Building Laboratory Capacity and Teaching Good Clinical Laboratory Practices

Not Just About Condoms and ARVs

An AIDS vaccine remains elusive. Until one is discovered, we treat AIDS patients by using combinations of anti-retroviral (ARV) drugs. Condoms can prevent people from contracting AIDS. ARVs can improve and extend the lives of people with HIV/AIDS. But ARVs are not useful if a patient is not properly diagnosed, or if infecting virus strains have become resistant to current medication. The best way to get to that information is through CD4 testing and monitoring.

CD4 testing quantifies the number of CD4 cells (the T helper cells, which are destroyed by the HIV/AIDS virus) in a patient's blood. This gives us a good measure of how the disease is progressing and assesses immune status. To then understand if and how well the drugs are working, periodic CD4 counts are determined and drug therapy is adjusted accordingly. Additionally, CD4 testing can identify patients who do not need ARVs, which saves money and prevents drug toxicity from affecting a patient adversely. Taking into account product reliability, availability of service, and training, CD4 testing is done most easily and inexpensively with the BD FACSCount flow cytometer. BD is in a very strong position to help with the crises in Africa, Asia and Caribbean, and we have begun.

What We Know

Increasing access—Worldwide, 40,000,000 people live with AIDS. Approximately 10% of those have access to drug testing and therapy. In the short term, BD is working to increase access to current technologies—like safety syringes, blood collection, and CD4 testing—and therapies that are underutilized in the developing world. This is accomplished partly through lowered pricing: our ongoing work with the Clinton Foundation (CF) extends the CD4 pricing agreement to 50 developing countries, where the number of HIV/AIDS-infected individuals is the highest.

Creating infrastructure—The healthcare community understands clearly from previous disasters that sending low-cost materials alone to an area in crisis doesn't do the job. We can't just send cytometers over to Africa with a user's guide and expect lab workers to apply clinical procedures and principles to generate quality test results. Through hands-on field training, we are transferring the knowledge of our associates so our technologies are useful to areas in crisis. Led by Burt Houtz of BD Biosciences and in conjunction with organizations such as the Centers for Disease Control (CDC) and the American Society for Clinical Pathology (ASCP), BD has conducted over 50 Good Laboratory Practice workshops, training over 900 participants in 23 countries on basic quality control and other critical lab procedures. By taking this approach, we build an infrastructure to sustain a long-term fight.

Collaboration—We can't do it on our own as one company. We've already received a tremendous amount of help from CF, the CDC, ASCP, the World Health Organization

(WHO), the African Medical and Research Foundation (AMREF), and others. Collaboration means accountability and increased funding and exposure.

Sustaining effort—This isn't about meeting our quarterly goals. We need to look at this as a long-term business proposal, as well as a necessary and moral response. One of the most difficult challenges is to educate lab workers on the need for good processes. Sustainability of all efforts won't be possible without quality control processes and documentation that focus on testing accuracy and reliability.

Building capacity—Massive numbers of people have died from AIDS. In developing countries, these include lab workers, doctors, nurses, and healthcare workers who haven't been replaced. Even if today, miraculously, there was enough money, drugs, testing equipment, and support, Africa and other developing countries lack the capacity to organize to effectively manage the HIV/AIDS crisis. Building capacity will take massive effort to increase access, create infrastructure, collaborate, and sustain effort.

Tanzania, A Case Study

The prevalence of AIDS in Sub-Saharan Africa is the highest in the world. This area has just over 10% of the world's population, but is home to more than 60% of all people living with HIV. In Dar es Salaam, Tanzania, a recent study of blood banks demonstrated that 40% of blood samples from prospective donors tested positive for HIV. Anti-retroviral drugs have only recently become available in urban centers in Africa.

Burt Houtz, BD Biosciences San Jose, was invited to Bagamoyo, Tanzania, a small town on the Indian Ocean several kilometers north of Dar es Salaam. Historically, it's known as an East African trading center. Burt arrived at dawn to heavy, breezy humidity, and was met by Tom Spira from the Centers of Disease Control and Prevention (CDC), and Candace Golightly from the American Society of Clinical Pathology (ASCP). They were able to meet only two hours to plan for a laboratory training program focusing on CD4 testing and good laboratory practices, to increase the country's capacity to support HIV/AIDS treatment.

The 24 students were trainers themselves, and came from five zones throughout Tanzania. Because of the intense national interest in the workshop, there were nearly as many collaborators represented as students/trainers. The collaborators included:

- World Health Organization (WHO)
- Tanzanian Department of Health Services
- US CDC
- Tanzanian CDC
- ASCP
- BD
- African Medical Research Foundation (AMREF)

These collaborators are the ones who will help spread the education, so their presence was welcome.

That same evening, BD's distributor, Biocare, and others arrived with instruments, training materials, and reagents for testing blood samples. This alone can be an incredible frustration in a poverty-stricken area: getting supplies sent to the right place at the right time. And when the supplies do get to the right place, they can disappear. In some countries, laboratory safety materials such as gloves end up being sold on the street. People are known to sell their own anti-retroviral drugs to buy caskets for their loved ones who have died of AIDS. Poverty creates desperation of proportions we're only just beginning to learn of.

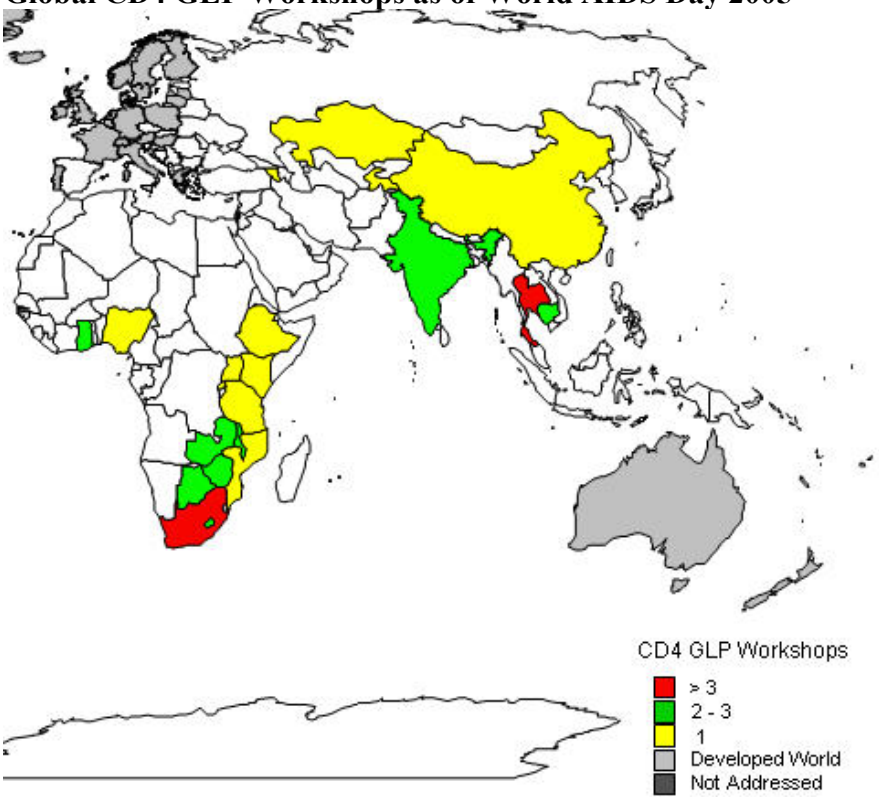
For the next four days, the collaborators worked together on an effective and joyously received workshop. The topics:

- **HIV biology**—the nature of the virus, AIDS as a disease, recommendations for monitoring treatment.
- **immunology and immunophenotyping**—understanding test principles and applying the technology of labeling specific blood cell populations. This is the first part of the test that will enable more effective patient treatment.
- **flow cytometry**—understanding why the BD FACSCount is an important tool. This is the second part of the test, and enables a critical CD4 count.
- **quality assurance**—how do you know when the tests are working? Without quality processes, there is no guarantee of accuracy and we might as well stop now.
- **blood collection and processing**—documentation to ensure proper identification of the patient, clinic, date, time, the blood collection personnel. Important considerations include sample transportation, laboratory receipt of specimens, and storage of blood.
- **laboratory safety**—universal precautions, needle safety, and proper disposal of sharps in specialized sharps waste containers.
- **laboratory management**—procurement, human resources, forecasting, laboratory design and setup, and quality processes.
- **troubleshooting**—this has been the most well-received part of some GLP workshops. Why? There was a desperation that when the workshop ended, these lab workers would be left alone in the field. BD's regional field service does help to provide infrastructure support as well as rapid response times, but it's still new and downtime can be disastrous for patients.

Workshops had been previously delivered on the same topics in other countries by using other resources. These workshops did not have the same benefit of equipment and collaboration. No hands-on, tangible experience. The result was not nearly as positive or effective.

After the Tanzania workshop, following local tradition, a solemn awards ceremony marked the importance of the workshop that had taken place. The participants were rewarded with profound gratitude.

Global CD4 GLP Workshops as of World AIDS Day 2005



Collaborators

- Clinton Foundation
- American Society of Clinical Pathology (ASCP)
- Centers for Disease Control and Prevention (CDC)
- World Health Organization (WHO)
- PharmAccess
- Academic Alliance Foundation
- Pasteur Institute
- Caribbean Epidemiology Centre (CAREC)
- African Medical Research Foundation (AMREF)
- Doctors Without Borders / Medecins Sans Frontieres (MSF)
- National AIDS Control Organization (NACO)
- National Institutes of Health (NIH)
- National Center for HIV/AIDS, Dermatology and STD (NCHADS)
- Ministries of Health

Challenges Ahead

The big challenge is the problem of capacity and resources in the developing world. Improving lab management, lab-worker turnover, and training is happening. Successes are tangible. Today, there are more medicines, more prevention options, more diagnostic equipment and more awareness than ever. It will take more money, greater collaboration, and stronger support from ministries of health in the developing world to make a bigger impact. And BD plans to stay on the battleground. . . making a difference, and keeping the promise.