The President's Emergency Plan for AIDS Relief (PEPFAR)

PEPFAR Guidance on Integrating Prevention of Mother to Child Transmission of HIV, Maternal, Neonatal, and Child Health and Pediatric HIV Services

FINAL

January 2011

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Objectives of the Guidance

Supporting the integration of Prevention of Mother to Child Transmission (PMTCT) and pediatric HIV with Maternal, Neonatal, and Child Health (MNCH) services at the levels of policy, program administration, or service delivery, offers an opportunity for The President's Emergency Plan for AIDS Relief (PEPFAR) to use limited resources to leverage other key programs and strengthen the MNCH platform in each PEPFAR country through Partnership Frameworks. In so doing, PEPFAR aims to strengthen national ownership of programs, increase the coverage of quality PMTCT and pediatric HIV services, increase program sustainability, strengthen the health system, and improve MNCH health outcomes overall. The U.S. Global Health Initiative (GHI) also presents an opportunity to strengthen synergies between various health services in order to produce significantly improved HIV, MNCH and reproductive health (RH) outcomes and impact.

Therefore, given the various benefits of integration outlined above, the objectives of this updated guidance are to:

- Highlight importance of integration for PEPFAR PMTCT, pediatric HIV, and MNCH program support.
- Identify an essential package of integrated PMTCT/pediatric HIV/ MNCH services and health systems strengthening activities.
- Recommend possible action steps to operationalize and evaluate integration efforts.

Background

PEPFAR supports the scale-up of PMTCT and pediatric HIV services as critical interventions in each country's HIV prevention, care, and treatment program. In 2008, the U.S. Congress reinforced this approach by mandating that PEPFAR: a) support HIV testing and counseling for 80% of pregnant women in countries most affected by HIV/AIDS; b) support antiretrovirals (ARVs) for PMTCT and/or their own health as medically indicated for 85% of HIV-positive pregnant women in those countries; and c) ensure that the proportion of children receiving care and treatment meets their proportion of the HIV-infected individuals in each country. In addition, PEPFAR, along with other key partners such as UNICEF, UNAIDS, and WHO, has committed to the goal of virtual elimination of mother-to-child transmission of HIV by 2015.

These important goals have been adopted in the context of significant scientific advances that have the potential to result in more effective programs, reduced transmission to infants, improved maternal morbidity and mortality, and enhanced infant HIV-free survival. Building on these advances, WHO has issued new guidelines that emphasize the need for all pregnant women living with HIV to be urgently assessed for

treatment eligibility, preferably with a CD4 count, and that those with CD4 < 350 or clinical stage 3 or 4 be immediately initiated on lifelong antiretroviral treatment regardless of gestational age. Achieving this will have a tremendous impact on both maternal health and transmission as women in these categories are at the highest risk for morbidity and mortality as well as for transmission to their infants. For those women not in need of treatment for their own health, antiretroviral prophylaxis is essential for PMTCT, including: (1) an early start for ARV prophylaxis (as early as 14 weeks gestation); (2) continuation of ARV prophylaxis to the mother during labor, delivery, and the immediate postpartum period; and for the first time, (3) extension of prophylaxis, based on national guidelines, to either mother or infant, throughout breastfeeding, recommended for 12 months.[1] All HIV-positive pregnant and breastfeeding women not yet eligible for treatment must receive ongoing care and monitoring to recognize if they become eligible and then must be immediately initiated, both for their own health as well as to help protect their infants.

WHO has also released new guidelines for infant feeding in the context of HIV and pediatric ART, including initiation of lifelong treatment for all HIV-infected children 2 years and younger and earlier initiation for those older than 2 years and continues its recommendation of cotrimoxazole for all HIV exposed children at 6 weeks of age until 15 months of age.[2+3]. Cotrimoxazole decreases morbidity and mortality by approximately 45% in HIV exposed children during this timeframe and is lifesaving, particularly for those patients in need of but not yet initiated on treatment due to limited access to pediatric treatment services. WHO also released the result of the WHO Technical Consultation on Postpartum and Postnatal Care, suggesting that all postpartum and postnatal care should be delivered in partnership with the woman and her family, and should be individualized to meet the needs of each mother-infant pair.[5]

Given these scientific advances and new guidelines recommending a longer period of health supervision for pregnant women, mothers and infants, the delivery of PMTCT and pediatric HIV services depends even more on the foundation of the antenatal care (ANC) setting and the larger maternal, neonatal and child health (MNCH) program of each country. ANC visits, facility births, postnatal and well-child visits, in-patient pediatric wards, and community and outreach efforts offer key opportunities for identifying individuals in need of HIV-related services, delivering counseling, testing, prevention, care, and treatment. Yet in many PEPFAR countries, this primary care platform is underdeveloped or underutilized. Many women access ANC services late in pregnancy, if at all. Home deliveries and late presentations to clinics with sick children are common. In some cases, the reasoning is that women may not believe the health facilities offer enough to justify the trouble and cost of seeking care, unless acutely ill. Additionally, where ANC, pediatric HIV, and MNCH services do exist, challenges such as poor infrastructure, competing demands and limited human resources make it

[1] WHO Document: Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: towards universal access 2010. Available online at http://www.who.int/hiv/pub/mtct/antiretroviral2010/en/index.html
[2] WHO Document: Guidelines on Infant Feeding and HIV 2010. Available online at http://www.who.int/child_adolescent_health/documents/9789241599535/en/
[3] WHO Document: Antiretroviral therapy for HIV infection in infants and children: Towards universal access. Recommendations for a public health approach: 2010 revision. Available online at http://www.who.int/hiv/pub/paediatric/infants2010/en/index.html
[5] WHO Document: Technical consultation on postpartum and postnatal care 2010 Available online at: http://whqlibdoc.who.int/hq/2010/WHO_MPS_10.03_eng.pdf

difficult to provide the basic services, outreach and follow-up necessary for quality care. These conditions can result in a disparity between the quality of PMTCT, pediatric HIV, and MNCH services, and pose real constraints to scaling up PMTCT and pediatric treatment. Indeed, PEPFAR reauthorization legislation requires PEPFAR to "ensure that women in PMTCT programs are provided with, or are referred to, appropriate maternal and child services."

Rationale for Integration

Smart integration of PMTCT, pediatric HIV, and MNCH services through the delivery of an integrated package, as described in this guidance, has the potential for increased synergy and efficiency across vertical programs aimed at the same population of pregnant women and young children. For example, strengthening post-natal care services should improve follow-up of mothers and their families for HIV prevention, care and treatment and early infant diagnosis. Another example is combining PMTCT and MNCH in-service training of health care workers; where appropriate, also strengthens human resources capacity in two sectors for a marginal cost increase, as demonstrated in Haiti with syphilis and HIV testing training.[6+7] Integrating new HIV services into the existing health system and the resulting efficiency gains also promote greater sustainability of programs over time.

Promising evidence from MNCH service integration suggests that the end result of integration has a greater impact on morbidity and mortality.[8] For example, through five trials, it has been shown that newborn mortality can be reduced by 34-62% through delivery of a package of interventions shortly after birth, typically between days 1 and 3 of an infant's life.[9+10] Pilot projects in Africa have demonstrated that integrated community PMTCT programs can increase timely diagnosis and intervention, as well as, follow-up of women and infants.[11]

Integration has been actively promoted by the global health community in several new global campaigns (e.g. WHO Initiative on Eliminating Congenital Syphilis), scientific journals (e.g. *Lancet* series on maternal health and newborn and child survival) and through the promotion of integrated MNCH packages.[12] A WHO Technical Consultation on integration and PMTCT scale-up concluded: "The current status of PMTCT implementation in countries [is] unacceptable, with an urgent need for a renewed public

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[6] Schackman, BR, Neukermans CP, Fontain, SN, Nolte C, Joseph P, Pape JW, Fitzgerald DW. Cost-effectiveness of rapid syphilis screening in prenatal HIV testing programs in Haiti. Public Library of Science Medicine 2007; 4(5) e183.

[7] Rydzak CE, Goldie SJ. Coste-effectiveness of rapid point-of-care prenatal syphilis screening in sub-Saharan Africa. Sexually Transmitted Diseases Journal. 2008 Sep; 35(9): 775-84.

[8] Bhutta, ZA, Ali S, Cousens S, Ali TM, Haider, BA, Rizvi A, Okong, P, Bhutta SZ, Black, RE. Alma-Ata: rebirth and revision 6 Interventions to address maternal, newborn, and child survival: what difference can integrated primary health care strategies make? Lancet. 2008 Sep 13; 372: 972-989.

[9] Baqui, AH, Williams, EK, Rosecrans, AM, Agrawal PK, Ahmed, S, Darmstandt GL, Kumar V, Kiran U, Panwar D, Ahuja RC, Srivastava, VK, Black, RE, Santosham, M. Impact of an integrated nutrition and health programme on neonatal mortality in rural northern India. Bulletin of the World Health Organization 2008 Oct; 86(10): 737-816.

[10] Darmstandt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L: Lancet Neonatal Survival Steering Team. Evidence-based, cost-effective interventions: how many newborn babies can we save? Lancet 2005 May28-Jun3; 365(9474):1846.

[11] J. Mwale, K. Musokotwene, L. Alisheke, C. Kanene. Abstract Using community structures to improve PMTCT services: Sinazongwe, Zambia. XVII International AIDS Conference, Mexico 2008.

[12] Examples include the WHO IMCI; WHO IMPAC; USAID's Minimum Activities for Mothers and Newborns-MAMAN; the UN Millennium Project task force on child and maternal health 2005 World Health report.

health approach to HIV control that ensures improved access to HIV prevention, treatment and care interventions for women and their children. A comprehensive approach to care based on simplification, standardization, and integration is needed to scale-up interventions and strengthen health systems to support integrated service delivery and improve quality of care."[13] Integration of service delivery also plays a crucial role in working toward UN Millennium Development Goals 3—Promote Gender Equality and Empower Women, 4—Reduce Child Mortality, 5—Improve Maternal Health and 6—Combat HIV/AIDS, Malaria and other diseases.

It is important to recognize that the science and evidence behind integration of PMTCT and MNCH services is still emerging. *Where* integration occurs (e.g. at the policy, program administration, service delivery points) and *how* it occurs depends heavily on the unique health system, as well as the epidemiological and political context of each country. This guidance uses the latest normative guidelines and programmatic evidence to identify an essential PMTCT/MNCH and pediatric HIV service package that is recommended for scale-up in each country, to strengthen the MNCH platform and scale-up PMTCT and pediatric HIV services. The guidance also lays out a possible process for using this package as a starting point in a discussion with Ministries of Health (MOH) and other stakeholders over what integration should occur in each country. Careful consideration is needed when deciding at which levels integration will occur and if 'tipping points' exist, where adding services begins to diminish planned outcomes by overloading staff or weak systems.

How to use the Guidance

This guidance identifies a recommended package of integrated PMTCT/pediatric HIV/MNCH services and related health systems strengthening activities for scale-up through PEPFAR and the GHI. U.S. country teams will need to discuss the package and health systems strengthening components with the MOH and other stakeholders to identify the appropriate interventions for the local context. U.S. funding through PEPFAR, the President's Malaria Initiative, Population and Reproductive Health and/or MNCH programs can be utilized to pay for the various components outlined in this guidance within the context of appropriate legislative and policy guidelines and requirements. In addition, multilateral partners and donors--such as the Global Fund to Fight AIDS, TB, and Malaria (GFATM) and the Global Alliance for Vaccines and Immunization (GAVI), partner country governments, and the private sector should be engaged to finance relevant services through Partnership Frameworks. To ensure a continuum of care, this guidance should be used in combination with PEPFAR guidance on reproductive health/family planning, prevention, treatment, OVC, care and support, PMTCT and pediatric services.

Current legislation requires that PEPFAR funds be used for the "prevention, treatment, and control of, and research on, HIV/AIDS." Therefore, any use of PEPFAR funds in the context of PMTCT, pediatric HIV and MNCH must have a clear link to HIV. In fact, this

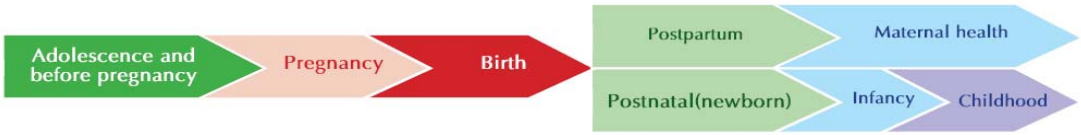
[13] WHO Technical Consultation on the Integration of HIV Interventions into Maternal, Newborn and Child Health Services. Available online at: http://whqlibdoc.who.int/hq/2008/WHO_MPS_08.05_eng.pdf

HIV link must serve as a lens to analyze and guide country planning and programming with PEPFAR funds, as well as to evaluate ongoing implementation. This consideration is relevant when assessing how PEPFAR resources and platforms can be used to support delivery of RH and MNCH services and to strengthen associated health systems. The ethical implications of offering certain services to HIV-positive populations and not to HIV-negative populations must be taken into account when structuring programs. PEPFAR country teams are encouraged to coordinate with other U.S. programs—as well as with other donors and country or local governments, to ensure that the health needs of all the populations PEPFAR serves, are met.

Integration of PMTCT, Pediatric HIV and MNCH: A Recommended Package

The WHO HIV/MNCH Technical Working Group developed an operational definition for integration that this guidance endorses. Integration is defined as: "the organization, coordination and management of multiple activities and resources to ensure the delivery of more efficient and coherent services in relation to cost, output, impact, and use (acceptability)." Effective integration requires coordination at multiple levels, within and among government and partner agencies, including: policies and guidelines, administration and governance, funding, human resources, information systems, and commodity supply chains. Integration may also require service delivery by a multidisciplinary team, often supported by several partners and provided in a mutually reinforcing manner at the facility, community and household levels. Integration may need to be incremental. It can also be conceptualized in terms of patient experience at the service delivery level (as illustrated in Figure 1) through a continuum of care: from a woman of childbearing age through pregnancy, delivery and beyond. The recommended package should be accessible, affordable, and acceptable to women and children, and is most effective if provided early and is accessible throughout the continuum of care.

Figure 1: The Lifecycle continuum of care



In the pages that follow, Figures 2 and 3 outline the recommended package of integrated PMTCT and MNCH services for women of childbearing age, while Figures 3 and 4 outline the recommended package of integrated PMTCT, pediatric HIV, and MNCH services for infants and children up to age 5.[14] This package should be used in conjunction with the Basic Preventive Care package, which is an evidence-based intervention already in use. Additionally, several cross-cutting issues need to be addressed, including effective communication within the interdisciplinary team and with their clients, end of life support for children and parent(s) in the event of death, special needs among pregnant adolescents (both HIV positive and negative), gender issues,

[14] The recommended service packages were based on UNICEF's "Integrated Care Package for PMTCT/MNCH Services" and USAID's Minimum Activities for Mothers and Newborns (MAMAN) and in discussion with technical review body of experts.

and the role of active referrals when services are not available within the MNCH setting (e.g. mental health, social development, and education).

Figure 2: Components of an Integrated Care Package for Women of Childbearing Age

WOMEN OF CHILDBEARING AGE

- HIV prevention efforts
- Voluntary family planning (FP) for HIV positive and negative women
- Provider-initiated HIV testing and counseling (PITC)

PLUS

PREGNANT WOMEN

- PITC and, if negative, ongoing HIV prevention/repeat testing at subsequent ANC visits, during L&D and while breastfeeding
- Partner outreach and testing with Positive Health, Dignity and Prevention interventions for discordant couples
- Routine ANC services including tetanus toxoid vaccination and 1st visit screening and same day treatment for anemia and syphilis
- TB screening, diagnosis and treatment with urgent HIV testing if TB-positive
- Interventions to promote safe water, preventive hygiene practices, sanitation and hand-washing with soap
- Malaria IPT and access to malaria control programs and ITNs
- Nutrition assessment, counseling and support, including micronutrient supplementation and deworming
- Infant feeding counseling including benefits to mother and infant of exclusive breast feeding (EBF)
- Voluntary FP, including birth spacing, modern methods and lactation amenorrhea (LAM), benefits of EBF and dual protection
- Delivery plan and safe delivery (skilled attendant, TBA, emergency obstetric care, active management of 3rd stage of labor)
- Community outreach efforts for promotion of facility delivery, follow up and ongoing care
- Postpartum follow up within 24-72 hours regardless of delivery site to identify & manage bleeding and infection
- For women suffering a pregnancy loss: testing for HIV, malaria and syphilis

PLUS

HIV-POSITIVE PREGNANT WOMEN

- CD4 testing to assess highly active antiretroviral therapy (HAART) eligibility with rapid return of results to patient and urgent initiation of care and treatment
- ARV prophylaxis or HAART as eligible. If not HAART eligible, combination ARV prophylaxis extended throughout breastfeeding is highly recommended over sdNVP whenever possible
- Infant feeding counseling and support including exclusive breastfeeding (EBF) if replacement feeding does not meet AFASS (acceptable, feasible, affordable, sustainable, safe) criteria and in line with national infant feeding guidelines
- Outreach and testing for partner and other children with referral to care and treatment for positives and Positive Health, Dignity and Prevention interventions for discordant couples
- Psychological and social screening and support including acceptance of HIV status, disclosure issues, grief, medication adherence and access to support groups
- Psychological and social counseling and support regarding possibility of having an HIV infected child
- Pain and other distressing symptom screening and management
- Opportunistic infection prevention, diagnosis and management including CTX prophylaxis if indicated
- Ongoing follow up and case management with monitoring of disease progression, medications, side effects and response to treatment if on HAART

Figure 3: Components of an Integrated Care Package for Newborns, Infants and Children up to Age 5 years

ALL NEWBORNS, INFANTS AND CHILDREN

- Essential newborn care (thermal care, hygienic cord care, early and exclusive breast feeding) for all and, if needed, resuscitation
- Prophylactic eye care
- Postnatal follow-up and care within 24-72 hours of birth regardless of place of delivery to support breast-feeding and identify and manage infection
- Complete and timely immunization
- Malaria prevention and treatment including access to malaria control programs and ITNs
- Case management of diarrhea, pneumonia and sepsis
- Nutritional assessment, counseling and support, and growth and development monitoring including Vitamin A and other micronutrient supplementation and deworming
- Interventions to promote safe water, preventive hygiene practices, sanitation and hand-washing with soap
- Community outreach efforts for follow up and ongoing care
- TB screening, diagnosis and treatment with urgent HIV testing if TB-positive
- PITC for every infant or child with signs, symptoms or history suggestive of HIV and rapid return of results to parent/caregiver

PLUS

HIV-EXPOSED INFANTS

- Pre- and perinatal maternal and infant ARV prophylaxis with continued prophylaxis to mother or baby (if the mother is not on treatment for her own health) throughout breastfeeding as per national guidelines
- Early Infant Diagnosis with rapid return of results to parent/caregiver and follow up plan
- Intensive nutritional assessment, counseling and support and growth and development monitoring including a recommendation for EBF if replacement feeding not AFASS, and in line with national guidelines
- Cotrimoxazole prophylaxis until final infection outcome determined
- Ongoing follow up and individual case management

PLUS

HIV POSITIVE INFANT OR CHILD
(HIV INFECTED)

- <u>INFANT < 2 years of age</u>: immediate initiation of ART
- <u>CHILD > 2 years of age:</u> ART initiation as eligible per WHO and national guidelines
- <u>BOTH</u>:
  - Clinical and lab monitoring of disease progression, medications, side effects and treatment response if on ART
  - Age appropriate social and psychological counseling and support addressing adherence, disclosure and grief
  - TB prevention, diagnosis and treatment
  - Pain and other distressing symptom management
  - Opportunistic infection prevention, diagnosis and treatment
- *See also PEPFAR Pediatric Treatment Guidance & PEPFAR Basic Pediatric Preventive Care Package*

HIV NEGATIVE INFANT OR CHILD
(HIV AFFECTED)

- Ongoing prevention and feeding counseling
- Repeat test after BF cessation and confirmatory test at 18 mos

PLUS

ORPHANS AND VULNERABLE CHILDREN

- Age appropriate disclosure, grief and bereavement support
- Intensive social assessment and support, particularly for child-headed homes, including food security, education, shelter, etc
- *See PEPFAR OVC Guidance*

Health Systems Strengthening Activities That Support the Integrated Package

PEPFAR and the GHI broadly support the strengthening of the public health and primary health care systems necessary to sustain the delivery of the full integrated package. The strengthening includes developing or enhancing existing policies and guidelines, leadership and governance, financing, human resources, information systems, supply chains, infrastructure, and laboratory networks related to integrated MNCH and pediatric services. This also includes monitoring and evaluation of integrated activities. These investments build health systems capacity and make a lasting and sustainable impact on countries' ability to provide PMTCT, pediatric HIV, and MNCH services in the future. A WHO package of services for FP and MNCH states that this will require additional investments to strengthen the performance of health system in particular regarding commodities, equipment and human resources and management.[3] Country teams must coordinate closely with MOH and other donors to prevent duplication, maximize efficiencies, assess the appropriateness of harmonized national systems around integrated MNCH and pediatric services, and where appropriate, promote integration.

The following are examples of health system strengthening activities that relate to PMTCT, pediatric HIV, and MNCH.

Policies and Guidelines

- Policy, guidelines, and training for all aspects of an integrated PMTCT, MNCH and pediatric HIV package, including service delivery, referral, feedback and supervision.
- Permissive policies for human resources to allow increased access to an integrated package, such as nurse initiation and management of pediatric HIV treatment
- Supportive systems for an integrated package, including integrated MNCH and pediatric information systems, referral processes, human resources (including supervision), supply chains, and laboratory networks. This may include policy and training at more decentralized levels to strengthen the capacity of district-level management teams and health care providers.
- Monitoring and evaluating programs at all levels of care delivery with routine, periodic, and accurate feedback to health care providers to identify challenges and acknowledge successes leading to constant quality improvement.

Leadership and Governance

- Promote integration and coordination of HIV/AIDS and MNCH program management, including at the national/ministerial level and the local/facility level
- Use US leadership to promote support within the multilateral community and with other bi-lateral donors for harmonized, integrated services for PMTCT, MNCH and pediatric health care.
- Assist with the design and/or strengthening of organizational units or governing bodies to manage aspects of an integrated package. (Example: integration task force)

- Strengthen national advocacy for:

  - High-quality, universal and early ANC care, safe delivery, postnatal/postpartum and follow-up care of infant and mother from the highest levels, with emphasis on ensuring that these services are accessible, affordable and acceptable.
  - Early infant HIV diagnosis, treatment and care integrated with a basic MNCH care package.
  - Retention of women, infants, children, and adolescents with HIV in care and treatment - including addressing issues related to adherence and regular monitoring and support.
- Training of national leaders and program managers on integration issues.

Financial management
- Assist countries in strengthening internal governance and management and accountability of finances for PMTCT/Pediatric HIV/MNCH services through (1) leveraging and coordinating resources of external and internal partners, and (2) supporting local organizations and agencies to develop their own financial management systems and similar activities.

Human Resources
- Assist countries in determining the most effective mix of health care staff to implement an integrated package of services.
- Support effective strategies for hiring, training, and retaining health care providers, laboratory personnel, and other allied health staff needed to allow essential integrated PMTCT, pediatric HIV, and MNCH services.
- Design, integrate and/or coordinate training curricula and accompanying materials (including pre-service and ongoing in-service training) for new and existing health care providers.
- Support mentorship and supervision for healthcare workers, focusing on skills and information needed for implementation of an integrated PMTCT, pediatric HIV, and MNCH package.
- Support systems to create safe work environments that ensure appropriate medical waste disposal, maintain privacy and confidentiality of health service information, enable health care workers to access counseling, testing and if necessary, treatment services in privacy and with confidentiality, and address health care provider burn-out.
- Empower and involve non-facility-based organizations and individuals to institutionalize linkages between facilities and communities, provide active case finding and follow up and offer valuable insight and feedback on feasibility of various outreach efforts.

Information Systems
- Support development or enhance existing integrated local program and national health management information systems that comprise harmonized reporting of patient and program data across all aspects of the integrated package.
- Support development and implementation of patient tracking and follow-up tools, case finding, referral, and adherence systems.
- Establish or support integrated national disease surveillance that informs planning and management of the integrated package.

- Establish or support existing human resources information systems (HRIS), as they inform planning and allocation of staff and service delivery for an integrated package.
- Support countries' capacity to evaluate programs, undertake operational research, and interpret and implement information learned.

Supply Chain Management

- Develop an integrated supply chain for drugs and commodities needed for delivery of the integrated package, including development of standard operating procedures (e.g. for forecasting and distribution), training of logistics personnel, integrated storage and delivery mechanisms, and quality assurance, to ensure a continuous, responsive, uninterrupted, and equitably distributed supply of all relevant commodities.

Laboratory Networks and Services

- Improve and strengthen laboratory capacity and quality assurance, including coordinated testing for multiple programs or diseases, point-of-care testing, biosafety/infection control, and strengthening the infrastructure and logistics of specimen transport, patient receipt of test results, and tracking and protecting patient confidentiality.
- Support WHO-led efforts to promote an integrated primary health care package of services, including appropriate level of laboratory services.

Technological innovation

As programmatic limitations and bottlenecks become apparent, it will be important to support the development of innovative technologies and solutions. For example, the ability to reliably and rapidly test CD4 levels in pregnant women and children to determine treatment eligibility and provide ongoing monitoring is severely limited. Remote sites must send blood samples to central laboratories and then await results. Patients often do not return for results or samples may be lost in transit necessitating repeat lab draws, resulting in increased discomfort for the patient and increased risk of accidental needle-stick for the provider. Life-saving initiation of antiretroviral treatment (ART) or necessary changes to a treatment regimen may be delayed or missed entirely due to long turn-around times on test results. The development of simplified point of care CD4 testing in PMTCT/MNCH settings would dramatically improve access to and quality of PMTCT and HIV/AIDS care and treatment at the primary care level.

Collaborative programming

Within the context of GHI, PEPFAR should seek to proactively partner with other U.S. programs in-country, as well as with national governments and other in country donors. Partnering should seek to access gaps and tailor provision of essential elements to the specific country context in recognition of other available programming and resources. Through Partnership Frameworks, U.S. country teams should support countries in taking a leadership role in networking, nurturing relationships and bringing all available resources and agents to the table to find solutions and forge partnerships in order to procure all elements essential to a high quality, comprehensive, integrated program.

Such partnerships are highly beneficial for multiple reasons. First, partnerships allow divisions of responsibility based on individual agency priorities and objectives and help to reduce wasteful duplication of services. For example, it would not be beneficial for PEPFAR to procure vaccinations for HIV-positive children in a country where GAVI is providing this service, or to purchase bed nets where the President's Malaria Initiative (PMI) is active. Second, partner communication helps anticipate upcoming challenges. For example, allowing for advance plans for transition of responsibilities if one partner is planning to cease operations within a country. Various programs can serve to inform each other's decision-making, resulting in higher quality and more effective outputs overall. For example, a primary PEPFAR PMTCT implementing partner is aware of plans to expand delivery services to peripheral health sites, the information could be extremely valuable for Millennium Challenge Corporation (MCC) planners who would need to provide for delivery room space in construction of a new facility. Finally, cooperation among agencies can help to streamline monitoring, evaluation and reporting requirements, reducing the burden on countries.

Operational Principles for Country-Level Integration

Integration is not an end or objective, but a means to achieve more effective and efficient service delivery. U.S. endorsement of the Paris Declaration on Aid Effectiveness (March 2005) requires any country-level integration supported by PEPFAR to be consistent with country ownership of the process, alignment with country systems and national priorities, country results frameworks, and mutual accountability. Integration should build upon existing program experiences and frameworks (e.g., national strategies for MDGs, MOH health sector donor coordination mechanisms, Global Fund Country Coordinating Mechanisms, etc.) within a country as well as globally.[15]+[16] In implementing an integrated service delivery plan, U.S. teams should consider the following:

1. Country-level processes to develop and scale-up integrated HIV/MNCH services must be government-owned and country-led, with complementary donor roles
2. Political commitment is necessary and advocacy at all levels (local, national, regional, global) is needed.
3. A national interagency coordination committee and continuous planning, coordination and management activities at the central and district levels are essential to support integrated service delivery at facility and community levels.
4. Community involvement is necessary for successful implementation/scale-up.
5. Integration planning and coordination meetings with feedback exchange on successes and challenges encountered must occur regularly at the district and community levels to facilitate progress.
6. Collaboration is necessary at structural, operational and service delivery levels.
7. Program-specific changes will not be sustainable without overall health system strengthening to support improved service delivery.

[15] UNICEF/WHO. *Scale Up of HIV-Related Prevention, Diagnosis, Care, and Treatment For Infants and Children: A Programming Framework*. Geneva: WHO, Sept 2008

[16] WHO. *Technical Consultation on the Integration of HIV Interventions into Maternal, Newborn and Child Health Services: Report of a WHO Meeting. Geneva, Switzerland, 5–7 April 2006*. Geneva: WHO, 2008.

Recommended Action Steps for Country-Level Integration
The following tables suggest a process for developing country-specific action plans to begin or strengthen integrated service delivery.

PHASE I: Conduct Needs Assessment / Situation Analysis	
1.	Working with key stakeholders, develop terms of reference (TOR) for conducting a Situation Analysis that includes policy and planning at the national level as well as supervision and implementation at district and facility levels
2.	Reach a consensus on the methodology, the tools, and the steps needed for the rapid assessments
3.	Describe the health services and epidemiology of morbidity and mortality related to MNCH
4.	Identify existing health system infrastructure and utilization of services such as FP, EPI, ANC, HIV testing, counseling and treatment, recognizing where gaps and vulnerable populations exist, such as areas with low ANC and high home births
5.	Gather data on current skill sets and capacities of providers
6.	Map key activities and programs, partners, funding, etc
7.	Describe the existing health and social support infrastructure including number of health care providers, laboratories, health care facilities and community / home based organizations
8.	Understand the state of existing information systems at various levels of the health system
9.	Identify available resources for service delivery, training and supervision
10.	Develop a situational assessment
PHASE 2: Develop Country Action Plan and Identify National Coordinating Body	
1.	Identify and bring together key stakeholders for national integration consultation - consisting at a minimum of representatives from the host government, other donor agencies, NGO/CSO/FBOs, and PLWH groups
2.	Review key findings from situation analysis and develop draft costed national action plan based on situation analysis. Action plan should include prioritized activities for restructuring the health system and a monitoring and evaluation plan with specific indicators to measure quality and scale up. Priority areas should be derived from analysis of the situational assessment
3.	Develop specific country level guidance and goals for programs, funding and coordination
4.	Develop an advocacy plan that engages key stakeholders and identifies appropriate strategies for and commitments from each stakeholder group
5.	Identify National Coordinating Body housed within most appropriate Government ministry(ies)
6.	Mobilize resources based on the identified priorities and stakeholder commitments in Step 4
7.	Maintain ongoing support and relationships and conduct regular progress assessments with national coordinating body

PHASE 3: Implementation	
1.	Maintain ongoing relationships and conduct regular progress assessments with key stakeholders
2.	Track program implementation
3.	Develop and maintain systems for program accountability
4.	Monitor and evaluate programs

Integration must consider the baseline disease risk for the women and children because the goal of chronic disease management is to reduce the risk to this norm. In developed countries, HAART has been successful at reducing women and children's risk of dying to background disease risk levels. Nevertheless, the impact of PMTCT or HAART on mortality will be more challenged in resource-limited countries with higher levels of malnutrition, maternal hemorrhage, malaria, sepsis, pneumonia, diarrhea, etc. This has direct bearing on how and where to integrate.

Integration should consider the timing of integration along the MNCH continuum. There are many opportunities for integration from ANC through delivery to post-natal care including immediate post-natal visits, FP visits, EPI, nutrition, and sick visits to out-patient department (OPD) or integrated management of childhood illness (IMCI) clinics. Because of relatively high coverage of the first ANC visit, some countries have used this as a point to start integration. Labor and delivery (LD) has also been a useful point of entry particularly in countries with high levels of health facility births. The new joint WHO/UNICEF statement on "Home Visitation of the Newborn Child" recommends visits for all newborns at 24 hours, 72 hours, and 7 days after delivery was created to address non-HIV infant mortality in the first week of life but these visits are also opportunities for HIV-related counseling and interventions. Timing may also prevent meaningful integration from occurring if the interventions do not have similar time windows (e.g. visits for "birth" dose vaccinations that actually occur several weeks after birth may not be effectively combined with infant PMTCT ARVs that must be given within 72 hours).

Integration should also consider the location along the home to hospital continuum. While integration may exist along this continuum, the nature and intensity/level of effort may vary. Following HIV epidemiology, integration has often focused first in urban area health centers and hospitals. For countries with little peri-urban or rural spread, continued improvement with integration in these urban health facilities may be a reasonable approach. If there are few health facility births, then it may make sense to use community health workers (CHWs) and traditional birth attendants (TBAs) to support integrated PMTCT activities allowed under national policies, with related strengthening of outreach from and referral to health centers. In these cases, consideration should be given to developing a better understanding of the variables influencing health care decision making by women and families and supporting professional development of health care providers that directly addresses women's concerns (eg. gender and age considerations).

Ongoing evaluation of integration efforts should produce beneficial results for the provision of more efficient and coordinated services in relation to cost, output, acceptability, uptake and impact. However, there is no single model for integrated

service delivery and ongoing operational/implementation research, basic program evaluations and public health evaluations (PHEs) are needed as part of this effort. PHE priorities should include: the impact of co-morbidity (for mothers as well as for infants and children); the incremental cost/benefit of integration over single, vertical activities; the quality of integrated activities; level of effort/intensity needed to conduct integrated activities; and impact of task-shifting and the enhanced role of community health workers in an integrated system.

Conclusion

To have the greatest impact and ultimately achieve healthy, HIV-free survival for infants and children and increased quantity and quality of life for mothers and those adults and children living with HIV, PEPFAR programs must move toward integrated delivery of PMTCT, pediatric HIV and MNCH services. Integration must happen at multiple levels, including among USG agencies, with governments and other donors, at all levels of service delivery, and between various programmatic areas. Integration helps move toward sustainability and away from vertical efforts that may impose additional burden on already struggling health systems. Additional integration research is needed to further guide decision making on implementation, cost-effectiveness and impact on MNCH health outcomes. As programs evolve and best practices emerge, PEPFAR, as part of the GHI, has a tremendous opportunity to lead the way in the sustainable integration and strengthening of health services.