectives from the country vantage point. These country representatives summarized ideas for the way forward for incorporating OR into national HIV/AIDS program priority activities, including:

- To conduct country level activities needed to support organizing consultative meetings to facilitate discussion and integration of PMTCT, pediatric HIV CST and OR;
- To prioritize OR needs in-country with the development of a research framework;
- To identify partners to facilitate the conduct of priority OR;
- To mobilize funding and resources to conduct the research including accessing existing mechanisms such as Global Fund to include OR; and
- To develop an action plan with an accompanying time frame.

Please refer to the accompanying document for the slide presentation.

Discussion Highlights

Capacity building and deeper engagement of the Ministry of Health (MOH) was strongly felt to be an important step forward for many of the participants. Their involvement is crucial not just for reasons of sustainability and their role as the owners of country programs, but also in terms of using OR as a platform for changing or creating new policy. MOH involvement was stressed even when the research in question is not considered one of the Government's priorities; the possibility of conducting such research should continue to be addressed through relevant committees, working groups, and vested communities. Supporting the forging of partnerships between the MOH and research organizations within or external to the country was also seen as a crucial step forward. Government collaborations may also have the advantage of providing guidance with regards to the facilitation of proposals through ethics committees and access to and use of routinely collected program data. Specific recommendations for greater MOH involvement included involving the MOH on the technical team developing the proposal or as a Co-Principal Investigator and the utilization of technical working groups as a vehicle for advising and providing OR support to ministries. Greater advocacy to raise the priority of research in MOH and training were also mentioned, but there were mixed responses in terms of their effectiveness.

Challenges raised include the limited number of experts in the HIV OR field and those working within programs are limited in the amount of time they can devote to OR. Moreover, those working in programs are well-positioned to contribute to the field but many need support on how best to conduct OR. The question of how to put in the initial investment in capacity was also mentioned as a challenge.

Other suggestions that emerged from the discussion on how to promote OR in countries include:

- Exploring the NIH Fogarty grants or training scholarships that can be used to support OR and implementation science
- Supporting the establishment of South-South partnerships
- Targeting field epidemiology graduates and training them in OR
- Using expertise outside the realm of HIV OR, such as mathematical modeling
- Forging partnerships with established OR/IR training programs, such as Analytics Operations Engineering in Massachusetts and University of Florida's Implementation Science Network
- Exploring potential contributions of private industry (e.g., pharmaceutical companies)

Given the practical nature of OR and its special emphasis on sustainability, it was also noted that a different standard and mindset needs to apply to OR compared with other types of research. This includes applying alternative study designs and timelines and disseminating information through means other than a published article in a peer-reviewed journal, including sharing information with other researchers on design, preliminary results, data sets, and considering the pooling of information to create larger data sets.

Dr. Heidari, on behalf of IAS, also encouraged participants to submit and publish OR articles to share other relevant information through JIAS (www.jiasociety.org), an online, open-access, peer-reviewed HIV/AIDS journal that aims to disseminate essential and innovative HIV/AIDS research, prevention and care efforts.

VII. RECOMMENDATIONS AND WAY FORWARD

On Day 3, a Closing Session was held to discuss final recommendations and the way forward; this session was moderated by Dr. Luo of UNICEF and Dr. Shaffer of WHO. In this section, the major recommendations of this session are summarized. Closing remarks were made by Amb. Jimmy Kolker, Chief of HIV and AIDS and Associate Director of Programmes at UNICEF.

Dissemination of consultation outcomes

The Conference Secretariat will generate an Executive Summary and a Final Report that will be reviewed by the Steering Committee and then disseminated to all consultation participants.

The Steering Committee will then adopt appropriate mechanisms for sharing these reports with other key partners including the IATT, the Global Fund, NIH, IAS, and other UN and funding agencies.

The Steering Committee will discuss the utility of making the OR publications database available on the internet for a broader audience, and the possibility that the Secretariat will maintain this database on an ongoing basis.

The Secretariat and the Steering Committee will work together to develop an abstract on the results of the consultation to be submitted to CROI 2010. They will also consider developing a manuscript for the peer-reviewed literature to be submitted to the Lancet or JIAS.

Promoting dialogue about operations research

The Steering Committee should promote further dialogue about OR issues through the IATT, potential funders, and other global partners. In addition, outreach is important to other programmatic initiatives that have extensive experience with OR such as vaccinations, maternal and child health, malaria, and tuberculosis. Improved linkages with donors should be established as these donors could be encouraged to develop their support for OR programs, and information on their funding programs and funding cycles should be obtained. Lastly, efforts should be made to integrate OR priorities into existing bodies rather than creating new working groups for operations research.

Development of operations research guidelines

The development and promotion of operations research guidelines for PMTCT and pediatric care and treatment should be considered by WHO and UNICEF.

Incorporating operations research into national HIV/AIDS program priority activities

Various strategies were suggested to incorporate OR into national HIV and AIDS programs. These included organizing consultative meetings to facilitate discussion and integration of PMTCT and OR; prioritizing OR needs in country with the development of a research framework; identifying partners to facilitate the implementation of priority OR; mobilizing funding and resources to conduct the research, including existing mechanisms such as the Global Fund; and developing an action plan with specific timeframes. At the international level, identifying mechanisms for sharing programmatic successes and research results and participating in an international partnership forum on OR would advance countries' research agendas and facilitate the broader scale-up of PMTCT and pediatric HIV CST services.

Further considerations

With the highest priority OR questions having been articulated, the participants expressed a strong interest in moving to the next level – to develop scientific operations research concept sheets and protocols, to prioritize countries that could be critical in moving the OR priorities forward, and to assess which populations need to be studied. In this context, it will be important to consider various aspects of alternative study designs, including human subjects and ethics issues, human capacity for research, and partnerships that could be leveraged.

It should be noted that on March 8, 2010, IAS and 15 other leading organizations released a comprehensive research agenda designed to significantly advance global responses to HIV in women, girls, and children. The joint consensus statement, "*Asking the Right Questions: Advancing an HIV Research Agenda for Women and Children*", includes 20 specific recommendations to expand and improve responses to the HIV-related challenges facing women and children worldwide. The statement can be accessed in its entirety at www.iasociety.org/Web/WebContent/File/Consensus_Statement_Asking_the_Right_Question_March_2010.pdf.

This document identifies 20 priority research questions within four broad categories: 1) clinical research on PMTCT and pediatric treatment; 2) clinical research on treatment issues for women; 3) operations research for women; and 4) operations research related to PMTCT, including pediatric care, treatment and support.

The agenda was developed through an extensive consultative process including an expert-led mapping exercise, literature review and a multi-stakeholder consultation with investigators, clinicians, civil society, and UN agencies initiated by the IAS-ILF. Recommendations in the fourth category of the agenda were developed though this expert consultation.

Summary

There has been great progress scientifically in knowledge about how to prevent mother-to-child HIV transmission and treat pediatric HIV infection. The challenge is in the implementation, at scale, of what is known in settings with limited resources. Implementation science is critical to provide strong evidence-based, scalable interventions to address current barriers to effective PMTCT/CST programs; to advance the field; and to achieve the goal of global elimination of pediatric HIV and AIDS. Successful operations research studies are those with results that change policy and practice and/or improve program and health system performance. The realization of the importance of OR/IR has come to the forefront as programs for PMTCT and pediatric HIV CST are scaled up worldwide in areas with limited resources and infrastructure during a difficult economic period that requires effective and efficient use of resources.

In summary, there has been remarkable progress in PMTCT and pediatric HIV CST in the last few years, but there is still a long way to go to reach all women and children in resource-limited settings with these services. There is a renewed focus on PMTCT as one of the most successful methods of HIV prevention, with the potential to eliminate vertical transmission of HIV. However there are significant bottlenecks and challenges to meeting the UNGASS 80% coverage goal and knowledge gaps in implementation that require strong OR as a basis for evidence-based approaches to overcome these challenges and increase program reach and effectiveness. Setting a priority research agenda to guide countries and programs, as was done during this consultancy, advocacy with donors around the importance of funding OR, and identifying mechanisms for sharing results quickly is needed to achieve these goals. National programs must focus their efforts, personnel, and resources on developing and implementing comprehensive PMTCT and pediatric HIV CST scale-up strategies that include OR to better inform these efforts to achieve the goal of the elimination of pediatric HIV and AIDS.

Annex 1:

Concept Note on Operations Research on PMTCT and Pediatric HIV Care, Support and Treatment

Please note: this concept note was developed by UNICEF and provided to GWU, EGPAF, and other participating members of the Steering Committee to provide the rationale and describe the objectives for an expert consultation. This was drafted in December 2008 and certain aspects have changed as the project evolved.

1. Background and rationale

In most resource-limited countries, especially in sub-Saharan Africa, prevention of mother-to-child transmission (PMTCT) programs were initiated through research projects sponsored by international research agencies. The objective of the majority of initial studies was primarily to assess the efficacy and safety of antiretroviral (ARV) regimens administered to women and/or their infants to reduce the risk of mother-to-child transmission (MTCT) of HIV. These studies were not designed to look at how PMTCT interventions can effectively be implemented as integral components of routine maternal, newborn, and child health (MNCH) services.

However, in resource-limited settings, MNCH programs represent a platform for the implementation of HIV prevention, care and treatment services for the majority of women and children. In general, PMTCT and pediatric HIV CST interventions are implemented across a wide range of services including, antenatal and delivery care services, postpartum care for mothers and newborns including well-child and nutritional services, and other reproductive health services, including family planning. Implementation of comprehensive PMTCT programs requires women to have large access to these services. Strengthening existing health care systems is therefore particularly important for PMTCT and pediatric HIV CST especially in order to establish sustainable long-term chronic, lifelong disease management systems. This will benefit both MNCH and MTCT prevention services through:

- Seizing the opportunity to provide a comprehensive package of health care services, any contact with women and their children with the health care system being considered as a single event
- Maximizing the health impact of a woman and/or child's visit to health facilities through increasing the effectiveness of different health interventions provided during the visit

The global partners, through the Inter-Agency Task Team (IATT) on the prevention of HIV in pregnant women, mothers and their children[2] has been instrumental in providing guidance and support to national governments in planning and implementing PMTCT and pediatric HIV CST programs. The overall

[2] The Interagency Task Team is represented by 20 partner agencies, including the United Nations Children's Fund (UNICEF), the World Health Organization (WHO), the United Nations Population Fund (UNFPA), the Joint United Nations Programme on HIV/AIDS (UNAIDS) Secretariat, the World Bank (WB), the United States Centers for Disease Control and Prevention (CDC) and the United States Agency for International Development (USAID), the Global Fund for AIDS, Tuberculosis and Malaria (GFATM), as well as prominent international non-governmental organizations such as the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), the International Center for AIDS Care and Treatment Programs (ICAP) at Columbia University's Mailman School of Public Health, Family Health International (FHI), the Clinton Foundation HIV/AIDS Initiative (CHAI), Catholic Medical Mission Board (CMMB), the Academy for Educational Development (AED), Population Council, the International Center for Reproductive Health (ICRH), Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau (ESTHER), Baylor International Paediatric AIDS Foundation (BIPAI), the International Community of Women Living with HIV/AIDS (ICW) and the International Planned Parenthood Federation (IPPF).

purpose of the IATT is to support, through concerted partnerships, national governments in addressing issues related to policies, strategies, resource mobilization and allocation, and progress tracking of global PMTCT and pediatric HIV care and treatment.

These last five years, the focus of the IATT has been on supporting national scale-up efforts through strong advocacy, engagement with the national governments for more demonstrable leadership, and commitment and accountability to deliver on the goal of universal access to PMTCT. Under this global leadership, progress has been accomplished with more political commitment at all levels and increasing funding opportunities including PEPFAR, the GFATM and UNITAID.

Recent data have shown notable progress made in coverage of PMTCT ARV prophylaxis and pediatric antiretroviral therapy (ART) since 2004-2005. The proportion of HIV positive pregnant women who received ARVs for PMTCT in middle and low income countries has increased from 10% in 2004 to 33% in 2007. As of December 2007, 198,000 children were on antiretroviral therapy up from 75,000 by end 2005 with a more than 250% increase.

In the framework of the global support to national programs, two levels of knowledge are of critical importance:

- Emerging scientific evidence informing primarily the design of evidence-based interventions to reduce HIV vertical transmission, especially the use of ARVs and safer infant feeding practices, and
- Program experience picturing the real world situation, especially in the context of human and financial resource scarcity

Remarkable progress has been made in the first area where WHO has provided continued leadership by keeping abreast of emerging evidence on interventions to reduce the risk of MTCT. This has resulted in the development of various guidelines which have been instrumental in the development of national policies and guidelines on the use of ARV for the prevention of MTCT of HIV. The latest WHO guidelines recommend the use of ART for all pregnant women in need of treatment for their own health and more efficacious ARV prophylactic regimens built around the combination of AZT plus sdNVP for those not eligible yet. Full implementation of these recommendations is expected to lead to a significant reduction in the number of pediatric HIV infections in low- and middle-income countries.

The body of evidence on implementation of known intervention in non research settings is still weak, partly because of the lack of formal channels to facilitate experience sharing and the non-existence of global mechanisms to identify priorities and set-up the global agenda for operations research.

National programs are increasingly asking for more guidance on how global guidelines could be implemented while taking into consideration local context. In line with this need, the IATT on prevention of HIV in Pregnant Women, Mothers and Children has identified operations research as a priority in setting the global agenda for PMTCT and HIV care for children. In the guidance for global scale-up of PMTCT, IATT partners call on global partners and national governments to support evidence-based strategic information to track progress, improve programming and guide policies. More specifically, partners are expected to support national programs to carry out operations research and to adopt learning-by-doing approaches. This support should include:

- Defining priorities and mobilizing resources for PMTCT-related research including operations research, and
- Documentation and dissemination of best practices and successful models

Most resource-limited countries are now in the process of moving from limited projects and initiatives toward national programs which address the need of the majority of women and their partners and children in need. This includes phasing in more efficacious ARV regimens for the prevention of HIV infection from an infected pregnant woman to her infant. This transitional process is challenged by various

political, structural and programmatic bottlenecks. The main bottlenecks identified in the majority of countries include:

- Weak health systems
- Poor coordination among national health programs and partners
- Low access and utilization of ANC, delivery and postnatal care services with high drop-out/loss to follow up of mothers and infants especially HIV-exposed infants and children. This includes weak continuum of care for HIV-infected pregnant and mothers including ART and family planning
- Limited availability and offer of HIV testing and counseling in ANC and delivery care settings
- Stigma and discrimination surrounding PMTCT and pediatric HIV CST
- Difficulties to implement infant feeding options (exclusive breastfeeding and replacement feeding)
- Limited community mobilization and involvement with poor male involvement in MNCH services and PMTCT interventions
- Lack of synergy between planning and implementation of ART and PMTCT
- Lack of sustainable procurement, storage, and distribution systems
- Shortage of skilled service providers and poorly motivated health providers
- Limited attention to primary prevention and prevention of unintended pregnancies among women living with HIV

Overall, there are knowledge gaps in achieving full effectiveness of known PMTCT and pediatric HIV CST intervention in different epidemic typologies and according to the strength of the health systems. Despite recent progress and lessons learned from programs, more evidence is still needed in various program areas to further expand PMTCT and pediatric HIV CST services through existing primary care systems. In fact, various initiatives are being undertaken to generate evidence on how existing guidance, guidelines and recommendations can effectively be operationalized in resource-limited settings. However, so far these efforts have not been systematic and there are no well defined channels or mechanisms through which lessons learned could be shared at all levels. Furthermore, there is no global agenda on operations research around PMTCT and pediatric HIV CST based on identified gaps and defined priorities.

To fill these gaps and provide further evidence-based guidance to national programs, UNICEF in collaboration with WHO, EGPAF and PEPFAR is planning a technical consultation on operations research on PMTCT and pediatric HIV CST. The overall purpose is to set-up a global agenda for operations research on PMTCT and pediatric HIV CST, establish mechanisms for experience sharing in order to improve effectiveness of PMTCT and pediatric HIV CST interventions in non-research context. This initiative is aimed at complementing the leadership role of WHO in the area of norms and standards, and that of the IATT on prevention of HIV infection in Pregnant Women, Mothers and their Children on global strategies, resource mobilization and allocation, and progress tracking.

2. Specific objectives

1. Map out key ongoing and planned operations research on PMTCT and pediatric HIV CST
2. Map out the knowledge gaps to achieve full effectiveness of known PMTCT and pediatric HIV CST known interventions in non research context, including operations bottlenecks to scaling up PMTCT and pediatric HIV CST in resource-limited settings
3. Identify specific national programs' needs in the area of operation research on PMTCT and pediatric HIV CST within the broader framework of MNCH
4. Define priorities for operations research agenda aiming at responding to country felt-needs in order to improve performance of health systems, quality, availability, acceptability and uptake of services
5. Develop a collaborative framework to promote and support in-country capacity building in operations research conducted on PMTCT and pediatric HIV CST in resource-limited settings

6. Set up global mechanisms to track emerging innovations from programs and share lessons learned through a three-monthly newsletter and online dissemination among key partners

3. Expected outcomes

1. A review of literature review on operations research on PMTCT and pediatric HIV CST. This includes a review of methodological approaches used
2. An inventory (mapping?) of key ongoing and planned operations research on PMTCT and pediatric HIV CST specifying area of assessment, key objectives, methodological approaches, and partners supporting the initiative
3. Report of the global consultation, including a description of key operations bottlenecks and gaps in operations research on PMTCT and pediatric HIV CST within the broader framework of maternal, newborn and child health (MNCH)
4. Agreed priorities for operation research in PMTCT and pediatric HIV CST aiming to respond to country needs
5. A collaborative framework to promote and support in-country capacity building in operations research conducted on PMTCT and pediatric HIV CST in resource-limited settings
6. Formation of a secretariat in charge of facilitating experience sharing through dissemination of lessons learnt through a quarterly newsletter

Annex 2: Steering Committee Members

Name	Organization	Department/Unit	Location
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Anirban Chatterjee	UNICEF	Nutrition and HIV Care and Support	NY
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Rene Ekpini	UNICEF	PMTCT and Paediatric HIV Care & Treatment Health Section - Programme Division	NY
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Laura Guay	EGPAF/GWU	Research Unit/ Dept of Epidemiology & Biostatistics	DC
Shirin Heidari	IAS	Senior Manager – Programmes and Initiatives	Geneva
Karusa Kiragu	UNAIDS Secretariat	Evidence, Monitoring and Policy Department	Geneva
Chewe Luo	UNICEF	HIV and AIDS Health Section - Programme Division	NY
Lynne Mofenson	NIH/NICHD	Pediatric, Adolescent, and Maternal AIDS Branch, Center for Research for Mothers and Children	MD
Nathan Shaffer	WHO	PMTCT Team/ Prevention in the Health Sector -- HIV/AIDS Dept	Geneva
Yves Philippe Henri Souteyrand	WHO	HIV/AIDS Department – Strategic Information Unit	Geneva

Annex 3: List of Meeting Participants and Organizations

EXPERT CONSULTATION ON OPERATIONS RESEARCH ON PMTCT AND PEDIATRIC HIV CST PARTICIPANT LIST

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Annex 4: Expert Consultation Agenda

Expert Consultation on Operations Research on PMTCT and Pediatric HIV CST

The George Washington University Washington, D.C. September 9-11, 2009

Day 1 - Wednesday, September 9

8:30 – 9:00 **Registration and Coffee and Tea**

9:00 – 10:30 **Opening Ceremony**
Moderators: Alan E. Greenberg, GWU; and Laura Guay, EGPAF

9:00 – 9:10 Welcome
Josef Reum, Interim Dean, School of Public Health and Health Services, GWU
Pam Barnes, President and CEO, Elizabeth Glaser Pediatric AIDS Foundation

9:10 – 9:20 Role of Steering Committee and Secretariat, Review of Agenda, Housekeeping Items
Alan E. Greenberg, Professor and Chair, Department of Epidemiology and Biostatistics, School of Public Health and Health Services, GWU; Michelle Gill, Partnership Executive Coordinator, GWU/EGPAF

9:20 – 9:30 Participant Introductions

9:30 – 10:00 Opening remarks
Chewe Luo, Team Leader Programme Scale-up, HIV Section, UNICEF Yves Souteyrand, Coordinator SIR, HIV/AIDS Department, WHO Karusa Kiragu, Senior Prevention Advisor, UNAIDS Secretariat

10:00 – 10:30 Meeting Objectives
Health system research within the context of MNCH and HIV service delivery
Rene Ekpini, Senior Advisor, Health Section - Programme Division, UNICEF

10:30 – 11:00 **Coffee and Tea Break**

11:00 – 12:45 **Plenary Session**
Moderator: Francois Dabis, ISPED

11:00 – 11:20 Operations Research to Address Barriers to HIV Prevention, Care and Treatment Scale-up in Resource Limited Settings
Laura Guay, EGPAF

11:20 – 11:55 Update on the new evidence on PMTCT and Pediatric Care and Treatment
Lynne Mofenson, Pediatric, Adolescent and Maternal AIDS Branch, Center for Research for Mothers and Children, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health

11:55 – 12:15 PMTCT and Pediatric CST OR in the context of changing PMTCT guidelines: Programmatic and Policy Implications
Nathan Shaffer, PMTCT Team Leader, PHS Unit, HIV/AIDS Department, WHO

12:15 – 12:45 Discussion

12:45 – 1:30 **Lunch Break**

1:30 – 2:15 **PEPFAR perspectives and IAS/ILF update**
Moderator: TBD

1:30 – 1:45 PEPFAR perspective on priorities for PMTCT and Pediatric CST OR, current and future plans
RJ Simonds, Deputy Director, Global AIDS Program, Centers for Disease Control and Prevention

1:45 – 2:00 Summary of the IAS/ILF meeting on building consensus on research priorities for women and children
Shirin Heidari, Senior Manager – Programmes and Initiatives, International AIDS Society

2:00 – 2:15 Discussion

2:15 – 5:30 **Update on published and ongoing OR; Preparation for Work Groups**
Moderator: Nick Hellman, EGPAF

2:15 - 2:55 Introduction of literature review, work group activities, and outcomes
Published and ongoing studies: Key knowledge and gaps in the field
- Part 1: PMTCT
- Part 2: Pediatric care and treatment

Laura Guay, EGPAF

2:55 - 3:25 Discussion

3:25 - 3:55 **Coffee and Tea Break**

3:55 - 4:20 Published and ongoing studies: Key knowledge and gaps in the field
- Part 3: Integration of PMTCT and pediatric care and treatment within MNCH services
- Part 4: Health systems

Christian Pitter, Director, Global Technical Policy, EGPAF

4:20 - 4:45 Discussion

4:45 – 5:00 Work Group Assignments and Objectives

5:00 – 5:30 Meeting with Work Group leaders, resource persons, and rapporteurs

6:00 – 9:00 **EGPAF-sponsored reception and dinner**

Day 2 - Thursday, September 10

8:00 - 8:15 **Coffee and Tea**

8:15 - 8:30 **Review of Day 1**

8:30 - 12:30 **Work Group Meetings (Coffee and Tea Break from 10:30 – 11:00)**

Group 1: PMTCT Program Effectiveness - Operations research priorities for addressing key gaps in achieving PMTCT program effectiveness, including:

- Program scale-up, coverage, and access of services
- PMTCT regimens including ART for eligible women and breastfeeding prophylaxis
- Cascade adherence, including HIV testing and counseling, ARV receipt, drug adherence, infant dosing, etc.
- Transmission through breastfeeding
- Family and community engagement
- Assessment of PMTCT effectiveness

Group 1 Leader: *Elaine Abrams, ICAP*
Group 1 Rapporteur: *Maggie Brewinski, USAID*

Group 2: Pediatric HIV Care and Treatment - Operations research priorities for addressing key gaps in providing optimal Pediatric HIV care and treatment, including

- Care and prophylaxis for HIV-exposed infants
- Identification of HIV-infected infants and children
- Retention and adherence to medication and postnatal follow-up
- Links to comprehensive HIV care and treatment for those infected (and their families)
- Infant feeding
- Community engagement
- Pediatric psychosocial support and counseling

Group 2 Leader: *Gordon Schutze, Baylor*
Group 2 Rapporteur: *George Siberry, NICHD*

Group 3: Integration within MNCH Services - Operations research priorities for addressing key gaps related to the integration of PMTCT and pediatric care and treatment with the broader MNCH services, including

- Linkages with other maternal services such as ANC, delivery care, PNC, reproductive health, family planning, STI programs, malaria, and TB
- Linkages with other pediatric services such as immunizations and nutrition

Group 3 Leader: *Pius Okong, Nsambya Hospital, Uganda*
Group 3 Rapporteur: *Barbara Rawlins, JHPIEGO/MCHIP*

Group 4: Health Systems - Operations research priorities for addressing key gaps related to health systems and program design to maximize sustainability, including

- Health care workforce
- Health information systems
- Program governance (e.g., district-based approach, decentralization, management and accountability)
- Program financing (e.g., PBF, district, community-based organizations)
- Logistics, drug procurement, and supply management

Group 4 Leader: *Luc De Bernis, UNFPA*
Group 4 Rapporteur: *Ameena Goga, MRC South Africa*

12:30 - 1:30 Lunch

1:30 – 5:00 Work Group Presentations and Discussions
Moderator: Annette Sohn, TREAT Asia/amfAR

1:30 - 2:15	Group 1 presentation and discussion
2:15 - 3:00	Group 2 presentation and discussion
3:00 - 3:30	**Break**
3:30 - 4:15	Group 3 presentation and discussion
4:15 - 5:00	Group 4 presentation and discussion
5:00 – 5:30	**Prioritization of OR Questions** *Alan Greenberg, GWU; and Laura Guay, EGPAF*

Day 3 - Friday, September 11

8:15	**Coffee and Tea**
8:30 - 11:00	**Discussion of Highest Priority Operations Research Questions and Approaches** **Moderator: Alan Greenberg, GWU**
8:30 - 9:00	Report back on key priority research questions and discussion
9:00 - 10:00	Discussion of approaches to high priority research questions and study designs *Anirban Chatterjee, Adviser, Nutrition and HIV Care and Support, UNICEF*
10:00 - 11:00	Presentation on country perspectives *Namwinga Chintu, CIDRZ*
11:00 - 11:30	**Coffee and Tea Break**
11:30 - 1:00	**Closing Session** **Moderator: Jimmy Kolker, UNICEF**
11:30 - 12:30	Wrap up and plans for the way forward *Chewe Luo, UNICEF; Nathan Shaffer, WHO*
12:30 - 1:00	Concluding comments *Jimmy Kolker, Chief, HIV and AIDS, Associate Director, Programmes, UNICEF*

Annex 5: Work Group Guidance

Expert Consultation on Operations Research on PMTCT and Pediatric HIV CST Work Group Guide

To identify the highest priority operations research questions, Work Groups have been created for each of four defined areas:

1) Maximizing PMTCT effectiveness
2) Pediatric HIV CST
3) Integration of HIV programs within broader MNCH programs
4) Health systems in the context of PMTCT and pediatric HIV CST

The purpose of these work groups is to discuss the operations research questions relevant to your group's topic area and to determine those questions that your group feels are *most crucial* to addressing key gaps in your assigned area. For each of the priority research questions identified, also discuss potential OR study designs or interventions to address them. Each group will be asked to make a 15-20 minute presentation on the consensus of the work group in the afternoon session using the PowerPoint template provided. The specific outputs requested from each of the work groups, which should be included in the presentation are listed below.

Group Work Questions

Your group will be expected to report back in the afternoon discussion with all meeting participants.

1. What are the five highest priority operations research questions for addressing key gaps in your group's topic area?

2. For each of the five questions chosen, please provide a brief rationale for why your group selected these as the most crucial OR priorities.

3. For each of the five questions chosen, please provide suggested approaches or interventions for addressing these OR priorities.

To make the best use of the allotted time to accomplish the output goals, it is important that the group stay focused on identifying the key research questions needed to address the gaps in knowledge and/or practice rather than spending a lot of time discussing the gaps and other programmatic challenges.

Criteria to consider in the prioritization of research questions (Q 1 & 2)

With the plethora of potential research questions on each of the four broad topics, each group should determine their prioritization process. Some criteria to consider in determining the prioritization include:

Answerability

- Can the question be answered through well designed and conducted OR?
- Would the OR study needed to answer the question be feasible within the current ethical, population and financial environment (logistically, financially, timely)?

Usefulness in filling an important knowledge gap

- Will answering the research question add significantly to the PMTCT and pediatric HIV CST knowledge base?
- Will the answers to the research question be relevant, useful, and generalizable to the global efforts to scale up PMTCT and pediatric CST services?

Potential impact on disease burden reduction

- Will answering the OR question have a large impact on the epidemic and/or the survival of the HIV infected population?
- Will it be feasible to rapidly and widely implement the results of the OR study needed to address the research question (logistically, financially, timely)?

Each group can decide how they will come to consensus on the top five priority research questions, whether done by voting, scoring, or discussion. However, after all four groups have presented and discussed their top five priority research questions, participants will be asked to score each of the 20 merged questions on the three criteria above (answerability, usefulness, and impact) using the following scale:

1 = not likely to fulfill the criteria
2 = may possibly fulfill the criteria
3 = will likely fulfill the criteria
4 = will almost certainly fulfill the criteria

The scores will be tallied and presented to the group at the beginning of Day 3 to start the discussion on potential OR designs to address the top priority research questions.

Considerations for potential OR design to address the priority research questions (Q 3)

As the group is discussing the priority questions and how they could be addressed, it would be helpful to consider: what would be the research question; what would be the key objectives of the OR study; what would be the most appropriate study design to answer the question; are there key ethical considerations that would need to be addressed?

Roles and Responsibilities

The **Work Group Leader** will be responsible for ensuring that the discussion remains focused on achieving the goal of coming to consensus on the priority research questions, that each group member is given the opportunity to contribute to the discussion, that the rights and opinions of all members are equally respected, that the group adheres to the time schedule, and that the conclusions of the group are reflected in the Rapporteur's summary presentation.

The **Rapporteur** will be responsible for providing a technical summary of the work group's discussion that will be used to assist with the completion of the final report of the consultation, for documenting the conclusions of the work group, and presenting the work group's response to the three questions above to the whole consultation when the groups come back together in the afternoon.

Additional **Resource Persons** will be positioned in each work group to assist the group in achieving the desired session outcomes. These resource persons will consist of member(s) of UNICEF/WHO who will support the group leader in ensuring that the Work Group is addressing the consultation objectives and an in-country representative to ensure that the discussion and prioritization are relevant, feasible, and address the needs of local governments/implementers.

A **Note-taker** will also be assigned to your group as an additional resource to document that content of the work group discussions and conclusions.

Avoidance of Overlap and Duplication of Efforts

To minimize duplication due to the overlap in these areas, specific areas for discussion for each group are presented below. The list of topics is not meant to be all inclusive- there may be areas of priority in the topical area that are not included in the list. They are intended as guides so that each group will know what topics the other groups are addressing so as to minimize overlap between groups.

Expert Consultation on Operations Research on PMTCT and Pediatric HIV CST
Group Work Guide for Group 1: PMTCT Program Effectiveness

The purpose of this work group is to discuss the operations research questions and to determine those questions that your group feels are *most crucial* to addressing key gaps in PMTCT program effectiveness.

Group 1 Leader: Elaine Abrams, ICAP

Group 1 Rapporteur: Maggie Brewinski, USAID

Group 1 Resource Persons: Nathan Shaffer, WHO and Kusum Nathoo, Department of Pediatrics and Child Health, University of Zimbabwe

Note-taker: Mariel Marlow

Discuss the priority operations research questions for addressing key gaps in the following topic areas under PMTCT: (Please note that this discussion should cover the PMTCT cascade of events, ending with the completion of the infant regimen; the Pediatric HIV Care and Treatment Group will address the topics beyond this):

- Program scale-up, coverage, and access of services
- PMTCT regimens including ART for eligible women and breastfeeding prophylaxis
- Cascade adherence, including HIV testing and counseling, ARV receipt, drug adherence, infant dosing, etc.
- Transmission through breastfeeding
- Family and community engagement
- Assessment of PMTCT effectiveness

Expert Consultation on Operations Research on PMCT and Pediatric HIV CST
Group Work Guide for Group 2: Pediatric HIV Care and Treatment

The purpose of this work group is to discuss the operations research questions and to determine those questions that your group feels are *most crucial* to addressing key gaps in pediatric HIV care and treatment.

Group 2 Leader: Gordon Schutze, Baylor

Group 2 Rapporteur: George Siberry, NICHD

Group 2 Resource Persons: Siobhan Crowley, WHO, Robert Gass, UNICEF, and Nathan Tumwesigye ANECCA

Note-taker: Laura Olsen

Discuss the priority operations research questions for addressing key gaps in the following topic areas under pediatric HIV care and treatment. (Please note that the PMTCT Program Effectiveness Group will address the PMTCT cascade of events ending with the completion of the infant regimen; your group should address the topics related to events beyond this):

- Care and prophylaxis for HIV-exposed infants
- Identification of HIV infected infants and children
- Retention and adherence to medication and postnatal follow-up
- Links to comprehensive HIV care and treatment for those infected (and their families)
- Infant feeding
- Community engagement
- Pediatric psychosocial support and counseling

Expert Consultation on Operations Research on PMCT and Pediatric HIV CST
Group Work Guide for Group 3: Integration within MNCH Services

The purpose of this work group is to discuss the operations research questions and to determine those questions that your group feels are *most crucial* to addressing key gaps related to the integration of PMTCT and pediatric care and treatment with the broader MNCH services.

Group 3 Leader: Pius Okong, Nsambya Hospital, Uganda

Group 3 Rapporteur: Barbara Rawlins, MCHIP

Group 3 Resource Persons: Namwinga Chintu, CIDRZ and Rene Ekpini, UNICEF

Note-taker: Leila Katirayi

Discuss the priority operations research questions for addressing key gaps in the following topic areas related to the integration of PMTCT and pediatric care and treatment with the broader MNCH services:

- Linkages with other maternal services such as ANC, delivery care, PNC, reproductive health, family planning, STI programs, malaria, and TB
- Linkages with other pediatric services such as immunizations and nutrition

Expert Consultation on Operations Research on PMTCT and Pediatric HIV CST
Group Work Guide for Group 4: Health Systems

The purpose of this work group is to discuss the operations research questions and to determine those questions that your group feels are *most crucial* to addressing key gaps in the area of health systems in the context of PMTCT and pediatric HIV.

Group 4 Leader: Luc De Bernis, UNFPA

Group 4 Rapporteur: Ameena Goga, MRC South Africa

Group 4 Resource Persons: Chewe Luo, UNICEF and Subhasree Raghavan, SAATHI, India

Note-taker: Emelie Bailey

Discuss the priority operations research questions for addressing key gaps in the following topic areas related to health systems and program design to maximize sustainability in the context of PMTCT and pediatric HIV:

- Health care workforce
- Health information systems
- Program governance (e.g., district-based approach, decentralization, management and accountability)
- Program financing (e.g., PBF, district, community-based organizations)
- Logistics, drugs procurement, and supply management

Annex 6: List of Work Group Members

Group 1: PMTCT Program Effectiveness (total = 13)

Group 1 Leader: Elaine Abrams, ICAP
Group 1 Resource Persons: Nathan Shaffer, WHO and Kusum Nathoo, Department of Pediatrics and Child Health, University of Zimbabwe
Group 1 Rapporteur: Maggie Brewinski, USAID

1. Ellen Weiss or Katherine Fritz, ICRW
2. Emilia Rivadeneira, CDC
3. Jeff Stringer, CIDRZ
4. Karusa Kiragu, UNAIDS
5. Laura Guay, EGPAF
6. Linda Kupfer, Fogarty International Center, NIH
7. Lynne Mofenson, NIH
8. Owen Ryan, Gates Foundation
9. Thu-Ha Dinh, CDC

Group 2: Pediatric HIV Care and Treatment (total = 16)

Group 2 Leader: Gordon Schutze, Baylor
Group 2 Resource Persons: Siobhan Crowley, WHO, Robert Gass, UNICEF, Nathan Tumwesigye ANECCA
Group 2 Rapporteur: George Siberry, NICHD

1. Andrea Ruff, JHSPH
2. Anja De Weggheleire, Institute of Tropical Medicine
3. Annette Sohn, TREAT Asia/amfAR
4. Ed Handelsman, NIH
5. Mary Lou Lindegren, CDC
6. Nancy Calles, Baylor
7. Nick Hellmann, EGPAF
8. Rabia Mathai, Catholic Medical Mission Board
9. Rosalind Carter, ICAP
10. Sara Bowsky, USAID
11. Shirin Heidari, IAS

Group 3: Integration within MNCH Services (total = 15)

Group 3 Leader: Pius Okong, Nsambya Hospital, Uganda
Group 3 Resource Persons: Namwinga Chintu, CIDRZ and Rene Ekpini, UNICEF
Group 3 Rapporteur: Barbara Rawlins, JHPIEGO/ MCHIP

1. Anirban Chatterjee, UNICEF
2. Elizabeth Mbizvo, Population Council
3. Gina Brown, NIH
4. Justin Mandala, FHI
5. Mary Bassett, Doris Duke Charitable Foundation
6. Nancy Binkin, UNICEF
7. Omar Sued, PAHO
8. Paul Bouey, OGAC
9. Rumbidzayi Masiyiwa, UNAIDS
10. Sten Vermund, Vanderbilt University
11. Stephen Arpadi, ICAP

Group 4: Health Systems (total = 14)

Group 4 Leader: Luc De Bernis, UNFPA
Group 4 Resource Persons: Chewe Luo, UNICEF and Subhasree Raghavan, SAATHII, India
Group 4 Rapporteur: Ameena Goga, MRC South Africa

1. Danielle Burke, UNICEF
2. Dianna Edgil, OGAC
3. Elizabeth McCarthy, CHAI
4. Hapsatou Toure, ANRS
5. Marc Nene, UNICEF Consultant
6. N'Della N'Jie, World Bank
7. Paul Ametepi, ICF Macro
8. Priscilla Akwara, UNICEF
9. Yves Souteyrand, WHO
10. Damodar Bachani, India MOH&FW

Annex 7: Results of Prioritization Exercise: Rank and Total Score

Rank	Score	OR Question	Group/ Priority
1	10.9	What are effective strategies for provision and monitoring of CD4 testing and antiretroviral treatment, if eligible, for pregnant and breastfeeding women?	1.1
2	10.2	For post partum prophylaxis during breast feeding: What are effective strategies for implementation; and what is the comparative effectiveness of infant versus maternal prophylaxis?	1.2
3	10.1	What is the feasibility and impact of providing ART for eligible pregnant women in ANC?	3.2
4	9.5	Task shifting: The effect and impact of task shifting on PMTCT and pediatric CST scale-up in various settings, at various levels of the health care system and amongst different cadres of health workers	4.1
5	9.5	What are the interventions at the program, facility, community and household levels that have greatest impact on retention in care, especially in the first 12 months of life?	2.3
6	9.4	What is the optimal model for delivery of comprehensive care and treatment for HIV-infected infants and children?	2.1
7	9.4	How can the maximum number of HIV-infected infants and children be identified early?	2.5
8	9.4	Data: The effect of different approaches / models to data collection on data quality and data use at all levels of the health care system.	4.2
9	9.3	What are the community strategies to effectively increase PMTCT uptake?	1.4
10	9.3	What is the feasibility and impact of integrating PITC services and care for HIV-exposed infants into routine MNCH services?	3.1
11	9.2	What are the best models to provide care and support services to exposed infants?	2.2
12	9.2	What are feasible and valid methods to measure PMTCT effectiveness for both maternal and infant outcomes at both the program and population levels?	1.3
13	9.1	What are the best interventions to support implementation and uptake of infant feeding recommendations?	2.4
14	9.0	How can community health workers and peers increase utilization of MNCH and HIV/AIDS services?	3.4
15	8.8	What are the benefits, challenges, cost-effectiveness, and effects on service utilization of integrating PITC into EPI services for children under five?	3.5
16	8.8	Logistics: To evaluate the impact of various approaches to supply chain management on PMTCT services/ scale-up	4.5
17	8.6	How can family and male partner involvement be increased? Does family and male partner involvement increase PMTCT uptake and successful completion of the cascade?	1.5
18	8.6	What is the appropriate timing, content, and setting within MNCH services to ensure the integration and provision of FP services to HIV-positive women?	3.3
19	8.2	Financial accountability and management: To evaluate cost-efficient models for delivering PMTCT and pediatric CST within the broader context of MNCH services	4.4
20	7.4	Governance: To evaluate the effect of innovative approaches for improving sub-national planning and management of health services, using PMTCT and pediatric CST as tracer interventions	4.3

Annex 8: Results of Prioritization Exercise:

By Criterion Score and Rank

Rank	OR Question	Answerability Score	Answerability Rank	Usefulness Score	Usefulness Rank	Potential Impact Score	Potential Impact Rank
1	What are effective strategies for provision and monitoring of CD4 testing and antiretroviral treatment, if eligible, for pregnant and breastfeeding women?	3.4	2	3.7	1	3.7	1
2	For post partum prophylaxis during breast feeding: What are effective strategies for implementation; and what is the comparative effectiveness of infant versus maternal prophylaxis?	3.3	4	3.4	2	3.6	2
3	What is the feasibility and impact of providing ART for eligible pregnant women in ANC?	3.3	3	3.2	10	3.5	3
4	Task shifting: The effect and impact of task shifting on PMTCT and pediatric CST scale-up in various settings, at various levels of the health care system and amongst different cadres of health workers	3.0	5	3.4	3	3.2	9
5	What are the interventions at the program, facility, community and household levels that have greatest impact on retention in care, especially in the first 12 months of life?	2.9	6	3.3	4	3.2	8
6	What is the optimal model for delivery of comprehensive care and treatment for HIV-infected infants and children?	2.9	9	3.3	8	3.3	5
7	How can the maximum number of HIV-infected infants and children be identified early?	2.9	12	3.2	12	3.3	4
8	Data: The effect of different approaches / models to data collection on data quality and data use at all levels of the health care system.	2.9	11	3.3	5	3.1	11
9	What are the community strategies to effectively increase PMTCT uptake?	3.5	1	3.2	11	3.2	6
10	What is the feasibility and impact of integrating PITC services and care for HIV-exposed infants into routine MNCH services?	2.9	10	3.3	7	3.1	12
11	What are the best models to provide care and support services to exposed infants?	2.8	14	3.3	6	3.2	10

12	What are feasible and valid methods to measure PMTCT effectiveness for both maternal and infant outcomes at both the program and population levels?	2.9	7	3.2	9	3.0	13
13	What are the best interventions to support implementation and uptake of infant feeding recommendations?	2.7	17	3.1	13	3.2	7
14	How can community health workers and peers increase utilization of MNCH and HIV/AIDS services?	2.9	13	3.1	14	3.0	14
15	What are the benefits, challenges, cost-effectiveness, and effects on service utilization of integrating PITC into EPI services for children under five?	2.9	8	3.1	15	2.9	17
16	Logistics: To evaluate the impact of various approaches to supply chain management on PMTCT services/ scale-up	2.8	16	3.0	16	3.0	15
17	How can family and male partner involvement be increased? Does family and male partner involvement increase PMTCT uptake and successful completion of the cascade?	2.8	15	3.0	17	2.8	19
18	What is the appropriate timing, content, and setting within MNCH services to ensure the integration and provision of FP services to HIV-positive women?	2.7	18	3.0	18	3.0	16
19	Financial accountability and management: To evaluate cost-efficient models for delivering PMTCT and pediatric CST within the broader context of MNCH services	2.5	19	2.8	19	2.9	18
20	Governance: To evaluate the effect of innovative approaches for improving sub-national planning and management of health services, using PMTCT and pediatric CST as tracer interventions	2.1	20	2.7	20	2.6	20