Consultation on Pain and Palliative Care in Resource-Limited Settings

Bethesda, Maryland
November 16 and 17, 2009

Meeting Report

Sponsored by:

NIDA
AIDS Research Program
Prescription Opioid and Pain Workgroup
International Program

In Cooperation with:

CLINTON FOUNDATION
CLINTON HIV/AIDS INITIATIVE

NATIONAL INSTITUTES OF HEALTH
Office of AIDS Research
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Executive Summary

The World Health Organization (WHO) estimates that millions of people around the world are in immediate need of pain management, including those suffering from end-stage HIV/AIDS, terminal cancer, and injuries caused by accidents and violence; as well as surgery patients and children in pain. The National Institute on Drug Abuse (NIDA) and the Clinton Foundation HIV/AIDS Initiative share a common interest in ensuring adequate access to pain relief medications for those who suffer. On November 16 and 17, 2009, these two organizations and the National Institutes of Health Office of AIDS Research brought together participants from several countries and international organizations working with a variety of diseases to discuss how to increase access to pain treatment and palliative care while minimizing the risk of drug diversion.

The meeting, held in Bethesda, Maryland, focused on resource-limited settings in developing countries where the challenges are particularly difficult. Participants made clear the scope of the problem: Fully 5 billion people live in countries with low or no access to controlled medicines such as morphine and other opioid analgesics, and have no or insufficient access to treatment for moderate to severe pain.

Participants discussed common problems of access to pain medication and control of medication abuse, identified the barriers to progress in pain control and palliative care, and explored ways to overcome these hurdles. The unique situations of three resource challenged countries—Zambia, Kenya, and Ethiopia—were presented, as well as a general review of the situation in Africa. A representative of the African Palliative Care Association described how that group has tried to foster appropriate drug policies to ensure adequate drug availability, to increase health care workers’ education in pain treatment, and to help implement palliative care programs. In addition, representatives of international organizations (such as WHO) and donor groups, nongovernmental agencies, and government agencies of developed countries described their programs to both stem the flow of medications for illicit use and to help developing countries increase access to pain medications.

Speakers noted that barriers to an adequate drug supply include inadequate policies and infrastructure in national health care programs, laws that restrict drug availability, lack of funding, lack of an adequate supply of drugs, and a shortage of trained health care providers. To overcome these barriers, they said, pain treatment and palliative care must be integrated into the treatment and care of disease at all levels of the community—from patients to palliative care experts. Doctors and nurses need to be trained in how to administer drugs in the correct and safe dosages, especially in pediatric care. And standards for the assessment of pain need to be developed.

Furthermore, the participants stressed that governments need to be prompted to develop policies and laws that strike a balance between the availability of opioids for pain treatment and control of these substances. Laws that restrict drug availability and are overly focused on the diversion of drugs for illicit uses should be changed so they do not restrict drugs for legitimate uses. At the same time, there is a need to develop safeguards for the distribution of opioid medications from the manufacturer to the patient, incorporating appropriate handling and storage procedures. Speakers also acknowledged the needs of suppliers of drugs, pointing out that they need incentives to make needed drugs widely available and keep prices affordable.

Participants also remarked on the importance of developing standards for the quality and formulations of medicines, particularly pediatric-specific drug formulations. In a related vein, they acknowledged that counterfeiting of medicines must be prevented.
The importance of initiating and supporting change from within a country and not attempting to impose approaches or methods from outside that do not fit the local situation was emphasized. Participants also stressed the importance of evaluating drug policies and laws country by country and developing national strategies to increase access to pain medications. As one speaker pointed out, policy change will require identifying key players and stakeholders such as health ministries, tax and immigration officials, treasury departments, and so forth, and then working with them to review national health policies and related regulations.

Advocacy efforts were described and suggested. Speakers noted that effective advocacy can help change opinions, behaviors, and policy. They also suggested that international reform efforts must be better coordinated to increase the profile of the problem. They recommended that countries’ action plans be presented to the media to spread the message and increase awareness of the problem. In all these efforts, “it is important to put a human face on the issue.”

Participants spoke of the need for more assistance from international agencies, and the need to increase funding for proven strategies and their advocates. They agreed that with the assistance of donors and partner governments, there must be coordination of country-driven national responses to these problems. All groups involved must share information and knowledge to prevent an overlap of efforts.

While sustained donor investment and involvement have been catalysts for change, there was agreement that the base of donors needs to be increased. But as one speaker remarked, more donors are needed not simply as providers of money but also as voices spreading the message that pain management and palliative care are important parts of adequate public health care.

Finally, there was a consensus on the need to develop methods of evaluating program effectiveness so that governments and agencies will understand how their funding and efforts are leading to results.
Meeting Report

Bethesda, Maryland
November 16 and 17, 2009

On November 16 and 17, 2009, the palliative care field’s international pain and palliative care researchers, clinicians, and policy experts met in Bethesda, Maryland, to formulate strategies and improve ongoing efforts to make pain treatment and palliative care available to all those who need it. Their focus was resource-limited settings in developing countries where the challenges are particularly difficult. The participants were brought together by the National Institute on Drug Abuse (NIDA) AIDS Research Program, the NIDA Prescription Opioid and Pain Workgroup, the NIDA International Program, and the National Institutes of Health Office of AIDS Research, in cooperation with the Clinton Foundation HIV/AIDS Initiative.

Forum for Common Concerns

The 52 experts from several countries represented national palliative care associations, government agencies, international funding and aid organizations, universities, and international health organizations. All these groups have an interest in expanding access to pain medication, incorporating pain management into standard treatments for a variety of communicable and noncommunicable diseases, and increasing the availability of palliative care in countries where resources are limited.

Speakers pointed out that pain, in addition to resulting from accidents and trauma, is a common component of many diseases, including HIV/AIDS and cancer. Pain treatment not only brings comfort to patients but also plays a role in adherence to medical protocols where ongoing and sustained care is needed, such as with HIV/AIDS. For patients at the end of their lives, palliative care—of which pain treatment is an important component—not only relieves suffering but also helps them and their families maintain dignity while they put their affairs in order.

As Megan O’Brien, M.P.H., Ph.D., of the Clinton Foundation HIV/AIDS Initiative, said, “We share a common belief that everyone in pain deserves treatment. We are past the time for pilot and case studies. We need to think broadly—we need large-scale thinking. How do we deliver pain treatment to everyone who needs it in the next 3 years?” This challenge, she noted, is exacerbated by the uneven access to pain treatment around the world. There is a need to bring together those working with different diseases, such as cancer clinicians and HIV/AIDS professionals, to develop a common strategy to address pain and to coordinate efforts to alleviate pain. Pain treatment should be recognized as part of a complete treatment of disease.

NIDA has long recognized that appropriate pain management, including widespread availability of opioid medications, is essential. The agency has a portfolio of research on pain ranging from basic research to clinical, epidemiology, and services research. NIDA also recognizes that many of the medications that relieve pain and suffering have significant abuse liability and are abused for non-medical purposes. As such, there is an important need to regulate and control the distribution of these drugs from their production all the way to the patient to prevent their redirection to illicit uses. To this end, international standards and enforcing agencies such as the International Narcotics Control Board (INCB) have been established (see textbox).
The adoption of this convention is regarded as a milestone in the history of international drug control. The Single Convention codified all existing multilateral treaties on drug control and extended the existing control systems to include the cultivation of plants that were grown as the raw material of narcotic drugs. The principal objectives of the convention are to limit the possession, use, trade-in, distribution, import, export, manufacture, and production of drugs exclusively to medical and scientific purposes and to address drug trafficking through international cooperation to deter and discourage drug traffickers.

The convention also established the International Narcotics Control Board (INCB), merging the Permanent Central Board and the Drug Supervisory Board.

The aims of NIDA's AIDS Research Program include improving HIV treatment in drug-using populations, which includes providing pain and palliative care. The NIDA Prescription Opioid and Pain Workgroup is a trans-NIDA group organized to disseminate current information and to plan research initiatives pertaining to the problem of prescription drug abuse and its interrelationship with pain and pain treatment.

NIDA and the Clinton Foundation HIV/AIDS Initiative share a common interest in limiting the abuse of drugs while maintaining adequate access to pain relief medications for HIV/AIDS patients and for those who suffer from other conditions. By bringing together experts not only from the fields of HIV/AIDS but also from cancer treatment and palliative care, a forum was created in which the common problems of access to pain medication and control of abuse could be discussed, the barriers to progress in pain and palliative pain care identified, and ways to overcome these hurdles explored.

What Are the Barriers to Treatment?

The meeting opened with a presentation by Faith Mwangi-Powell, Ph.D., of the African Palliative Care Association (APCA), who discussed the barriers that limit access to pain treatment and palliative care. The challenges to be met, she said, vary by country, and it is important to develop and implement strategies appropriate to each situation. Within each country there must be an understanding of how far the availability of drugs falls short of the need for those drugs. She recommended that governments be encouraged to engage in “action plans” that will close this gap. And she stressed the need to leave the meeting with a clear strategy for overcoming the barriers to pain treatment.

Dr. Mwangi-Powell enumerated a list of barriers to an adequate drug supply: lack of leadership and inadequate policies and infrastructure in national health care programs; laws that restrict drug availability and that are overly focused on the diversion of drugs to illicit uses; lack of funding; lack of an adequate supply chain of drugs, including shortages in the amounts of drugs, inefficient distribution around a country, lack of dispensers, lack of secure storage, and inadequate storage conditions that may degrade drugs; lack of health care providers trained in assessing pain requirements and in prescribing and administering pain medications; fear of opioids among health care professionals; the high cost of medications; patients’ lack of access to basic health care; ignorance and false beliefs of both providers and patients—for example, about the necessity for diminishing pain during disease treatment and in end-of-life situations; and the dangers of various drugs.

To identify and overcome these barriers, Dr. Mwangi-Powell said, it is important to understand how all these factors interact—during clinical care and health service provision, among various types of diseases, and at the patient level—to ensure adequate opioid availability and to provide good patient outcomes. In the end, the key is, how many patients actually get pain control and is it adequate? She stressed that it is important to measure these outcomes and to use that information to improve pain treatment and the palliative care of patients.

Dr. Mwangi-Powell further recommended that drug policies and laws be evaluated country by country and that action plans or national strategies be developed to increase access to pain medications. To do this, key players and stakeholders need to be identified. And, advocacy efforts must be fostered to change policies that are barriers to increasing pain treatment. Educational opportunities need to be strengthened as well. Pain treatment and palliative care, she concluded,
need to be integrated into the treatment and care of disease at all levels of the community—from patients to palliative care experts.

Experience in Expanding Access to Pain Treatment

Speakers presented the unique situations of three countries—Zambia, Kenya, and Ethiopia—as well as a general review of the situation in Africa, including the barriers each country faces and the steps being taken to overcome them. All shared common problems such as limited access to medications; a shortfall in the numbers of hospices and palliative care facilities; understaffing of the facilities, particularly a shortage of trained physicians, nurses, and social workers; the lack of adequate storage facilities; and the need for changes in government policies to increase drug availability and training for health care providers.

Zambia

Patricia Zulu Ulaya, Acting National Coordinator of the Palliative Care Association of Zambia (PCAZ), related that in Zambia, a considerable number of patients report pain as a major ailment, yet there is limited access to pain medications such as codeine, and even less to morphine. Among health workers and policymakers, there is an underlying fear of opioids. Moreover, few health care workers are trained in palliative health care, and the country has no national policy for palliative care.

The PCAZ approaches these problems through advocacy, education, and information distribution, and by expanding access to service. A 2-year oral morphine pilot project will begin in January 2010. The lessons learned will be used to design a national strategy to increase morphine availability. The program’s key elements are to increase collaboration among stakeholders, to better train and mentor staff, to develop methods to measure the effectiveness of pain relief for patients, and to establish ways to support the implementation of a national program. Future plans include the development and distribution of palliative care standards and guidelines, more specialized palliative care training, and continued enhancement of coordination and collaboration efforts to increase palliative care.

Kenya

The problems in Kenya were described by Zipporah Ali, M.D., M.P.H., National Coordinator of the Kenya Hospices and Palliative Care Association (KEHPCA). They include significant numbers of HIV cases and a large number of new cancer cases reported each year. In Kenya, moreover, there is a shortage of hospices and palliative care facilities, and the existing facilities are understaffed. In particular, there is a shortage of trained physicians, nurses, and social workers. And storage facilities often are inadequate. Kenya has no national policy for pain and symptom management, and the country has not endorsed the World Health Organization (WHO) standards for pain relief.

KEHPCA, Dr. Ali pointed out, is pushing for improved narcotic control legislation and the inclusion of analgesics in the country’s Essential Drug Kit. It is encouraging the government to take a number of steps, including bringing high prices under control, changing laws to allow people other than doctors to prescribe opioids, increasing the number of certified dispensers, and including palliative care training in nursing and pharmacist curricula. KEHPCA also is working with legislative bodies to educate palliative care providers about the rights of patients and their families. And the association’s staff are holding workshops and meetings about the usefulness, availability, and safety of opioids in the community and among professional health care providers.
Ethiopia

Ethiopia faces barriers to adequate pain treatment that include a poor health care infrastructure with a lack of properly trained health care workers and little access to drugs. Sefanit Mengistu Gebreab of the Drug Administration and Control Authority of Ethiopia observed that cultural attitudes also play a role—the belief, for example, that pain is not a priority of care and that narcotics are dangerous and addictive. Initiatives are underway in Ethiopia to create a public drug supply chain to supplement the government chain and to improve the stock of pain treatment drugs in the government supply chain. An in-country oral morphine production program has been launched to develop syrups in three strengths and in formulations that will be palatable and safe to use with children. An important part of this program is to optimize the oral morphine formulations so that the solutions are stable and have increased shelf life, especially given the lack of suitable storage facilities. The plan is to produce tablets at a later stage in the study.

Sefanit Mengistu Gebreab noted that training in Ethiopia has been improved through the development of a training syllabus and a palliative care toolkit. And to address the negative cultural attitudes about pain care, advocacy efforts such as a media campaign for “Palliative Care Day” have been launched.

African Palliative Care Association Efforts

Dr. Mwangi-Powell described APCA’s efforts to foster appropriate drug policies in countries around Africa, the aims being to ensure adequate drug availability, to increase health care workers’ education in pain treatment, and to assist in the implementation of palliative care programs.

Dr. Mwangi-Powell emphasized the importance of initiating and supporting change from within a country and not attempting to impose approaches or methods from outside that do not fit the local situation. She explained that APCA takes steps to find out what problems people in the country view as most significant and what solutions exist or might be implemented to solve them. The association then tries to use the same language to bring to bear its experience in solving problems—for example, the need for communications between groups such as regulators, pharmacies, and health care providers and the need to address supply issues, such as stock-out or lack of suitable storage facilities. By talking to local people, Dr. Mwangi-Powell advised, there is a better chance of determining the real problems. Those problems may be small and easily fixed with adequate resources. Further, she said, governments need evidence that is directly relevant before they proceed with changes to policy and legal structures or provide funding.

To foster education and palliative care programs, APCA does the following: It identifies opinion leaders and educational and health experts such as deans of medical, nursing, and pharmacy schools; determines the target audiences; and helps develop or enhance curricula, always looking for opportunities to implement programs that will work and then to “scale those programs up.” Regional advocacy workshops conducted by APCA help to identify the challenges, the “players,” and the possible solutions.

APCA has learned, Dr. Mwangi-Powell said, that the government must be engaged in the process of change, that supporting local champions helps drive programs forward, and that training health care providers to improve their skills leads to better patient care.

National-Level Strategies to Increase Access to Therapeutic Opioids

Scott Burris, J.D., of Temple University Beasley School of Law, discussed national-level strategies to increase access to therapeutic opioids and how improvements in policies can increase access to opioid pain medications. He described how barriers to opioid access operate in a cycle that just
reinforces the barriers. Tight controls of drugs lead to limited supplies of drugs, which in turn are
ill-utilized by undertrained professionals. Patients are poorly informed by care providers and have
little awareness of what opioids could do for their pain, and they often are afraid they will become
addicted to the drugs. The fear of addiction fosters tight controls and the cycle continues.

Mr. Burris pointed out that reform of the system is difficult, as policy and practice are largely
inseparable. And because of scarce health care resources, it is hard to break into the cycle at any
given point. He noted that the cycle is further reinforced by the lack of reliable estimates of the
amount of drugs required, as well as too few doctors and nurses, low demand, and procurement
problems.

Still, Mr. Burris noted, successful reforms have been possible in some countries where sustained
donor investment and involvement have acted as catalysts for change. Donors have done this
by assessing the need for drugs and the barriers to their access, crafting reforms to overcome the
barriers, and implementing and then evaluating the effectiveness of new policies. Success at each of
these steps can reinforce other steps in policy development.

Challenges remain. These include: obtaining more effective assistance from international agencies,
increasing funding for proven strategies and their advocates, and better coordinating international
reform work to increase the profile of the problem. Mr. Burris pointed out that evidence of
successful efforts shows that increased resources can be put to use effectively. And it is important
to gain public recognition of these successes, because efforts to increase funding are impeded by
significant public apathy about the problem.

Role of International Organizations

In addition to the work being done in individual countries, numerous international organizations,
donor groups, nongovernmental agencies, and governmental agencies of developed countries
have programs in place to both stem the flow of medications to illicit use and to help developing
countries increasing access to pain medications. Participants described how these international
groups also help developing countries with related educational and training efforts, the creation
of pain management and palliative care programs, and the development of policies and laws; and
they help them address human rights issues—the idea that freedom from certain kinds of pain
should be a fundamental human right.

WHO, INCB, and ACMP

As one example, Willem Scholten, Pharm.D., M.P.A., of WHO, described how in 2007, WHO,
in association with the International Narcotics Control Board (INCB), launched the Access to
Controlled Medications Programme (ACMP). ACMP addresses all medicines that are controlled
under international drug conventions but pays particular attention to “essential medicines.” Its
aims are to assess problems and solutions, to find allies to make advances, and to share information
and knowledge to prevent overlap of effort by different groups.

ACMP focuses on support at the country level, mainly with developing countries. Its activities
approach the problems from a number of angles, including normative work on developing
guidelines for pain assessment, collecting data to estimate drug use, updating WHO policy
guidelines on how to achieve balance in national opioid control policies, and developing model
legislation that countries can use to ensure adequate supplies for health care uses while controlling
access to drugs.
**PEPFAR**

The work of the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), which supports programs in more than 100 countries around the world, falls into three areas—treatment, prevention, and care. According to Carol Langley, PEPFAR ensures that national governments play a central role and helps them to gradually take over ownership of the programs. In its focus, she said, PEPFAR is moving from emergency response toward building sustainable programs. PEPFAR provides technical assistance and mentoring models and helps coordinate country-driven national responses to problems with the assistance of donors and partner governments. The aim, Ms. Langley explained, is to maximize efficiency and effectiveness, including strengthening health care systems by integrating services and avoiding duplication of effort. An important aspect is the implementation and strengthening of program impact evaluation.

PEPFAR also supports regulatory and policy reform, reform of national and international HIV care guidelines, development of clinical training programs, and expansion of the types of medications available for pain and symptom relief. The organization also promotes the tracking and assessment of the effectiveness of policies and programs for pain management. PEPFAR also has supported model curricula development, distance-based diplomas, and development of easy-to-use pocket guides to supplement treatment.

**Global Coordination and Support Needs**

**Clear, Consistent Messages**

Jim Cleary, M.D., of the University of Wisconsin Pain and Policy Studies Group, described a lack of clarity in the messages coming from the many international organizations involved with access to opioid medications for pain management and the development of medication assessment tools (MAT). He stressed the need to coordinate those messages. In other cases, he said, the messages about the full role of various organizations may not be getting through completely, leading to misunderstandings of their efforts and intentions. Some groups, such as the INCB, are seen by some countries as being restrictive and focused only on illicit drug use. Some have seen WHO as concentrating too much on the health system and having too few links to drug regulators.

To overcome these barriers, organizations must coordinate efforts to put forward consistent messages and develop tools to train health care professionals so they will understand what resources are available and how to put them to use. An organization whose message has been misunderstood, such as the INCB, needs to make a clear statement about its support for access to opioids for pain treatment and to work on developing relationships with countries to change their perceptions of the organization’s aims.

**Model Laws and Regulations**

Dr. Cleary added that organizations also need to work together to develop model laws and regulations that support access to pain medications. Specifically, it is important to develop step-by-step safeguards for the distribution of opioid medications—from the point of manufacture all the way to the patient. Training curricula need to be developed for a number of audiences, including drug regulators, law enforcement personnel, doctors/prescribers, nurses/ dispensaries, and clients/patients to ensure that the needs of medications for pain management and for treatment of drug users are met.

Organizations also need to understand that countries must identify and solve their own problems, and the organizations’ efforts must be directed toward providing input that supports these efforts while taking direction from the countries themselves. The goal, Dr. Cleary said in summary, is to achieve a balance between the availability of opioids for pain treatment and their control.
The Challenges of International Donors

The challenges large international donors face in achieving their goal of increasing the use of pain medications was the subject of Kathleen M. Foley, M.D., and Mary V. Callaway of the Open Society Institute International Palliative Care Initiative (IPCI). Among the challenges they described:

- Health care professionals are conflicted with dual loyalties—to both regulating authorities and their patients. And in some cases, the providers themselves may be part of the problem because of their attitudes and their behaviors in how they acknowledge the need to treat pain.

- In some countries, there is no voice to advocate for pain and palliative care. An example is the lack of support for pain management for IV drug users. The speakers stressed the importance of engaging civil and HIV/AIDS activists and getting them to speak out about the need for pain care.

- Around the world, there has been a lack of recognition of the many people who do not receive care. While 4 million people are on antiretroviral treatments, many more are not, and many receive no treatment for pain.

- Cancer treatment has seen a focus on survivors, not on the suffering of those who did not survive. And patients’ families, too, are burdened and bereaved by this lack of care. Moreover, much of the professional focus has been on treatment—the curing of disease—without addressing the care of the suffering and the pain that goes along with the disease and treatment. A goal, the speakers said, must be to avoid needless suffering by patients. Palliative care needs to be part of treatment.

Dr. Foley and Ms. Callaway stressed that pain management and palliative care need to be fully integrated and available at the point of contact between patient and care provider, with continuity of care—and particularly end-of-life care. Key aspects are the need to advocate for essential medications, including pain medications, as part of a basic package for HIV/AIDS care. All providers need to be educated about a palliative care framework and guidelines and standards for care. Steps toward achieving these goals include analyzing the legal framework in different countries that govern the access to pain and palliative care medications. And, finally, the donor base must be increased, with donors viewed not simply as providers of money but also as voices spreading the message that pain management and palliative care are important parts of adequate public health care.

Medication Supply Chain Management

J. David Haddox, D.D.S., M.D., of Purdue Pharma, discussed the problems of diversion and illicit/criminal use of opioid analgesics and how this creates a challenge for the safe, controlled supply of pain medicines in all countries around the world.

Diversion of drugs from the medication supply chain can occur at several points in the chain, he explained, and losses can be significant. It is up to each country to build controls in its supply chain. But on the downside, pain control efforts may be compromised if illegal or illicit use increases and countries place controls on the use of drugs. The balance between allowing access for legitimate use and the control of illegal use is an important consideration.

Another concern Dr. Haddox mentioned was counterfeit medicines: about 15 percent of the world supply is counterfeit. Medicines may be fraudulently mislabeled; they may contain the wrong amounts of the correct ingredients; they may contain the wrong ingredients that still have some degree of effectiveness; or, they may lack active ingredients entirely. Fake packaging can
be a problem. Dr. Haddox therefore recommended that countries also develop ways to control counterfeit drugs and to prevent the introduction of substandard medicines.

**Increasing the Supply of Medications**

Inder Singh of the Clinton Foundation HIV/AIDS Initiative outlined a number of important factors that are essential to increasing access to medications. He noted that coordination among partners on a range of activities can have a dramatic impact on the pricing and supply of medications. Suppliers of drugs need incentives or reasons to supply those drugs, and profits are important to suppliers. Price is a factor both on the supply side and the user side, as drugs must be affordable in order to be used widely. A broad supply base of the drugs also is important, as is optimizing systems that will ease the distribution of useful drugs. It is important to help establish markets that will both increase the availability of existing drugs and help bring new types of medications into use.

Mr. Singh also talked about the need to develop and consolidate demand for a product so that suppliers will see an attractive market and thus be willing to respond. Competition among suppliers also needs to be developed, as this may foster innovation in how the drugs are formulated or supplied. At the same time, suppliers need help in reducing production costs and reducing their risks so that their potential profit increases. During this process, negotiation at every step is important. And the need to engage with suppliers is even greater for drugs with lower demand volumes.

**Increasing the Number of Trained Care Providers**

Pain management requires a combination of skills for assessing pain and administering medications, as well as the development of an attitude that it is important to control pain, observed Michelle Meiring, M.D., of the University of Cape Town and the Hospice Palliative Care Association of South Africa (HPCA). She drew a distinction between training—which develops skills in the ways to control pain, and education—which is a process of thinking about underlying issues such as attitudes, beliefs, assumptions, and values that will inform the decision to manage pain.

Those who need to be educated and trained in pain management include those who teach, and the best teachers, in Dr. Meiring’s view, usually are those involved in clinical practice. She added that skills in how to present information need to be developed. And not only do physicians, nurses, and pharmacists need to be trained, so, too, do caregivers, patients, and families.

Dr. Meiring recommended that new methods of training and educating need to be considered—methods that address different thinking and learning styles. And both formal and informal settings for the transfer of knowledge are necessary. Moreover, different techniques—experiential learning, distance-based training, and reflective- and work-based learning, for example—need to be applied. Finally, there needs to be ways to assess which approaches are effective and to provide ongoing mentorship to foster learning.

**Special Problems: Pediatric Pain Management—Gaps, Challenges, and Needs**

Assessing pain in babies and young children involves challenges beyond the assessment of pain in adults, said René Albertyn, Ph.D., of the Red Cross Children’s Hospital in Cape Town, South Africa. Doctors and nurses need to be trained in how to administer drugs in the correct and safe dosages and in how, after the patient is discharged, to educate parents to administer and store drugs safely.
Dr. Albertyn pointed out that not only are medications in short supply, but the formulations available are not optimized for pediatric use. Thus the medications may require dilution or handling, which may introduce errors, or they may be in a form that is too strong for children (e.g., morphine tablets) but cannot be safely divided into an acceptable dosage. Many of the drugs available—about 60 percent in South Africa, she estimated—have not been tested for use in children, or the instructions for their use may be confusing or contraindicated for that use. Other problems include tastes that are not palatable to children, lack of stability of the preparation, and lack of suitable storage facilities. The difficulties occur not only in the hospital setting. And they may be magnified in post-discharge care where parents may not have the skills to correctly dilute or administer difficult-to-use drugs and where suitable storage conditions are difficult to provide.

Advocacy: Raising Visibility and Creating Momentum

The question “How do we make people care?” was posed by Kaia Lenhart of GMMB, Inc., a political, issue, and cause communications firm with offices in Washington, D.C., Los Angeles, Seattle, and London. Noting that global health efforts face many challenges and obstacles, she asked how “the message of pain gets recognized in that larger scope?” In the past, she said, it was thought that good science would drive good policy, but that approach has led to disappointment. She suggested that a more active and direct approach is needed: “With knowledge already available, there are steps that can be taken to reshape the discussion of pain and palliative care.”

Ms. Lenhart sees advocacy as a means to change opinions, behaviors, and policy; it can elevate the issue and build momentum. She stressed that it is important to identify stakeholders such as researchers, practitioners, policymakers, financial partners, patients, and others. The messages being advocated need to be clear about what is needed, and what steps need to be taken. Simply calling attention to a problem is not enough, said Lenhart: There must be direction in order to achieve progress.

Ms. Lenhart offered a five-step approach to effective advocacy: (1) creating a high-level advisory board; (2) honing the goals and objectives; (3) engaging professional societies for different diseases to advocate with one voice; (4) executing high-profile, country-specific actions that target decision makers; and (5) recognizing countries and policymakers that make the cause a priority and finding ways to reward them for their support.

Pain management, Ms. Lenhart said, should be linked to larger global health issues, such as Millennium Development Goals (MDGs), HIV/AIDS, cancer, and burn treatment. A unified voice needs to be presented and a human face put on the issue. Moreover, clear, understandable language must be used to convey the message and educate people about the problem. She noted, too, that all advocacy is local. Stories need to be compassionate and compelling. Champions “who will be voices and drive the issue forward” need to be identified and supported. Messages need to present consistent and doable action steps. And the message, she stressed, needs to be more than simply asking for more funding: We need to present evidence on what is already working and the experience of field practitioners.

Ms. Lenhart also observed that physicians must be convinced to “buy-in” to the message. She suggested that to do this, education and influence through the fraternal network and medical boards can be used. And the focus should be on target countries where progress can be made more quickly initially.

Engaging the media is important as well, she said, but it must be understood that the platform of communications has broadened. For example, just putting a message out with a press release isn’t enough. There are many types of media today, and their attention is more divided among...
diverse targets. There needs to be an effort to work with reporters to help them develop stories—to provide them with “back-end” or source information to help them shape their stories. And it is important to continue to engage the media and maintain the contact.

**Bringing About Change**

Over the course of the meeting the participants identified a number of barriers to treatment, discussed the challenges of overcoming these barriers, and identified steps that can be taken to bring about solutions and increase access to pain care.

These barriers include the unavailability and shortage of drugs due to the lack of an adequate supply chain, high costs, inefficient distribution, lack of secure storage, and inadequate storage conditions. Other barriers are the shortage of trained health care professionals, and of adequate training in how to assess pain and prescribe and administer drugs. Many patients also lack access to basic health care and are unaware of what pain treatments might be available to them.

Participants also talked about the need to overcome ignorance and false beliefs on the part of both providers and patients—beliefs, for example, surrounding the need to diminish pain during treatment of disease and in end-of-life situations, as well as the dangers of various drugs.

Many countries have policies and laws in place to restrict the flow of drugs into non-medical, illicit uses, and these laws can limit the supply or use of drugs for legitimate pain care in medical settings.

**Implications for Policy**

During the 2-day meeting common themes and implications for policy emerged. To overcome barriers, change must be brought about in a variety of ways. Most basic is education: Government support must be gained to develop programs to educate and train more doctors and nurses and to strengthen educational opportunities to train and mentor staff. In addition, specialized training curricula need to be developed for a number of audiences, including drug regulators, law enforcement personnel, and clients/patients, as well as doctors/prescribers and nurses/dispensers.

Pain treatment and palliative care must be integrated into the treatment and care of disease at all levels of the community—from patients to palliative care experts. Doctors and nurses need to be trained in how to administer drugs in the correct and safe dosages. Standards for the assessment of pain need to be developed. Palliative care needs to be part of treatment, not just of care. Pain management and palliative care need to be fully integrated and available at the point of contact between patient and care provider—with continuity of care, and particularly end-of-life care. All providers need to be educated about a palliative care framework and about guidelines and standards for care.

In the legislative and law enforcement arena, governments need to be prompted to develop policies and laws that strike a balance between the availability of opioids for pain treatment and control of these substances. Diversion of drugs to illicit uses can occur at several points along the supply chain. Step-by-step safeguards need to be developed for the distribution of opioid medications from the manufacturer to the patient, incorporating appropriate handling and storage procedures. Supply issues such as stock-out or lack of suitable storage facilities must be addressed. Suppliers of drugs need incentives to supply drugs, as a broad supply base is important, and systems need to be optimized to ease the distribution of useful drugs. More information must be collected about forecasting the quantity of drugs needed in different countries.

Drug policies and laws must be evaluated country by country and action plans or national strategies developed to increase access to pain medications. Laws that restrict drug availability and
that are overly focused on the diversion of drugs to illicit uses need to be changed so that they
do not restrict the availability of drugs for legitimate uses. Countries need help in updating their
essential medicine lists and drug policies and in expanding the types of medications available for
pain and symptom relief.

Counterfeit medicines are a concern. Medicines may be fraudulently mislabeled; they may contain
the wrong amounts of the correct ingredients; they may contain the wrong ingredients that still
have some degree of effectiveness; or they may lack active ingredients entirely. Fake packaging can
be a problem. Standards for the quality and formulations of medicines need to be developed, and
a crackdown on counterfeit medicines is in order. Furthermore, there is an urgent need to develop
pediatric-specific drug formulations and to strengthen the training needed to use them.

To bring about these changes, one must identify key players and stakeholders such as health
ministries, tax and immigration officials, treasury departments, and so forth, and then work with
them in reviewing national health policies and related regulations. It is important to present
doable action steps—and to send a message that what is wanted is not simply more funding. It is
important to know what is being asked of whom and the specific steps that need to be taken.

Around the world, there has been a lack of recognition of the many people who do not receive
care. While 4 million people are on antiretroviral treatments, many more are not, and many
receive no treatment for pain. Cancer treatment has seen a focus on survivors, not on the suffering
of those who did not survive.

Advocacy efforts to change opinions, behaviors, and policy can elevate these issues and build
momentum for a change in policies. As they are developed, advocacy meetings and country
action plans must be presented to the media to spread the message and increase awareness of the
problem. And in doing so, it is important to put a human face on the issue.

Additionally, international reform work must be better coordinated to increase the profile of
the problem. And change must be initiated and supported from within a country rather have
approaches or methods imposed from outside that do not fit the local situation. Advocates also
must bear in mind that in some countries, there is no civil society voice to speak up for pain and
palliative care. But champions in different countries, with modest outside assistance and support,
can significantly increase access to pain medications.

More assistance must be obtained from international agencies, and funding must be increased
for proven strategies and their advocates. At the same time, all groups involved must share
information and knowledge to prevent an overlap of efforts.

With the assistance of donors and partner governments, there must be coordination of country-
driven national responses to these problems. And while sustained donor investment and
involvement have been catalysts for change, the base of donors needs to be increased, not simply as
providers of money but also as voices spreading the message that pain management and palliative
care are important parts of adequate public health care.

Finally, there is a need to develop methods of evaluating program effectiveness so that governments
and agencies will understand how their funding and efforts are leading to results.
**Meeting Objective:** The meeting will allow palliative care's international thought leaders from academia, clinical practice, and the donor community to come together and develop a strategy to coordinate and catalyze ongoing efforts to make pain management and palliative care widely and immediately available to those living in the developing world.

**Meeting Moderator:** Faith Mwangi-Powell, African Palliative Care Association (APCA)

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<tr>
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<tr>
<td>8:00-9:00 a.m.</td>
<td>Registration and Continental Breakfast</td>
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<td>9:00-9:20 a.m.</td>
<td>Welcome and Introductions</td>
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<tr>
<td>Lynda Erinoff, NIDA</td>
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<tr>
<td>9:20-9:30 a.m.</td>
<td>Vision for the Initiative</td>
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<tr>
<td>Meg O’Brien, Clinton HIV/AIDS Initiative</td>
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<tr>
<td>9:30-10:00 a.m.</td>
<td>Plenary: Shifting the Frame of the Pain Treatment Conversation</td>
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<tr>
<td>Faith Mwangi-Powell, African Palliative Care Association (APCA)</td>
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<tr>
<td>10:00-10:45 a.m.</td>
<td>Generating Progress at the Government Level</td>
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<tr>
<td>Sefanit Mengistu Gebreab, Drug Administration and Control Authority of Ethiopia</td>
<td>Experience in Morphine Roll-Out in Ethiopia</td>
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<td>Zipporah Ali, National Coordinator, Kenya Hospice and Palliative Care Association</td>
<td>Experience in Expanding Access to Pain Treatment in Kenya</td>
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<td>Patricia Ulaya, National Coordinator Palliative Care Association of Zambia</td>
<td>Experience in Expanding Access to Pain Treatment in Zambia</td>
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<tr>
<td>10:45-11:00 a.m.</td>
<td>Tea Break</td>
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<tr>
<td>11:00-11:15 a.m.</td>
<td>World Health Organization Update</td>
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<td>Willem Scholten, World Health Organization (WHO)</td>
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<tr>
<td>11:15-11:30 a.m.</td>
<td>Review of Current National Strategies</td>
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<tr>
<td>Scott Burris, Temple University</td>
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<tr>
<td>11:30-11:45 a.m.</td>
<td>African Palliative Care Association</td>
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<tr>
<td>Faith Mwangi-Powell, African Palliative Care Association (APCA)</td>
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<tr>
<td>11:45-12:15 p.m.</td>
<td>Audacious Approaches Brainstorm</td>
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<td>12:15-1:30 p.m.</td>
<td>Lunch</td>
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<td>1:30-1:50 p.m.</td>
<td>Global Coordination and Support</td>
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<td>Jim Cleary, University of Wisconsin Pain and Policy Studies Group</td>
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<tr>
<td>1:50-2:20 p.m.</td>
<td>U.S. Government Update on Ongoing Work Within PEPFAR</td>
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<td>Carol Langley and Karina Raposelli Office of the Global AIDS</td>
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### Monday, November 16, 2009

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<tr>
<td>2:20-4:20 p.m.</td>
<td>Breakout Session 1:</td>
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<tr>
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<td>- Regulatory Issues: Jim Cleary</td>
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<td>- Inclusion of Pain Treatment Into National and International Guidelines: Shaffiq Essajee</td>
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<td>- Supporting National Governments to Respond to the Needs of People in Pain: Zodwa Sithole</td>
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<tr>
<td>4:20-4:35 p.m.</td>
<td>Call to Action Piece: Publication Outline, Timeline, and Plan</td>
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<td></td>
<td>Meg O’Brien, Clinton HIV/AIDS Initiative</td>
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<td>4:35-4:50 p.m.</td>
<td>Audacious Approaches Brainstorm</td>
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<tr>
<td>4:50-5:00 p.m.</td>
<td>Wrap-Up and Discussion</td>
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<td>Faith Mwangi-Powell, African Palliative Care Association (APCA)</td>
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<tr>
<td>8:00-8:30 a.m.</td>
<td>Continental Breakfast</td>
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<tr>
<td>8:30-9:00 a.m.</td>
<td>The Other Side of the Coin: Diversion and Abuse of Opioid Analgesics</td>
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<td>David Haddox, Purdue Pharma</td>
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<td>9:00-9:15 a.m.</td>
<td>Pain Medication Formulation Availability</td>
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<td>Rene Albertyn, Red Cross Children’s Hospital</td>
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<tr>
<td>9:15-9:30 a.m.</td>
<td>Formulations Experience With Pediatric ARVs</td>
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<td>Inder Singh, Clinton HIV/AIDS Initiative</td>
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<td>9:30-10:00 a.m.</td>
<td>Clinical Provider Training</td>
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<td>Michelle Meiring, Hospice Palliative Care Association of South Africa</td>
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<tr>
<td>10:00-10:15 a.m.</td>
<td>Tea Break</td>
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<tr>
<td>10:15-10:45 a.m.</td>
<td>Donor/Funding Landscape</td>
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<td>Kathy Foley and Mary Callaway, The Open Society Institute Palliative Care Initiative</td>
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<tr>
<td>10:45-11:30 a.m.</td>
<td>Raising the Visibility and Creating Momentum</td>
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<td>Kaia Lenhart and Annie Burns, GMMB</td>
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<td>11:30-2:45 p.m.</td>
<td>Breakout Session 2:</td>
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<tr>
<td></td>
<td>- Leveraging PEPFAR to Increase Access to Pain Treatment: Carol Langley</td>
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<td>- Prescribing Practices: Moving to Nurse-Delivered Treatment: Zodwa Sithole</td>
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<td>- Donor Alignment and Innovation: Olivia Dix</td>
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<td>- Integrating Pain Treatment Into HIV Care and Treatment Programs: Tanya Medrano</td>
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<td></td>
<td>(With lunch break 12:15-1:30 p.m.)</td>
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<tr>
<td>2:45-4:45 p.m.</td>
<td>Breakout Session 3:</td>
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<tr>
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<td>- Formulations: Owen Robinson</td>
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<td>- Cancer/HIV Coordination: Cary Adams</td>
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<td></td>
<td>- Addressing Diversion Issues: Sefanit Mengistu</td>
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<td>- Innovations in Clinical Training: Michelle Meiring</td>
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<tr>
<td>4:45-5:00 p.m.</td>
<td>Audacious Approaches Brainstorm/Future of the Initiative</td>
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<tr>
<td>5:00-5:30 p.m.</td>
<td>Wrap-Up and Closing</td>
</tr>
<tr>
<td></td>
<td>Faith Mwangi-Powell, African Palliative Care Association (APCA)</td>
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</table>
List of Participants

Cary Adams  
Chief Executive Director  
International Union Against Cancer

Will M. Aklin, PhD  
Program Official  
Behavioral and Integrative Treatment Branch  
Division of Clinical Neuroscience and Behavioral Research  
National Institute on Drug Abuse  
National Institutes of Health

René Albertyn, PhD  
Senior Researcher, Pain Management  
Department of Paediatric Surgery  
Red Cross Children’s Hospital  
University of Cape Town

Zipporah M. Ali, MD, MPH, Dip. Palliative Care  
National Coordinator  
Kenya Hospices and Palliative Care Association

Annie Burns  
Partner  
GMMB, Inc.

Scott Burris, JD  
Professor  
Temple University Beasley School of Law  
Principal Investigator  
Drug Control and Access to Medicines Consortium

Mary V. Callaway  
The Open Society Institute International Palliative Care Initiative

David Casarett, MD, MA  
Associate Professor of Medicine  
University of Pennsylvania

Martin D. Cheatle, PhD  
Center for Studies of Addiction  
University of Pennsylvania
James F. Cleary, MD, FAccPM
Associate Professor of Medicine (Medical Oncology)
University of Wisconsin School of Medicine and Public Health
Director, Palliative Care Service
University of Wisconsin Hospital and Clinics
Program Leader, Cancer Control Program
UW Paul P Carbone Comprehensive Cancer Center
Director, UW WHO Collaborating Center for Policy and Communication in Cancer Care

Ari Clowney
Innovations Projects Officer for HIV
Tearfund UK

Stephen R. Connor, PhD
Senior Executive
Worldwide Palliative Care Alliance
Palliative Care Consultant
Open Society Institute
Altarum Institute

Richard C. Denisco, MD, MPH
Medical Officer
Division of Epidemiology, Services and Prevention Research
National Institute on Drug Abuse
National Institutes of Health

Olivia Dix
Head
Palliative Care Initiative
The Diana, Princess of Wales Memorial Fund

Mhlauli William Duma, MB, CHB
Jhpiego/South Africa
Senior Technical Advisor
National Department of Health, South Africa

Jo Ecclestone
Trust Executive
The True Colours Trust

Lynda Erinoff, PhD
Associate Director
AIDS Research Program
National Institute on Drug Abuse
National Institutes of Health

Shaffiq Essajee MD
Director of Clinical Support
Clinton Health Access Initiative
William J. Clinton Foundation
Kathleen M. Foley, MD  
Medical Director  
Open Society Institute International Palliative Care Initiative

Susan Fowler-Kerry PhD  
Director  
RBC Nurses for Kids Program  
College of Nursing  
University of Saskatchewan

Stuart A. Grossman, MD  
Professor of Oncology, Medicine and Neurosurgery  
Director, Cancer Pain Service  
The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins  
The Johns Hopkins University School of Medicine

J. David Haddox, DDS, MD  
Vice President  
Health Policy  
Purdue Pharma LP

Susan Huff, RN, MSN  
Director of Pediatrics at Home  
Johns Hopkins Medicine

Nancy Hutton, MD, FAAP, FAAHPM  
Associate Professor of Pediatrics  
Johns Hopkins University School of Medicine  
Director, Pediatric and Adolescent HIV/AIDS Program  
Medical Director, Harriet Lane Compassionate Care  
Johns Hopkins Hospital Children’s Center

Khaliah A. Johnson, MD  
General Pediatrics  
Johns Hopkins Hospital  
Baltimore, MD

Eric L. Krakauer, MD, PhD  
Assistant Professor of Medicine  
Instructor of Global Health and Social Medicine  
Director of International Programs, Center for Palliative Care  
Harvard Medical School  
Associate Physician, Palliative Care Service  
Massachusetts General Hospital

Carol Langley  
Office of the US Global AIDS Coordinator

David A. Lee, MD, PhD  
Chief Executive Officer  
The LAMB Pain Foundation
Kaia Lenhart
Senior Vice President
GMMB, Inc.

Brent Mancha, PhD
Johns Hopkins Bloomberg School of Public Health

Colin McIff
Office of the US Global AIDS Coordinator

Tanya Medrano
Senior Technical Officer for Vulnerable Children
Family Health International
Co-chair
Orphans and Vulnerable Children (OVC) Task Force

Michelle Meiring, MBChB, FCPaeds, MMED (Paeds)
Paediatric Palliative Care Consultant
Hospice Palliative Care Association of South Africa
University of Cape Town
The Bigshoes Foundation

Sefanit Mengistu Gebreab
Acting Head
Narcotic Drugs and Psychotropic Substances Control and Abuse Prevention Division
Drug Administration and Control Authority of Ethiopia

Ivan Montoya, MD, MPH
Medical Officer
Division of Pharmacotherapies and Medical Consequences of Drug Abuse
National Institute on Drug Abuse
National Institutes of Health

Faith Mwangi-Powell, PhD
Executive Director
African Palliative Care Association

Megan O’Brien, PhD
Research Director
Center for Strategic Health Operations Research
Clinton Health Access Initiative
William J. Clinton Foundation

Gabriela Olivera
Humphrey Fellow 2009-2010 (Fulbright)
Virginia Commonwealth University Humphrey Fellowship Program
Institute for Drug and Alcohol Studies
Coordinator Demand Reduction Area at the National Drug Assembly
Presidency of the Republic of Uruguay.
John G.H. Palen, PhD, MPH, PA
Senior Technical Advisor
HIV/AIDS Care and Support
Co-Chair, PEPFAR Care and Support TWG
US Agency for International Development

Karina Raposelli
US Agency for International Development

Owen Robinson, MPP
Manager of New Initiatives
Clinton Health Access Initiative
William J. Clinton Foundation

Lucy Sainsbury
Trustee
The True Colours Trust

Rebekkah Schear, MIA
Program Manager, Global Mission
Lance Armstrong Foundation

Willem Scholten, PharmD, MPA
Team Leader, Access to Controlled Medicines
Medicine Access and Rational Use
Department of Essential Medicines and Pharmaceutical Policies
World Health Organization

J. Donald Schumacher, PsyD
President and CEO
National Hospice and Palliative Care Organization
National Hospice Foundation
President, Foundation for Hospices in Sub-Saharan Africa

Inder Singh, MBA, MPP, MS
Director of Drug Access
Clinton Health Access Initiative
William J. Clinton Foundation

Zodwa Sithole, BCur
Advocacy Manager
Hospice Palliative Care Association of South Africa

Shelley Smith, MPH
NPI Project Director
Foundation for Hospices in Sub-Saharan Africa (FHSSA)

Karen Stewart, MPH, MT
Health Development Officer
Office of HIV/AIDS
Strategic Planning, Evaluation and Reporting Division
US Agency for International Development
Laura Thomas, BSc, LLB, LLM
Fellow
Health and Human Rights Division
Human Rights Watch

David Thomas, PhD
Program Officer
National Institute on Drug Abuse
National Institutes of Health

Viktoriia Tymoshevskaya, MD, MPH
Public Health Program Director
International Renaissance Foundation

Patricia Ulaya
Acting National Coordinator
Palliative Care Association of Zambia

Joni Waldron
Volunteer
Clinton Health Access Initiative
William J. Clinton Foundation