

QUESTIONS SUMMITTED FOR THE RECORD
ROUNDTABLE ON
THE PRESIDENT’S EMERGENCY PLAN FOR AIDS RELIEF
BEFORE THE
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
DECEMBER 11, 2007

Questions from Senator Edward Kennedy for Dr. Peter Piot

1. Numerous stakeholder reports and discussions with implementing partners and agencies have shed light on the need to better communicate and coordinate across all management levels to ensure enhanced coordination of fiscal management, policy guidance, and planning and reporting.

Based on your work, can you speak to the special challenges of central, intra-agency, field team and donor coordination? Please comment on ways of improving upon coordination and communication between implementing agencies, donors, and teams to help us plan for transitioning from an emergency effort toward a sustainable long-term strategy?

Answer: At UNAIDS, “making the money work” is paramount, a principal question through which we critically evaluate the relative strength of HIV programming. We aim to strengthen coordination for countries in partnerships with national governments and non-governmental organizations, the United States Global AIDS Initiative, and the Global Fund. It means maximizing our effectiveness by improving coordination among donors, government implementers, and everyone in the global response to AIDS. Partnering where possible produces significant coordination and significant results. In Rwanda, where governments are full partners, and the United States Global AIDS Initiative effort is fully integrated with national strategies, progress has been measurable, meaning the difference between fighting AIDS effectively and losing ground.

Until recently, AIDS advocacy focused largely on 1) fostering leadership and commitment and 2) mobilizing the financial resources required to mount an effective response to AIDS, globally and within countries. More leadership and more money are still urgently needed, and thus these two areas of focus remain essential, but now there is widespread recognition that a third focus is also vital: making the money work more effectively.

In Washington, DC in April 25th, 2004, UNAIDS, the governments of the United States and the United Kingdom, and the World Bank brought together representatives from

governments, donors, international organizations and civil society who considered and endorsed the “Three Ones” principles for concerted action against AIDS at country level as follows:

- One agreed AIDS action framework that provides the basis for coordinating the work of all partners;
- One national AIDS coordinating authority, with a broad-based multisectoral mandate; and
- One agreed country-level monitoring and evaluation system.

All donors pledged to support implementation of these principles and UNAIDS was called on to help facilitate this process.

In London on March 9th, 2005, UNAIDS, the governments of the United States, the United Kingdom, and France, as well as other key stakeholders again gathered and stated: “We affirm our commitment to promoting and supporting the application of the ‘Three Ones’ principles, recognizing that their application will result in adaptations appropriate to each country and the situations and institutions concerned. We affirm that the development and adaptation of the ‘Three Ones’ is intended to be a consultative and iterative process between donors, multilateral and country-level partners. We note the leading role of national governments in ensuring the full implementation of the ‘Three Ones’ principles.” With that in mind, all participants agreed to review their individual practices and to work closely with partners at country level to accelerate the effective implementation of the “Three Ones.”

To examine and assist in this implementation effort, UNAIDS and the United States President’s Emergency Plan for AIDS Relief held a bilateral meeting in Washington, DC on April 27 and 28, 2005.

What follows are key points of agreement that arose from these discussions. While the actions delineated below were discussed and agreed to as part of a UNAIDS-U.S. Office of the Global AIDS Coordinator bilateral partnership, participants noted that they are best executed, not as bilateral actions, but in the context of nationally-led processes that involve all key stakeholders – as envisioned by the “Three Ones.”

A. The “Three Ones”

One National AIDS Action Framework

1. Support national government leadership in a broadly participatory process for developing and regularly updating the national AIDS action framework, including the development of a costed and results-based annual operational plan.
2. Support the national AIDS action framework and operational plan, by basing individual programming and assistance within these national guiding documents.

3. In an effort to maximize coordination and complementarity, make every effort to harmonize support with that of others, through ongoing dialogue with government and other key stakeholders about priorities, geographic and service mix, and division of labor, recognizing that each partner works within the specific parameters of its own mandates and rules (including procurement).
4. Work together to harmonize key programmatic tools (i.e. reviews of national response, technical working groups, activities database), and promote and participate in joint action in these areas. The formation of joint working groups on the key crosscutting issues of procurement, gender, and human resources were suggested. Avoid the establishment of parallel tools, groups and systems whenever possible.
5. Promote and participate in “partnership forums” to share information and coordinate implementation.

One National AIDS Coordinating Authority

1. Within the context of the Three Ones, urge each country to conduct a government-led joint assessment of the national coordinating authority leading to clear recommendations for strengthening its effectiveness including attention to areas such as: human capacity requirements, financial resource requirements, infrastructure needs, streamlining of operations, performance-based monitoring systems.
2. Provide support (financial and technical) to the national coordinating authority based on these recommendations. Some donors may consider performance-based incentive mechanisms in the provision of their support.
3. Strengthen political leadership and government commitment to a multisectoral national coordinating authority through diplomatic engagement at the highest levels.
4. Implement programming and assistance within the overall framework of the national coordinating authority and, to the greatest extent possible, within an agreed to division of labor.

One Monitoring and Evaluation System

1. Build local monitoring and evaluation capacity, participate regularly in national monitoring and evaluation activities, and support the development and operationalization of one national monitoring and evaluation system for the national AIDS response with a set of standardized and multisectoral indicators.
2. Support the development of a set of best practices for monitoring and evaluation for broad dissemination of lessons learned for replication.

3. Develop mechanisms for data and report sharing as well as data utilization for evidence-based program planning.
4. To the fullest extent possible, seek to synchronize the timing of surveys and reporting cycles among partners and the government in an effort to maximize harmonization opportunities.
5. Participate in joint monitoring and evaluation team visits by donors and multilateral partners to assess and support further progress on the above described monitoring and evaluation actions, to avoid duplication of effort, and to decrease the burden of individual agency missions on the national coordinating authority and other local stakeholders.

B. Other Key Issues

Central to the effective implementation of the “Three Ones” at country level are issues related to policy development and the coordination of technical assistance. Therefore key points of agreement have been put forward in these areas as well.

Policy

AIDS policy dialogue and development should actively involve all partners – government, donors, multilaterals, and non-governmental stakeholders such as non-governmental organizations, faith-based organizations, civil society, persons living with HIV, and the private sector.

Engage in consensus-building processes to:

- support the capacity of national authorities to develop and monitor policies; and
- seek policy agreement to the fullest extent possible and, in areas where differing policy approaches exist, seek to maximize complementarity, recognizing the conditionality of some sources of funding.

Technical Support

Technical support needs are best identified at the country level, and the development of in-country capacity is essential to an effective national AIDS response. To the fullest extent possible, technical support should be provided by local expertise.

Work within the national AIDS action framework to develop and implement a joint technical support plan which:

- recognizes and responds to the specific country context;
- identifies technical support needs;
- identifies core expertise and comparative advantages of individual partners to meet those needs; and

- provides for the sharing of terms of reference, results, and reports.

Continuum of Coordination & Collaboration

It is envisioned that collaboration will evolve along a continuum ranging from the current levels of engagement, whatever they are, toward the goal of full and complete implementation of the “Three Ones.” Obviously, current placement along this continuum varies from country to country as does the timing and support needed to effectively move toward the ideal collaboration embodied in the “Three Ones.” The chart below seeks to provide an illustration of how progress along this continuum plays out in the context of the each of the “Three Ones.”

Three Ones Principle	Minimal Engagement	Coordination and Collaboration Around Specific Issues	Ideal Collaboration
One National AIDS Action Framework	Sharing information on individual programs	Participate in periodic reviews and updates of National Strategic Frameworks	Joint planning and shared division of labor on implementation of overall response
One National AIDS Coordinating Authority	Attending meetings of the National AIDS Authority	Jointly identify country needs in specific areas (i.e., TA needs), and jointly respond	Provide ongoing coordinated support to the National AIDS Authority
One Monitoring and Evaluation System	Sharing program indicators	Harmonizing program indicators	Support the establishment of, and utilize, one national monitoring and evaluation system

As these programs and services are in place, they need reliable information to monitor their outputs (e.g. the number of people provided with preventive education) and outcomes (e.g. changes in the number of people using condoms) and longer-term impacts (e.g. changes in HIV prevalence). The third “One”, an agreed country-level monitoring and evaluation system, points to the most efficient and effective way of gathering, analyzing, and reporting this information.

The U.S. Global AIDS Initiative and other external partners’ efforts have had their greatest successes (i.e. Rwanda) where governments are full partners and the United States’ response is fully integrated into national strategies.

To that end, United States' efforts can empower "country-driven" efforts to increase access by:

- Actively engaging in national planning, costing and joint evaluation/review processes and sharing information it gathers to support and improve national program implementation;
- Aligning U.S. Global AIDS Initiative investments with national AIDS strategies, priorities, plans, and targets and synchronizing the timing of U.S. Global AIDS Initiative planning and reporting cycles with those of the national AIDS authority to the fullest extent possible;
- Expanding access to technical assistance through support for the development of national technical assistance plans, quality assurance, coordination of technical assistance provision and follow up, (including utilizing innovative mechanisms such as the UNAIDS technical support facilities and technical assistance funds.)

As highlighted by the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, a key feature of U.S.' leadership is commitment to coordination at all levels.

At the global level, it is essential for the United States. to continue to work closely with UNAIDS, the Global Fund, and other multilateral and bilateral donors to ensure that the comparative strengths of each are maximized and have a positive, synergistic impact on countries, rather than a duplicative, inefficient, and empowering one.

2. There has been much talk lately about the need to strengthen health systems in developing countries. How can PEPFAR help to improve the health systems in developing countries and address health worker shortages? Have we considered how to use our technological prowess to address the challenge of the health care brain drain?

Answer: The world is now paying the price, in the context of the AIDS crisis, for decades of inadequate investment in the developing world's public and private services to promote education and health. Lack of human capacity is the single biggest obstacle to an effective response to AIDS in many developing countries. Poor surveillance, planning and administration; bottlenecks in the distribution of funds; failures in the implementation, monitoring, and evaluation of activities; and inadequate provision of services are all largely due to systems of too few people with too few skills. According to the WHO World Health Report 2006, there is currently an estimated shortage of almost 4.3 million doctors, midwives, nurses, and support workers worldwide. The shortage of trained health-care workers is due in part to the ongoing "brain drain" of health-care providers from Africa and other heavily affected areas. A recent study estimated that, to cope effectively with AIDS and other health emergencies, sub-Saharan Africa will need to find 620,000 new nurses over the next few years (Chaguturu and Vallabhaneni, 2005).

- Curbing this exodus of professional people calls for action at both ends. Measures to improve working conditions and remuneration and other incentives to keep trained people at home are essential, as are formal agreements between countries and recruitment practices.
- National governments and international donors should take measures, where needed, to retain and motivate health workers, educators and community workers, and to increase financing for training and accreditation centers in countries facing severe human resource shortages.
- Speeding recruitment and training of health workers at all levels is also urgent. Countries should identify opportunities for drawing in new players from populations or sectors that are not yet fully engaged with the response, and should consider innovative ways of educating and training people.
- Where needed, countries should adopt alternative and simplified delivery models to strengthen the community-level provision of HIV prevention, treatment, care and support, including measures to enable "task shifting."
- National governments should also greatly expand their capacity to deliver comprehensive AIDS programs in ways that strengthen existing health and social systems, including by integrating AIDS interventions into programs for primary health care, mother and child health, sexual and reproductive health, and diagnosis and treatment of tuberculosis, malaria, and sexually transmitted infections.

- Education and other systems must be simultaneously strengthened. Most HIV prevention takes place outside the health-care delivery system, making the private and voluntary sectors particularly important.

A principal UNAIDS recommendation for reauthorization of the U.S. Global AIDS Initiative is to prioritize the strengthening of health care delivery systems, human resource capacity, and local community-based service organizations. Specifically, we recommend that the U.S. Global AIDS Initiative:

- Maximize current capacity by task-shifting, in-service and pre-service training/retraining, and increasing incentives for retention;
- Build greater indigenous national and local capacity – from doctors to nurses to community health workers and persons living with HIV– through training, accreditation, and adequate support and supervision;
- Target HIV training to education and social services sectors as well; and
- Support strategies that help countries operate their national AIDS program over the long term and avoid creating parallel United States systems and structures.

Many country teams have previously expressed concern that they were not allowed to fund activities unless they were specifically part of the AIDS response and thus could not support, for example, the training of new clinical officers, who in some countries are the mainstay of the treatment effort. UNAIDS maintains that the successful creation and sustainability of an HIV care delivery system should be fashioned in a manner that enhances the larger health care workforce/public health infrastructure rather than detracts from it.

UNAIDS supports Recommendation 8-3 of the recent Institute of Medicine (IOM) report which addressed the implementation of the U.S. Global AIDS Initiative: “To meet existing targets for prevention, treatment, and care, the U.S. Global AIDS Initiative should increase the support available to expand workforce capacity in heavily affected countries. These efforts should include education of new health care workers in addition to AIDS-related training for existing health care workers. Such support should be planned in conjunction with other donors to ensure that comparative advantages are maximized and be provided in the context of national human resource strategies that include relevant stakeholders, such as the ministries of health, labor, and education; other ministries; employers; regulatory bodies; professional associations; training institutions; and consumers.”

Questions from Senator Michael B. Enzi for Dr. Peter Piot

1. With the AIDS epidemic in the United States we were able to curtail the spread of the disease by closing bath houses in San Francisco. This direct threat to one of the cities social norms was effective, yet controversial. What prevailing social norms are assisting in the spread of HIV/AIDS in PEPFAR countries? What is the best and most appropriate way to stop them from occurring and educate individuals on this danger?

Answer: As I said on September 20th, 2007 to the Woodrow Wilson International Center for Scholars, “anything that has the word ‘only’ in it doesn’t work for AIDS, whether it is treatment only, prevention only, condoms only, abstinence only, male-circumcision only...we need it all.”

Risk behaviors and vulnerabilities are linked to economic, legal, political, cultural and social norms that must be analyzed and addressed at the policy and program levels. Therefore, comprehensive programming is necessary for the effective prevention of this disease. Effective HIV prevention programming focuses on the critical relationships between the epidemiology of HIV infection, the risk behaviors that transmit HIV and the social and cultural factors that aid or impede peoples’ abilities to access and use HIV information and services, and can thus make them more or less vulnerable to HIV infection. The term “driver” relates to the structural and social factors, such as poverty, gender inequality and human rights issues that are not easily measured that increase people’s vulnerability to HIV infection.

The prevailing social norm driving the epidemic worldwide is inequality. In the UNAIDS *Practical guidelines for intensifying HIV prevention*, there is clear recognition of the importance of tackling the social drivers of the epidemic. Three specific social drivers (all examples of inequality) are repeatedly cited as being central:

- **Human rights,**
- **HIV-related stigma and discrimination**
- **Gender inequality.**

These may express themselves in dozens of different ways including: child marriage; transgenerational sex; the sexual exploitation of girls; violence against women; multiple partners inside and outside of marriage; the taboo of condom use; the disenfranchisement of high-impacted populations such as men who have sex with men, injecting drug users, sex workers, and others (which drives the epidemic further underground); and so forth.

Recognizing that each country is different, UNAIDS’ *Practical Guidelines* are designed to provide policy makers and planners with practical guidance to tailor their national HIV

prevention response so that they respond to the epidemic dynamics and social context of the country and populations who remain most vulnerable to and at risk of HIV infection.

Reforming laws and policies that are based in deeply-rooted social attitudes and norms such as gender inequality requires multisectoral collaboration. Civil society, including organizations of people living with HIV, international organizations, and donors, have a critically important role to play. The protection of human rights, both of those vulnerable to infection and those already infected, is not only right, but also produces positive public health results against HIV.

Questions from Senator Christopher J. Dodd for Dr. Peter Piot

Prevention of Mother-to-Child Transmission (PMTCT)

Every day more than 1,100 children across the globe are infected with HIV, the vast majority through mother-to-child transmission. What is most tragic is that research has shown that these infections are largely preventable. The simple reason that the infection rate among children remains so high is that pregnant mothers and their babies are not getting the life-saving care they need. Less than 10 percent of pregnant women with HIV in resource-poor countries have access to prevention of mother-to-child transmission services.

1. What do you think have been the specific barriers to reaching more mothers and babies?
2. Where is PEPFAR succeeding in overcoming these barriers and where is it falling short?
3. In 2001 the United Nations set a goal to cut the number of pediatric infections by half in 2010. To reach this goal, it is estimated that 80% of pregnant women must have access to PMTCT services. As you may know, I recently introduced the “Global Pediatric HIV/AIDS Prevention and Treatment Act,” along with Senator Gordon Smith, which would set a target that within five years (by 2013), in those countries most affected, 80% of pregnant women receive HIV counseling and testing, with all those testing positive receiving antiretroviral medications for the prevention of mother-to-child transmission.

Are you supportive of such a target?

Answer: UNAIDS agrees that prevention of mother-to-child transmission (PMTCT) is a critical priority for the use of prevention dollars through the U.S. Global AIDS Initiative. A comprehensive set of activities--including counseling and testing, prophylactic antiretroviral therapy in late pregnancy and delivery, as well as for the newborn; safe delivery practices; and use of breast milk substitutes when safe water is available--has been found to be effective in preventing transmission of HIV to infants.

We agree that to be fully successful in the prevention of HIV transmission to newborns that multiple interventions throughout pregnancy and nursing are required including: HIV counseling and testing of pregnant women; the provision of antiretroviral prophylaxis; counseling of behavior modification around breast-feeding; follow-up with mother and child post-delivery; and HIV testing and assessment for the infant at 18 months. In addition, interventions should also include primary HIV prevention for women (including integration of HIV prevention into reproductive and sexual health services), prevention of unintended pregnancies in HIV-positive women, and broader access to antenatal care.

There are a number of factors that impede the full prevention of HIV testing from mother to child in PEPFAR-focus countries including: denial of HIV infection among pregnant women, opposition from male partners, women's fear of disclosure of HIV status to their partner and fear of being "found out" if they are taking drugs or not breastfeeding, concern about taking drugs during pregnancy, failure to return for checkups in the month before delivery, home delivery, and premature delivery before treatment can be given.

Though there have been significant successes in mother-to-child prevention through the U.S. Global AIDS Initiative. At the national level, the initiative provides technical assistance to host governments in the development and adoption of guidelines and policies aimed at improving the standardization and quality of such efforts. In addition, by helping to strengthen commodity management systems, partners of the U.S. Global AIDS Initiative increase the availability of many commodities essential to these prevention efforts including medications and test kits.

According to the United States Office of the Global AIDS Coordinator in 2007, approximately six million women in the focus countries have received PEPFAR-supported services to prevent mother-to-child transmission. The proportion of eligible pregnant women receiving services such as counseling and testing has increased from seven to 16 percent, and the proportion of HIV-positive pregnant women receiving antiretroviral prophylaxis has increased from nine to 21 percent.

UNAIDS is supportive of an aggressive targets as high as 80 percent of pregnant women having access to prevention of mother-to-child transmission services as we have been since 2001.

Pediatric Treatment

Despite the recent expansion in HIV/AIDS care and treatment around the world, children continue to lag behind adults in access to lifesaving medicines. Of the 2.5 million-plus new HIV infections in 2007, more than 420,000 were in children. But while children account for almost 16 percent of all new HIV infections, they make up only 9 percent of those on treatment under PEPFAR. Without proper care and treatment, half of these newly-infected children will die before their second birthday, and 75% will die before their fifth.

1. What steps do you believe should be taken in PEPFAR reauthorization to level the playing field for children, so that they are accessing treatment at the same rate as adults?
2. The legislation I introduced with Senator Smith sets a target that within five years (by 2013), 15% of those receiving treatment under PEPFAR be children, to keep pace with the infection rate.

Are you supportive of such a target?

Answer: UNAIDS recognizes the disappointing statistics regarding the number of HIV-infected children who are not antiretroviral therapies that could delay or prevent the life-threatening illnesses of untreated HIV disease. We agree with the following statement from the recent Institute of Medicine report addressing PEPFAR implementation: “The reasons for this are multiple and most are being addressed by PEPFAR. Diagnosis of HIV-related disease in children has been limited in part because most counseling and testing programs in the focus countries have targeted primarily young adults. The general lack of linkage of prevention of mother-to-child-transmission to infants and small children has lessened the likelihood of identifying those who are HIV-positive at that level. Many children who are found to be HIV-positive are orphans or living with orphan heads of households, further complicating adherence to treatment regimens and follow-up clinical visits.”

With over 600,000 children contracting HIV infection each year, mostly through mother-to-child-transmission, access to affordable HIV diagnostics and treatment responses represents an urgent global health priority. In 2005, UNAIDS and UNICEF issued a global call to action that challenges the world to ensure that antiretroviral therapy and prophylaxis with the antibiotic cotrimoxazole reach 80% of children in need by 2010. The U.S. Global AIDS Initiative is vital towards achieving that goal.

Accurate diagnosis of HIV infection in children can be difficult in resource-limited settings. Because of the persistence of maternal antibodies up to 18 months after birth, highly sensitive tests such as polymerase chain reaction or viral load testing are typically needed to render a definitive diagnosis in infants. While such tests have long been regarded as not feasible in low-resource settings (because of their high cost and the difficulty of collecting blood from newborn infants), more recent technical developments using dried blood spots show promise, enabling earlier diagnosis and avoiding the need to take blood from a vein.

Formulations of antiretrovirals suitable for use in children remain rare and tend to be more expensive than adult regimens. Most pediatric antiretroviral formulations are syrups that taste unpleasant to many children, potentially complicating adherence. Some must be diluted with drinking water or refrigerated, which may be unpractical in certain settings. In many places, dosages of adult medications are simply reduced for children, risking under-treatment (which can lead to drug resistance) or over-treatment (which can

produce side-effects because of the drugs' toxicity). Recently, some manufacturers have piloted the production of mini-pills, which are particularly suitable for young children. However, all new products need to be properly tested, pre-qualified and licensed to use.

Access to cotrimoxazole is critical, especially in settings where antiretrovirals are not yet accessible. The antibiotic, which provides protection against life-threatening opportunistic infections and can delay the need to initiate antiretroviral therapy, has been shown to reduce the risk of death in children living with HIV by more than 40% (Chintu, et. al, 2004). However, even though cotrimoxazole costs as little as 3 cents a day, an estimated four million children who need the drug are currently unable to obtain it (WHO and UNAIDS, 2005).

Because HIV-positive children are vulnerable to severe infections, timely and proper immunization is especially important. Routine vaccinations are generally safe to administer to HIV-infected children, but additional research is needed to find ways to ensure the effectiveness of routine immunization in children living with HIV and to enable clinicians to make more informed treatment decisions (Obaro et. al, 2004).

There are still no available FDA-approved combination preparations in dosages appropriate for small children and infants. This problem is exacerbated by the fact that several focus countries have few, if any, pediatricians and general practitioners are often reluctant to assume responsibility for treatment of small children with HIV-related disease.

UNAIDS believes that all of the above issues and strategies should be addressed in the upcoming reauthorization of the U.S. Global AIDS Initiative. Moreover, UNAIDS supports the prioritization of basic and clinical research within the NIH and other prominent research facilities to assess the pharmacokinetics for the safe and effective development of antiretroviral therapies for infants and children. We recognize the limited options available to be a significant barrier to the effective delivery of treatment to HIV-infected children around the world.

UNAIDS supports aggressive targets for aligning the percentages of those on antiretroviral treatment to mirror percentages by age of those who are infected.