New Strategies for HIV/AIDS Surveillance in Resource-Constrained Countries



Addis Ababa, Ethiopia
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LIST OF ABBREVIATIONS

AFRO, WHO Regional Office for Africa
ANC, antenatal clinic
ART, antiretroviral therapy
ARV, antiretroviral
ASICAL, *Asociación para la Salúd Integral y Ciudandania de América Latina*
BSS, behavioral surveillance system
CDC, U.S. Centers for Disease Control and Prevention
CI, confidence interval
CSW, commercial sex worker
DHS, Demographic and Health Survey
DSS, Demographic Surveillance Sites
EIA, enzyme immunosorbent assay
EPP, Epidemic Projections Package
FHI, Family Health International
GAP, Global AIDS Program
HAART, highly active antiretroviral therapy
HRSA, U.S. Health Resources and Services Administration
IDU, injection drug user
IUATLD, International Union Against Tuberculosis and Lung Diseases
MSM, men who have sex with men
PCR, polymerase chain reaction
PEPFAR, Presidential Emergency Program for AIDS Relief
PLACE, Priorities for Local AIDS Control Efforts
PMTCT, prevention of mother-to-child transmission
QA, quality assurance
QC, quality control
RDS, respondent-driven sampling
RPR, rapid plasma reagin
STARHS, serological algorithm for recent HIV seroconversion
STI, sexually transmitted infection
TLS, time-location sampling
UNAIDS, Joint United Nations Programme on HIV and AIDS
UNGASS, United Nations General Assembly Special Session
UNICEF, United Nations Children's Fund
USAID, United States Agency for International Development
USD, United States dollars
WHO, World Health Organization

This document provides a summary of the presentations, deliberations of the expert consultations and recommendations that emerged from the conference. It is anticipated that the journal supplement will be published in early 2005. Slides from authors' presentations are available as read-only files at http://www.igh.org.

UPDATES

Update 1. Overview of the History, Current Status and New Approaches for HIV/AIDS Surveillance in Resource-Constrained Settings

Dr. Kevin DeCock from CDC-Kenya provided an overview of the history of public health surveillance for HIV and AIDS and a discussion of the current status of surveillance in generalized epidemics.[1]
Historically HIV and AIDS surveillance began in the United States in 1981. The first case definition of AIDS was "a disease, at least moderately predictive of a defect in cell-mediated immunity, occurring in a person with no known cause for diminished resistance to that disease."[2] While this definition reflects the limited understanding of the disease at that time, it allowed for characterizing affected groups, risk factors and modes of transmission. The AIDS case definition was changed successively in the United States in 1985, 1987 and 1993 to incorporate laboratory testing for HIV and to better capture severe morbidity associated with HIV infection. Other reasons were to simplify reporting, to be consistent with clinical practice and to better reflect the spectrum of HIV disease in minorities, women and injection drug users (IDU).

Following the development of the HIV antibody test, a meeting was held by WHO to develop an AIDS case definition for surveillance in Africa. At that time it was assumed that serological testing would not be possible on a widespread basis, and consequently, a clinical definition was developed. This Bangui case definition for AIDS was proposed in 1985 and required the presence of two major symptoms and one minor one,* which has subsequently been expanded to include additional indicator diseases and HIV antibody testing, when available. The increased availability of HIV testing and the growing recognition of the importance of tuberculosis in AIDS, led to a change in the African case definition in 1994 that included using the Bangui definition in areas without HIV testing and an expanded definition with HIV testing and one indicator condition. However, AIDS case reporting in generalized HIV epidemics suffers from a variety of limitations, including underreporting. Nonetheless, it does have some modest utility, primarily for documenting AIDS in a country or region and providing limited information on demographics and risk groups. In the developed world, the combination of active AIDS case finding, the ability to link registries and the strength of vital statistics systems has allowed monitoring of AIDS-specific mortality. However, weak vital statistics systems in most of the developing world will preclude such linkages.

* Major signs include weight loss greater than 10% of body weight, chronic diarrhea for more than one month and prolonged fever for more than one month. Minor signs include persistent cough, generalized pruritic dermatitis, history of Herpes zoster, oropharyngeal candidiasis, chronic progressive or disseminated Herpes simplex and generalized lymphadenopathy.

To reduce reliance on AIDS incidence as the primary proxy for HIV incidence, the United States instituted a family of unlinked anonymous seroprevalence surveys in 1988 that included patients with sexually transmitted infections (STI), IDUs, women of reproductive age, prisoners, students, military recruits and Job Corps entrants. These surveys had the primary advantage of eliminating non-response bias because participants had leftover serum from syphilis serologies tested anonymously and did not have to consent to testing. WHO issued guidelines on sentinel surveillance in 1990, and since then, unlinked anonymous seroprevalence surveys of women attending sentinel ANCs have become the lynchpin of HIV surveillance in much of the developing world and specifically in countries with generalized epidemics. In addition at various times and in various countries sentinel surveillance has also included blood donors, military recruits and personnel, patients attending STI clinics, commercial sex workers (CSW), tuberculosis patients and hospitalized patients. UNAIDS and WHO have used data from ANC seroprevalence surveys to estimate the prevalence of HIV infection among 15-to-49-year-old adults in countries with generalized epidemics.

Recently, population-based surveys such as the Demographic and Health Survey (DHS) in Kenya, Mali and Zambia, which have included HIV testing (or DHS+), have provided lower estimates of adult prevalence than estimates derived from ANC-based sentinel serosurveillance (Table 1). In Kenya there was close correlation between prevalence in DHS (6.7%) and ANC sentinel surveillance (9.4%), and there were consistent trends in women by urban and rural location. However, the measured male prevalence in DHS (4.5%) was lower than expected with a male-to-female ratio of 1.9:1, resulting in a estimate of 1.0 to 1.8 million infected Kenyans, substantially lower in comparison to earlier ANC-based estimates. However, there were likely problems with response bias as the response rate was only 70%.

Table 1. Adult HIV prevalence estimates derived from DHS, Kenya, Mali and Zambia.

	ANC sentinel surveillance	DHS survey	Difference (%)
Kenya	9.4%	6.7%	-28.7%
Mali	2.1%	1.7%	-19%
Zambia	21.5%	15.6%	-27.4%

Data on AIDS-related mortality have been difficult to obtain in developing countries. There are some "population laboratories" that can provide data on births, deaths, migration and orphans. One site in Asembo, Kenya, has documented life expectancy in men and women and has measured the impact of HIV by tracking the number of orphans. However, in general these data are lacking in Africa.

The expansion of VCT represents a potential additional data set that can be used to estimate adult HIV prevalence. Unfortunately these data are even more biased than ANC sentinel surveillance or population-based surveys with higher prevalence rates largely due to sicker patients seeking diagnosis.

Historically, HIV incidence was estimated from back calculation models derived from AIDS incidence, cohort studies or measurement of seroconversion rates among persons serially tested for HIV. However,

the widespread availability of successful therapy has decoupled the link between incident HIV infection and incident AIDS, severely limiting the utility of AIDS incidence data for modeling. Newer methods, including special studies using CDC's serologic testing algorithm for recent HIV seroconversion (STARHS or "detuned" assay) in 1998,[3] have been used to estimate HIV incidence in limited settings. A key strength of STARHS is that incidence can be calculated from a single specimen. There is hope that the assay will be used to establish incidence estimates, detect foci of ongoing HIV transmission and identify the leading edge of the epidemic. Efforts are underway in the United States to link HIV reporting with STARHS to calculate a national HIV incidence estimate. However, there are technical problems with the detuned assay, including the lack of validation on non-subtype B HIV-1 infections, making it unsuitable at this time for use on a large scale in all parts of the world.

Several recommendations were made:

- Avoid collection of unnecessary data
- Focus on data quality and communication of results
- Use multiple approaches ("triangulation")
- Focus at multiple levels – on HIV infection, advanced HIV disease, death, impact and orphans
- Collect data on HIV testing and care and begin surveillance for ARV resistance
- Use focused behavioral surveillance, for instance, on youth

With regard to seroprevalence surveys:

- Strengthen ANC-based sentinel surveillance
- Invest in population-based HIV surveys
- Develop methods to compare and reconcile the data between the two
- Continue unlinked anonymous testing and explore how high participation in PMTCT programs needs to be for the data to be representatives

With regard to measuring incident infections:

- Conduct serial seroprevalence surveys in young people to get insight on HIV incidence
- Continue efforts to conduct cohort analyses

With regard to measuring burden of disease:

- Use WHO expanded case definition consistently
- Conduct immunologic testing of persons with HIV infection
- Calculate the minimum AIDS incidence and prevalence
- Doing better tuberculosis cases reporting in concert with routine diagnostic HIV testing to provide a method for achieving AIDS case reporting. This is particularly appealing as tuberculosis registries have greater completeness than AIDS registries in Africa and are therefore easier to strengthen.

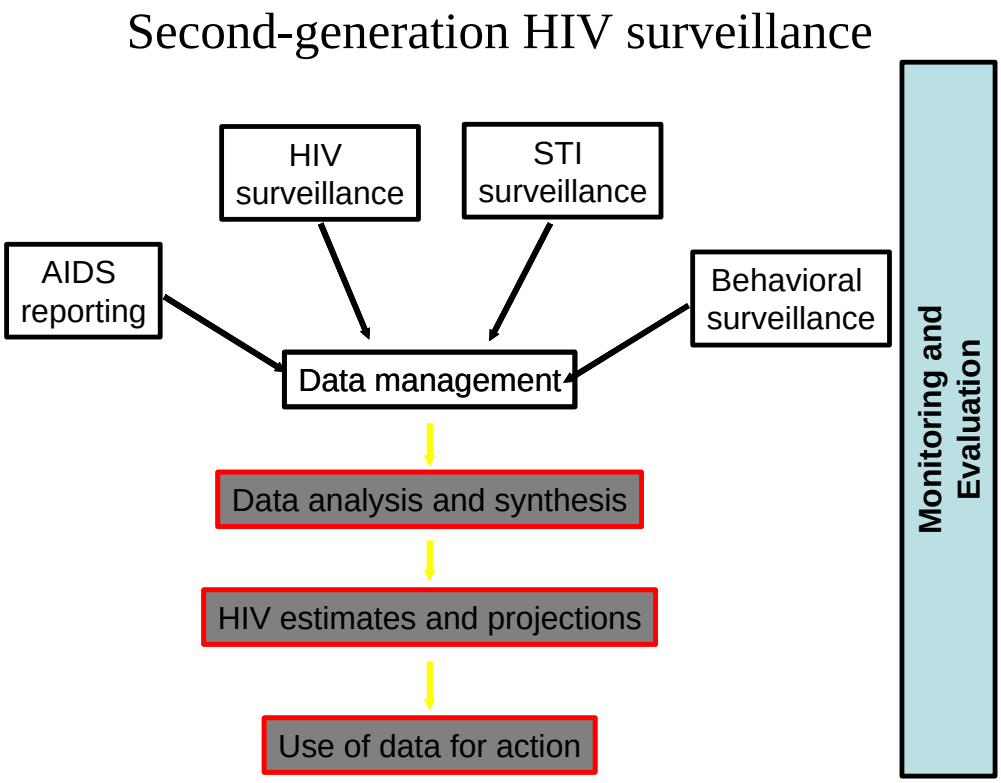
With regard to mortality surveillance:

- Undertake special studies should to assess the rates and proportions of HIV-related deaths. These should include sentinel testing of cadavers for HIV and following cohorts of HIV-treated patients, such as the CDC HIV Outpatient Study (HOPS) in the United States.
- Make additional efforts to monitor pediatric surveillance as a measure of the success of the efforts to prevent mother-to-child transmission.

Although better surveillance data are needed, there is a wealth of data currently that has, unfortunately, not been translated into action. It is important that as HIV surveillance improves to keep in mind the interface between data and policy, particularly prevention policy, and the obligation to use fully the data collected.

Dr. Timothy Brown of the University of Hawai'i East-West Center discussed surveillance in low-level and concentrated epidemics.[4] Surveillance in low-level and concentrated epidemic situations began with the publication of WHO's field guidelines for first-generation surveillance in 1989 and emphasized early warning by measuring the prevalence of HIV infection in key groups and by monitoring trends over time. Second-generation surveillance, begun in 1997, seeks to combine several data streams, including AIDS case surveillance, HIV seroprevalence surveillance, STI surveillance and behavioral surveillance, into a comprehensive data stream (Figure 1). The fundamental idea of second-generation surveillance in low-level and concentrated epidemics is to tailor surveillance to meet the local situation, focusing on locally relevant groups and on new infections and risk behaviors. It stresses the use behavioral data as markers of the future direction of the HIV epidemic that could theoretically allow pre-emptive action to be taken prior to increases in infection. Underpinning the theory of second-generation surveillance is the idea that existing and new epidemiologic and behavioral data will be analyzed in an integrated fashion and lead to a better understanding of the epidemic.

Figure 1. Second-generation surveillance.



However, the reality of how well the goals of second-generation surveillance in low-level and concentrated epidemics have been met is less than ideal. An evaluation team from UNAIDS and WHO in 2000 examined HIV serosurveillance systems in terms of the frequency and timeliness of data collection, the appropriateness of the populations surveyed, the consistency in sites and groups studied and the extent to which relevant adult populations were covered and representative of the risk populations. The evaluation found that serosurveillance systems were fully implemented in 47 of 167 countries, partially implemented in 51, and poorly implemented or not implemented at all in 69.

Similar problems exist with regard to collecting appropriate behavioral data. UNAIDS and WHO are in the process of evaluating behavioral surveillance systems, and preliminary results with reveal serious data gaps in our knowledge of HIV risk behaviors in countries with low-level and concentrated epidemics. While two-thirds of Asian countries have begun behavioral surveillance, only half conduct surveys in MSM or IDU. This is a notable lack given the continuing transmission among IDU and a growing body of evidence of high HIV infection levels among MSM. In Latin America and the Caribbean, where MSM have been heavily affected by HIV, only one-fourth of countries conduct behavioral surveillance in female CSWs, MSM or IDUs. In East Europe and Central Asia, one half of the countries conduct surveillance in CSW and MSM. In North Africa and the Middle East, one half conduct behavioral surveillance in female CSW but only one-quarter in MSM and IDU.

Several notable issues have arisen in behavioral surveillance in low-level and concentrated epidemics. First, access to key populations is limited. One of the most common reasons for a data gap is difficulty inherent in accessing key stigmatized or extra-legal populations such as, MSM, IDU and CSW. In many places the national surveillance system simply does not have access to these populations. Moreover, the representativeness of the current samples, especially when sampled using convenience methods, is questionable. A third major gap is that in virtually every country the size of the key populations — MSM, IDU and CSW — involved in HIV transmission in low-level and concentrated epidemics is unknown. The current numbers have huge errors that lead to substantial uncertainties about estimates, although capture-recapture and multiplier methods have been used effectively in some situations. A related problem is the lack of information on levels of risk in the population at-large. The frequency and extent to which the general adult population comes into contact with these high-risk populations, such as male clients of female CSWs, is unmeasured and unknown even where good behavioral surveillance data exist. Finally, the extent to which these key populations have been reached by prevention programs and what percentage of at-risk persons have been exposed to these programs remain unknown. These data will become increasingly essential.

With regard to integrated analysis of epidemiologic and behavioral data, questions arise regarding the systematic study of new infections,[5] analysis of epidemiologic and behavioral data together, understanding the extent to which behavior is influencing national epidemics and how well we can predict the future of low-level and concentrated epidemics. Integrated analysis is not occurring routinely and is not generally a part national programs in developing countries. Furthermore, data analysis to help understand how behavior is influencing national epidemics and to predict the future of low-level and concentrated epidemics is missing. Measures of the extent to which second-generation surveillance has contributed to appropriate changes in responses suggest that responses in key populations are not improving.

There are a number of reasons for this poor performance and failure to motivate a response in low-level and concentrated epidemics. First, surveillance data which show low levels of HIV infection are unconvincing to decision makers. Also, efforts to demonstrate that there are links between surveillance

and prevention have been inadequate. There are political costs and stigma associated with discussing marginalized populations making it difficult for policymakers to act. There is a general lack of understanding of the epidemiology of HIV in these populations and a sense of waiting for generalized spread before needing to act. Old problems in data quality remain — defining the right populations, sampling in a consistent manner and reporting findings to the central level. Data gaps are significant, and there are still critically important populations with high HIV prevalence that remain outside of surveillance systems.

Although there are serious gaps in current HIV surveillance and continued need for better data analysis, there are new approaches that merit consideration. New tools for measuring HIV incidence, which, once operationalized, will be of value. Use of HAART will affect surveillance, and surveillance will affect the use of HAART. HAART may affect risk behaviors as well. VCT and PMTCT programs are expanding, and techniques for integrating data from these sources should be explored. Finally, as surveillance data are used for purposes beyond what they were designed for, such as for estimations, projections and integrated analyses, gaps in knowledge will be identified that will need to be addressed. So far, there has so far been a general failure to implement surveillance in low-level and concentrated epidemics in the right populations. New approaches and data sources will help, but the fundamental issue remains building the capacity to do better with what data that are already available.

Dr. Asseged Woldu of CDC GAP-Ethiopia presented an overview of the HIV/AIDS epidemic in Ethiopia.[6] Asseged W. HIV/AIDS in Ethiopia. New Strategies for HIV/AIDS Surveillance in Resource-Constrained Countries, Addis Ababa, Ethiopia, 26 January 2004: Update 1.

The Ethiopian surveillance system is based on ANC sentinel surveillance, surveys including the Behavioral Surveillance System (BSS) and military recruits, universal AIDS case reporting and universal STI reporting. The ANC sentinel surveillance system, which started with a few sites in Addis Ababa in 1989, is now up to 67 sites in 2003. In urban areas the prevalence is between 6% and 23%, and in rural areas it is 5% or less. Prevalence is highest among women 15 to 24 years old (12.1%) and declines to 11% among 25-34 year olds and 7.3% among 35-49 year olds. From 2001 data the national prevalence estimate is 6.6% (13.7% urban and 3.7% rural); among military recruits prevalence rates are 7.2% among those from urban areas and 3.8% among those from rural areas with peak prevalence among 25 to 29 year olds.

Overall, there are an estimated 2.2 million people in Ethiopia living with HIV infection, an estimated 219,400 AIDS cases and 1.2 million orphans. Nationally 15,202 AIDS cases have been reported; this represents only 6.9% of the total estimated number of AIDS cases. The peak age of AIDS is among 25-29 year olds, and there have been increases in both HIV-related tuberculosis and non-HIV-related tuberculosis; 51% of all tuberculosis cases are now estimated to be due to HIV infection. An estimated 2.1 million Ethiopians will have died from HIV by the end of 2004 and 3.5 million by 2009. By 2009 the annual number of deaths among 15 to 49 year olds, which would have been 214,000 without HIV, will be 405,000. This will lead to a decrease in life expectancy at birth from 54 years to 45.2 years and 1.7 million orphans.

Discussion

With regard to the general population-based HIV surveys and their relationship to ANC sentinel surveillance, cautions were voiced about how to communicate changing estimates and how results from general population-based surveys still need to be analyzed carefully both by themselves and in an integrated fashion with other data.

Questions were raised about the epidemiologic construct of low-level epidemics (<1% prevalence in ANC populations) implying a relatively minor problem or even a non-problem, and the potential need for a new classification system. The 1% cutoff was felt to be problematic and, since low-level and concentrated epidemics typically involve only a few socially stigmatized groups, make the epidemic easy to ignore politically. Discussants suggested that bringing the high-risk communities themselves into the equation and helping them to "own" the problem is one step. Others are improving communications with the media and policymakers, particularly around the potential for the epidemic to bridge to the general population, and the fact that low-level epidemics do not necessarily stay at low levels. The availability of ARV therapy (ART) will force governments to address these populations, and their decisions will be aided by arguments about the cost-effectiveness of prevention programs. Additionally the importance of detailed epidemiologic analysis of what was happening in high-risk groups was emphasized.

A point was raised about the challenges of pediatric surveillance. Historically the AIDS case definition in children in generalized epidemics has not been sensitive with a lot of overlap between HIV-related and HIV-unrelated clinical syndromes, and for this reason HIV testing will need to be central to any surveillance effort in children.

With regard to the specific case of Ethiopia, the vast underreporting of AIDS cases was discussed. Various reasons were given for underreporting, including patients not accessing health-care institutions, reporting delays and lack of capacity in hospitals for testing needed for diagnosis. Additionally, in response to a specific question, Dr. Asseged responded that there is no evidence of an IDU epidemic in Ethiopia; modes of transmission are predominantly heterosexual intercourse, vertical transmission and parenteral transmission through blood.

Update 2. Ethical Issues in Surveillance

Dr. Michael St. Louis of CDC GAP opened the session with an overview of ethical issues in surveillance for HIV in resource-constrained settings.[7] The context of the HIV surveillance has changed. In this era of increased resources, there is an effort to make HIV testing more routine primarily through "opt-out" consent processes as well as ARV drugs; there is, accordingly, substantially increased political oversight and media interest. There is a general lack of societal consensus on the ethics of unlinked anonymous testing and a shift toward using data obtained from facility-based services (e.g., VCT, PMTCT data). In addition, newer population-based sampling approaches will presumably provide more accurate data than ANC sentinel surveillance. These circumstances lead to four key ethical questions:

- Should ANC sentinel serosurveillance be continued?
- How should we approach HIV testing in general population-based surveys?
- What approaches should be used for outreach for surveillance?
- How should human subjects committees figure into these decisions?

The first issue is whether or not ANC sentinel surveillance should be continued in the era of vastly expanded PMTCT programs and HAART. Since ANC sentinel surveys utilize unlinked anonymous testing, there is no consent and no opportunity for results to be used clinically. Historically the need to understand the epidemiology of HIV infection in countries with generalized epidemics has overshadowed the inability of this ANC-based sentinel surveillance to benefit individual patients. Methodologically, as PMTCT testing coverage increases, there should be a convergence at some point between ANC sentinel surveillance data and PMTCT program data, which would obviate the need for unlinked anonymous testing. However, how much coverage is needed is not yet clear from empirical evidence, and, as PMTCT and VCT become more widespread, it is unclear whether the increased availability of testing will increase or decrease societal concerns regarding the value of unlinked anonymous testing.

Adding HIV testing to general population-based behavioral surveys is another option for obtaining estimates of the prevalence of HIV infection in a country. There are both methodological and ethical issues surrounding this approach as well. For instance, should participants be required to get their test results, and, if they are, how will this affect non-participation bias? If it is an ethical requirement that VCT should be immediately available in areas where the household surveys are being conducted, there is a possibility that resources would have to be redirected posing its own ethical concerns regarding the beneficence of using limited resources to conduct such surveys.

If there is outreach for surveillance, should protocols for the use of the data generated be reviewed by a human subjects committee and should informed consent of those tested be obtained? Standards will need to be developed for referring individuals found to be HIV-infected through these outreach programs to prevention and care services, which in turn will report these patients in their own monitoring data. In the end, this sort of surveillance may be an even more ethical approach than that represented by the research model with informed consent and human subjects committee approval.

With respect to appropriate institutional responses, the role of human subjects committees in approving surveillance activities in general is evolving. CDC's model of "research determination", which classifies public health surveillance activities as either constituting research or public health practice based on a number of criteria, is one model that may be applicable. A basic distinction is that research is designed to produce generalizable knowledge whereas surveillance describes the current status of a disease in a

population. CDC's process of research determination both divides research from public health practice and provides a documentable process to demonstrate that potential ethical concerns in surveillance projects have been addressed; this model may also be appropriate for Africa.

In conclusion the expansion of the global response to AIDS and the expanded surveillance repertoire will prompt new ethical concerns, rekindle old ones and bring new attention to these issues. Attention needs to be paid to emerging ethical concerns proactively, and a documented, institutionalized approach should be used to encourage the development of well-designed, defensible surveillance strategies. In addition, it is important to pay attention to public opinion on ethical issues of research and other interventions at both the national and international levels. Finally some true ethical problems that are usually not discussed and omitted in ethics reviews. These include not publishing data or delaying publication excessively, using data known to be flawed without full disclosure of their limitations, such as poor lab quality or incorrect sampling procedures, allowing or supporting interpretations of data that are known not to be correct and conducting surveillance or surveys that are not really needed.

Professor Ronald Baer of the Columbia University Mailman School of Public Health provided a framework for discussion of surveillance ethics.[8] There is little systematic knowledge of the ethics of surveillance, and there is a false dichotomy between public health research and public health practice, including surveillance. Research, whose goal it is to obtain generalizable information, has an institutional system in place for ethical oversight. However, public health practice does not have an institutional mechanism to assure ethical conduct of surveillance. Although both activities require ethical oversight, the research model is specifically not applicable to surveillance.

The principles of research ethics favor the individual over society by setting guidelines for informed consent and confidentiality. This presumption cannot serve as the ethical foundation for surveillance. The public health practice model has two basic assumptions: that individuals forego or undergo certain things for society's good and that paternalism is a defining value. There is an affirmative duty for health agencies to conduct surveillance as a societal good. The role of ethics in surveillance is to provide shape to the duty to monitor the incidence and prevalence of diseases, to facilitate its control and to place bounds on such efforts. Importantly, social good alone cannot justify violation of human rights.

There are several questions that should be considered in developing ethical standards for surveillance (Table 2). Mandatory case reporting has been an aspect of surveillance in many countries and has served as the primary source of information on the incidence and prevalence of diseases. Case reporting usually requires that health care providers report individually identifying information about their patients to public health registries. The mandatory aspect of reporting means that neither the patient nor health care provider has a choice in reporting. The lack of consent raises questions about the limits of privacy in public health practice. In fact, at times physicians have felt that reporting intrudes on the privacy of their patients, and this has contributed to incomplete reporting.

There are no definitive answers that are universally applicable. Factors that must be considered are the state of the epidemic, the infrastructure, the public health and medical capacity, the availability of resources to manage and secure a disease registry and the political culture. A relevant example comes from the experience in the United States when unlinked anonymous HIV seroprevalence surveys were first implemented. There was an initial consensus that it was ethical because there was a lack of effective treatment for HIV infection and VCT was available so that persons tested through the unlinked surveys could choose to be screened for HIV.

Table 2. Ethical issues in HIV surveillance

1. What role should implicit or explicit individual consent or community approval play in surveillance?
2. How should we think about surveillance activities the involve adolescents or children and the role of their parents?
3. Are there circumstances where the benefits of surveillance justify measures that may intrude upon privacy? How deep may the intrusions be to be acceptable?
4. How are the benefits of surveillance among those at greatest risk balanced against the belief that such efforts will increase societal burden or increase stigmatization among those populations that are already marginalized?
5. How should confidentiality of data be assured and when it cannot be guaranteed, what should the impact on surveillance activities be?
6. How does the prospect of effectively using surveillance data affect the ethics of data acquisition and dissemination?

Privacy was also assured, and the knowledge gained was beneficial. WHO subsequently approved unlinked anonymous surveys in developing countries. Even then, these surveys provoked some controversy, and several developed countries delayed instituting unlinked anonymous surveys.

This paradigm changed with the availability of effective treatment. In 1994 zidovudine was found to reduce the risk of perinatal transmission and, as a result, there was increasing discomfort over testing women and not providing results and treatment that could reduce the risk of acquiring disease. Based on growing ethical concerns, the United States discontinued its survey of childbearing women. Although the United States no longer conducts the survey of childbearing women, funds from the U.S. are used and U.S. agencies have collaborated with developing countries in designing and conducting ANC surveillance. Are ethical standards being applied differently in these situations?

A goal of surveillance is to gather information for public health benefit. When this link is not present, the ethical foundation of surveillance is subverted. Although one cannot always ensure that public health data will lead to increases in services or other direct benefits, there must be, at a minimum, a commitment to use the information to benefit the populations under surveillance including advocacy for vulnerable populations. It must also be noted that release of public health information may cause harm to marginalized populations. This risk should always be considered and balanced against the possible benefits of communicating surveillance findings. Surveillance activities must be done within the context of ethics and standards, and the ethical practice of surveillance must be institutionalized and applied systematically as it has been for research.

Dr. Shabbir Ismail of CDC GAP-Ethiopia discussed the Ethiopian experience with ANC sentinel surveillance and the attendant ethical issues.[9] Ethiopia uses ANC sentinel surveillance, universal AIDS case reporting and routine syphilis screening among pregnant women as its three sources of HIV/AIDS surveillance information. The backbone of the system is ANC sentinel surveillance, which is conducted at 77 sites through the nation and utilizes unlinked anonymous testing of serum samples left over from prenatal syphilis screening. Specimens in most ANC sites are tested at locations other than where they are drawn, and ANC staff does not receive information on the HIV test results.

Ethical concerns have focused around operational issues including anonymity, lack of linking results and patients and confidentiality. National guidelines for ANC surveillance have been developed and these address ethical issues. Training of regional staff has been done, and after they completed the training, they then trained the onsite staff on the appropriate procedures and ethics of ANC surveillance. Field observations have noted some areas of ethical concern. For example, most site staff consider ANC surveillance to be research and, therefore, think that consent should be obtained. In some areas syphilis screening is done only during the months when HIV sentinel surveillance is carried out and has caused anxiety in women at some of the sites. ANC codes have been found on both specimen tubes, which indicates that the specimens were linked, and at some centers there were backlogs of data to be entered.

Suggestions to improve the ethical conduct of unlinked anonymous testing included:

- Developing clear national operational guidelines that address ethical issues
- Ensuring strict adherence to the guidelines
- Well designed training for federal and regional coordinators and for surveillance site staff
- Providing close supervision at all levels
- Monitoring of client and data flow by site coordinators to identify and prevent break downs in procedures that protect anonymity
- Separating sample collection and testing geographically
- Regular and frequent review of all procedures at each site
- Orienting of other non-surveillance health care workers at the site
- Maximizing efforts to maintain confidentiality
- Offering confidential VCT and PMTCT services available on site

Discussion

The subsequent discussion focused on the evolving ethical standards for unlinked anonymous testing of pregnant women in ANC sentinel serosurveillance systems. There was a general consensus for strongly articulating the centrality of the ANC sentinel surveillance system to HIV surveillance and the clearer linking of surveillance activities to intervention activities. One point of discussion was that efforts to offer VCT and/or PMTCT at ANC surveillance sites may create a situation in which surveillance needs are driving programs. In resource-constrained areas, should the presence of an ANC surveillance site be the sole justification for offering VCT or PMTCT programs, or should other criteria be used to determine where these program services should be instituted?

The extent to which these issues represented American standards (the term "ethical imperialism" was used in a subsequent summary) and how much of it represented a problem perceived by African nations was also discussed. The consensus was that there was an affirmative duty to conduct surveillance. One discussant suggested that data are becoming available from PMTCT sites that can be compared with ANC sentinel surveillance data to provide an empirical basis for weighing the necessity of unlinked anonymous testing. He also suggested that we have underestimated the importance of ANC sentinel surveillance data, as evidenced by the role of these data in decisions leading up to the U.S. Presidential Emergency Plan for AIDS Relief (PEPFAR).

A separate point of discussion was the failure to use data collected for surveillance purposes. This failure was viewed in the words of one discussant as a "rupture of the ethical underpinnings of surveillance", and there was general consensus that it was unethical to conduct surveillance and not use the data.

Update 3. Quality Assurance with HIV Testing Technologies

Dr. Robert Martin of CDC provided an overview of quality assurance (QA) and HIV testing and suggested recommendations for the implementation of QA especially with regard to GAP.[10] The opportunity to focus on quality exists because of the need for credible results and because funding QA is no longer viewed as a cost but as an investment in building a lasting infrastructure for all laboratories to respond to new health threats. Examples of lab quality initiatives in several countries were provided. At the Government Hospital for Thoracic Medicine in Tamil Nadu, India, steps have been taken to institute a number of improvements in patient care and surveillance, build a new laboratory facility, identify a QA officer and conduct a week-long QA workshop at the hospital. In Cambodia the first QA assessment was conducted in April 2003, and a national meeting of laboratory directors in all Cambodian provinces was subsequently held to develop a national laboratory network and a national QA program and to address communication issues among laboratories. In Ethiopia steps are being taken to develop a laboratory at the Ethiopian Health and Nutrition Research Institute, identify a QA officer for the laboratory and implement QA activities. The first national conference for all laboratories in Ethiopia was recently held to discuss a national QA program.

One of the first steps to assure quality in laboratory practice is to conduct an assessment of laboratory systems within each country. Within the CDC GAP country support system, there is an ongoing joint program of CDC, the United States Association of Public Health Laboratories, the Australian National Reference Laboratory and ministries of health to assess the laboratory system in each country. Following the assessment, steps typically involve the determination of three or four initiatives that will begin the process of improvement and outlining discrete and practical next steps. Under the systems approach to quality, the goals are to ensure the quality of the overall process, to detect and reduce errors, to improve consistency within and between laboratories and to contain costs.

QA is part of a larger quality systems approach that includes both quality control (QC) and QA. The overall quality system involves 12 components (information management, organization, personnel, equipment, purchasing and inventory, process control, documents and records, occurrence management, assessment, process improvement, customer service and facilities and safety). Process control includes validation and QC. Quality management incorporates all activities in an overall management function that determine quality policy objectives and implementation through activities such as quality planning, QC, QA and quality improvement within the system. QA refers to planned and systematic activities to provide adequate confidence that requirements of quality will be met and includes internal QC, proficiency testing, test standardization, training, competency evaluation, equipment maintenance, pre-post analytic phase, management and organization. QC is the set of procedures for continually assessing laboratory work and the emergent results. The key steps in developing a quality systems initiative are to develop a framework for common approach, develop training materials and conduct workshops that present the framework, provide information and training and encourage the development and implementation of a national quality systems plan.

Barriers to quality often include a lack of understanding of and commitment to QA, inappropriate staff, lack of training programs and the absence of appropriate leadership at each management or control level. Embracing the quality system concept, providing assistance in the development of national quality systems, providing training and training materials for local use and providing long-term technical support for quality system development and implementation are CDC GAP priorities.

Dr. Mark Rayfield, also of CDC, provided an overview of QA with various HIV testing technologies, and how to integrate them in algorithms that provide good testing data for surveillance.[11] Key elements to designing a testing strategy to support surveillance in country include an assessment of tests currently used in country, choosing the right tool and recognizing that specimens are central to the entire process. The testing environment used thus far in most surveillance approaches employs centralized testing, which has the advantages of ease of management, QA, ability to apply advanced technologies, efficiency of scale and ease of data management. However, this approach limits the dissemination of technologies within country and tends to overemphasize the logistics of getting an optimal-quality specimen to a central lab in a limited time frame. Decentralized testing, on the other hand, offers the opportunity to disseminate technologies across countries, allows for local involvement and consensus building around methods being used by laboratories and allows for improved, integrated surveillance systems. However, decentralized testing requires an expanded QA effort, and there is a need for improved data management and logistical support and heightened concerns for confidentiality (Table 3). Most GAP countries rely on central laboratories, which often have the disadvantage of a weak national reference laboratory, poor resources, an aging professional staff, weak QA at the national level, poorly integrated services and limited data exchange. QA and QC issues that still need to be considered include developing a standardized method of specimen collection and transport, establishing standard operation procedures, deciding personnel qualifications, designing proficiency testing programs, procurement and management of instruments and reagents, record keeping and reporting and conducting pre- and post-analytic checks. While QA and QC are being standardized throughout GAP countries, expansion of testing has created the possibility for increased decentralized testing. With the expansion of decentralized testing, there needs to be an assessment of needs and capabilities at each site, development of site-specific protocols and consideration of alternative testing formats, such as rapid tests and the use of dried blood spots.

Table 3. Issues in centralized and decentralized testing.

Centralized testing – advantages	**Decentralized testing – advantages**
Ease of management and QA	Local involvement and consensus building
Advanced technologies	Improved integrated surveillance systems
Efficiency of scale	Need for improved data management and logistical support
	Disseminated technologies
Ease of data management	Expanded QA effort
Centralized testing – disadvantages	**Decentralized testing – disadvantages**
Limited dissemination of technologies	Confidentiality with positive tests
Huge premium on specimen transport	

Table 4. Rapid test formats and commercially available products.

Format	Commercial test kit	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Agglutination device	Capillus HIV 1/2®	98.9%	99.7%	99.4%	99.4%
Lateral flow (dip stick)	Determine®	99.4%-100%	99.6%-99.8%	97.9%-99.7%	99.7%-100%
	HemaStrip®	100%	100%	100%	100%
	Determine® and HemaStrip® combined	100%	100%	100%	100%

There are several different algorithms that can be employed in surveillance. The first is either single or multiple enzyme immunosorbent assays (EIA), which provide for optimal sensitivity and specificity. The need for and choice of a confirmatory test is dependent on prevalence of disease and sensitivity and specificity of screening tests. A second option involves multiple simple or rapid tests, which have the disadvantage of losing the efficiency of scale provided by a centralized laboratory but have the distinct advantage of being able to expand access to VCT and PMTCT programs. Third is a combination of EIAs and rapid tests, either using rapid tests as the first test and EIAs as the confirmatory test in decentralized settings or using EIAs as the first test and rapid tests as the confirmatory tests in centralized settings. Examination of these algorithms is ongoing and results are expected within one year. An important consideration is that time needs to be allotted for establishing the quality of the tests in country, development of algorithms incorporating the test, pilot testing the algorithms and then nationalizing the process.

With regard to simple rapid tests, there are three formats — flow-through devices, agglutination devices and lateral flow devices (Table 4). Agglutination devices include Recombigen®, Serodia®, Capillus® and Simpli-Red®. Commercially available lateral flow devices include Unigold®, HemaStrip®, Determine® and OraQuick®. All perform reasonably well in the field with high sensitivities, specificities and predictive values.

Dried blood spots can be used as a specimen collection format. They have been integrated into a number of countries in the context of external QA of test performance at remote sites. The samples are stable, and there is substantial interesting in pursuing dried blood spot methodology. However, several steps are needed before considering implementation at the national level, including standardized training, standardized elution protocols, development of transport controls and internal assay controls and optimization of standard EIAs using dried blood spots. Future directions in alternative technologies include incidence assays with both dried blood spots and rapid tests, oral fluids and using dried blood spots for infant polymerase chain reaction (PCR) assays, ARV resistance testing and HIV genotyping.

Two speakers, Dr. Achara Teeraratkul from CDC GAP-Thailand and the Thai Ministry of Public Health, and Dr. Eugénie Kayirangwa of the Rwandan Treatment and Research AIDS Center and Family Health International (FHI)/IMPACT, provided updates from the field regarding HIV testing.[12],[13] In Thailand surveillance systems include AIDS and symptomatic HIV surveillance, HIV serosurveillance, behavioral surveillance and perinatal HIV outcome monitoring. The development of laboratory QA for HIV testing has included guidelines and training, test kit evaluation and external and internal QA. HIV test kits in Thailand are required to have a sensitivity greater than 99.5% and a specificity greater than 98% for licensure. Additional steps for licensure include reviewing manufacturers' documents, laboratory evaluation and clinical evaluation.

Routine external quality assessments involve 994 laboratories, 80% of which are government laboratories. The network for external quality begins with four regional reference centers, which conduct assessment of local laboratories. The Thai National Institute of Health conducts assessment of the four regional reference centers and provides technical support to improve laboratory performance. External QA methods also include proficiency testing using serum specimens from blood donors, HIV-infected and non-infected persons. Each reference center receives and tests the samples, assesses the ability of blood samples and reports results to the Thai National Institute of Health laboratories. Internal QC involves the national reference centers providing well-identified samples and daily testing assessment.

The success of the Thai program was attributed to having guidelines for testing and standard operating procedures, adequate financial resources, appropriate facilities, adequate human resources, educational and supervisory support and linkage to international organizations. The national laboratory QA program has benefited patients by providing them with reliable diagnoses and has benefitted diagnostic laboratories through improvement of overall laboratory performance. The national QA program has improved public health programs by supporting reliable nationwide surveillance. Manufacturers have benefitted from the program by being able to use the information from laboratories to determine batch-to-batch variation. Challenges to the program include increasing knowledge and understanding of lab QA among participants, increasing coverage of participants, expanding follow-up activities to identify ways to correct for errors, obtaining more government financial support and commitment for sustainability and government reform. Government reform includes improvement in such issues as decentralization of administration, government freeze on manpower and a limited number of qualified supervisory personnel. In summary, reliable and reproducible HIV testing is an important component of HIV serosurveillance. Thus, laboratory QA is similarly important, and sustainability of the program requires strong support from local authorities and international alliances.

In Rwanda, external and internal QC is conducted through the coordination of the Treatment and Research AIDS Center, the National Reference Laboratory, district level centers and sentinel sites at the local level. Parameters of good quality include coordination, supervision, data management and laboratory QA. The Treatment and Research AIDS Center is generally responsible for coordination and supervision of district level centers and for data management. The National Reference Laboratory coordinates the sentinel sites to record and store the samples and to test for HIV. Each of the sentinel sites is responsible for collecting, labeling, storing and sending samples to National Reference Laboratory to be tested for HIV.

Internal QC in Rwanda is achieved through several mechanisms: samples of known serostatus in addition to the manufacturer's controls are incorporated onto each plate, 10% of samples negative on screening with the Vironostika EIA are tested with a confirmatory test (Murex) and maintenance of the equipment

and calibration of pipettes are regularly performed. For external QA, 5% of the negative sera and 50% of the positive sera are sent to the external accredited CDC-Ugandan Viral Research Institute in Entebbe, Uganda, 10% of negative and all positive syphilis serologies are retested at the National Reference Laboratory and the National Reference Laboratory receives lyophilized samples of WHO external QA serology three times per year. When discrepancies occur, they are usually due to bacterial contamination, poor storage of sera and reagents, poor distribution of antigens and late reading of results; however, resolving discrepancies is usually accomplished through formative supervision, training and rotating the personnel. These QA methods in Rwanda have accounted for the 100% concordance with the WHO external QC serology.

Update 4. Informatics

Dr. Meade Morgan of CDC-Atlanta discussed the use of information systems to support HIV surveillance.[14] Information systems are defined as the organizational framework and technical infrastructure for collecting and managing data and for turning data into information that is used productively. Several examples of information systems that support HIV programs can be found in Table 5.

The key issue for HIV information systems is to build national health informatics infrastructure balancing the need to meet short-term data and reporting requirements with the long-term need to build sustainable health management systems. At least for now the primary emphasis is on short-term solutions. The types of data that need to be reported are threefold:

- In the short term, aggregate monthly or quarterly statistics on adverse health outcomes with paper-based systems at the clinic level and computerization at the district, regional hospital or national level
- In the medium term, yearly or less frequent surveys with computerization capacity resting with the implementing organization
- In the long term, clinical records that are needed immediately to weekly and involve simple forms or computerization at the clinic level

The bottom line is that the HIV pandemic demands a rapid response. Short-term solutions should be implemented first but, to the extent possible, should strengthen the national health information system.

There are several potential strategies to meet both short and longer needs at the same time. First, information technology capacity can use existing health informatics systems, such as WHO Regional Office for Africa's (AFRO) integrated disease surveillance system). Secondly, human resources should be strengthened by building a culture, through training, that understands and appreciates the utility of health information. To the greatest extent possible the emphasis should be on building a general-purpose, rather than vertical, infrastructure. Using, for example, cellular networks or the Internet for communication and standardized tools, such as EpiInfo or Health Mapper, whenever possible makes the information technology system more adaptable to other diseases and other situations. Finally, applying standards in data collection and analysis is key. This includes integrating logbooks, reporting forms, software and security across the entire surveillance system. A number of other key issues must be borne in mind as well. The design and construction of a health information system should be able to support longitudinal care records, such as electronic medical records, facilitate inter- and intrasite program

Table 5. Examples of information systems supporting HIV programs.

Pharmacy management
Laboratory management information
Logistics/supply chain management
Program monitoring
Targeted program evaluation
Facility-based patient information systems ✓
National notifiable disease reporting systems ✓
Vital Statistics registries ✓
Facility-based surveys (e.g. ANC clinics) ✓
Population-based surveys ✓

✓ Indicates part of surveillance system or used by surveillance system

communication thus ensuring referral linkages from the facility to the field and back and to transmit the data needed for the monitoring and evaluation system once there is consensus on indicators. Throughout these efforts the emphasis should be on practical use of innovative technology.

There are a series of principles for information systems. First there is a need to identify stakeholders' needs and to build their buy in. Once identified their needs must be understood, and throughout the design phase their input and that of the end-users need to be obtained because the quality of the data in the system will in the end be a function of how useful the users think the data are. Finally the design team needs to be sure that adequate staff is allocated for data systems from data collection all the way through to analysis and use. There are similar needs for adequate training and human resources. A central tenet of his design principles is the data retrieval and analysis should drive data entry, that is, using the data regularly should reinforce the need for careful data entry rather than careful data entry being a disembodied activity for its own sake. Standards should be incorporated where feasible, and building out existing solutions rather than creating them de novo should be considered. Maintainability and extendibility are key principles when designing information systems.

There are three noteworthy existing systems that are being used – the Routine Health Information Network (RHINO), the WHO's Health Metrics Network and UNAIDS' Country Response Information System (CRIS)* -- which are ongoing efforts to improve the quality of data gathered in resource-constrained settings. Among efforts to improve HIV surveillance data specifically were the Epidemic Projections Package (EPP) for generalized epidemics from WHO, UNAIDS' Workbooks for estimating prevalence in concentrated and low-level epidemics, Tulane University's SPECTRUM for demographic projections and GOALS for resource allocation and the U.S. Bureau of the Census's data base on HIV surveillance data. There are also other valuable adjuncts, such as WHO's Health Mapper and CDC's EpiInfo.

* RHINO: http://www.cpc.unc.edu/measure/rhino
Health Metrics Network: http://www.who.int/mip/2003/other_documents/en/health_metrics-boerma.pdf
CRIS: http://www.unaids.org/en/in+focus/monitoringevaulation/country+response+information+system.asp

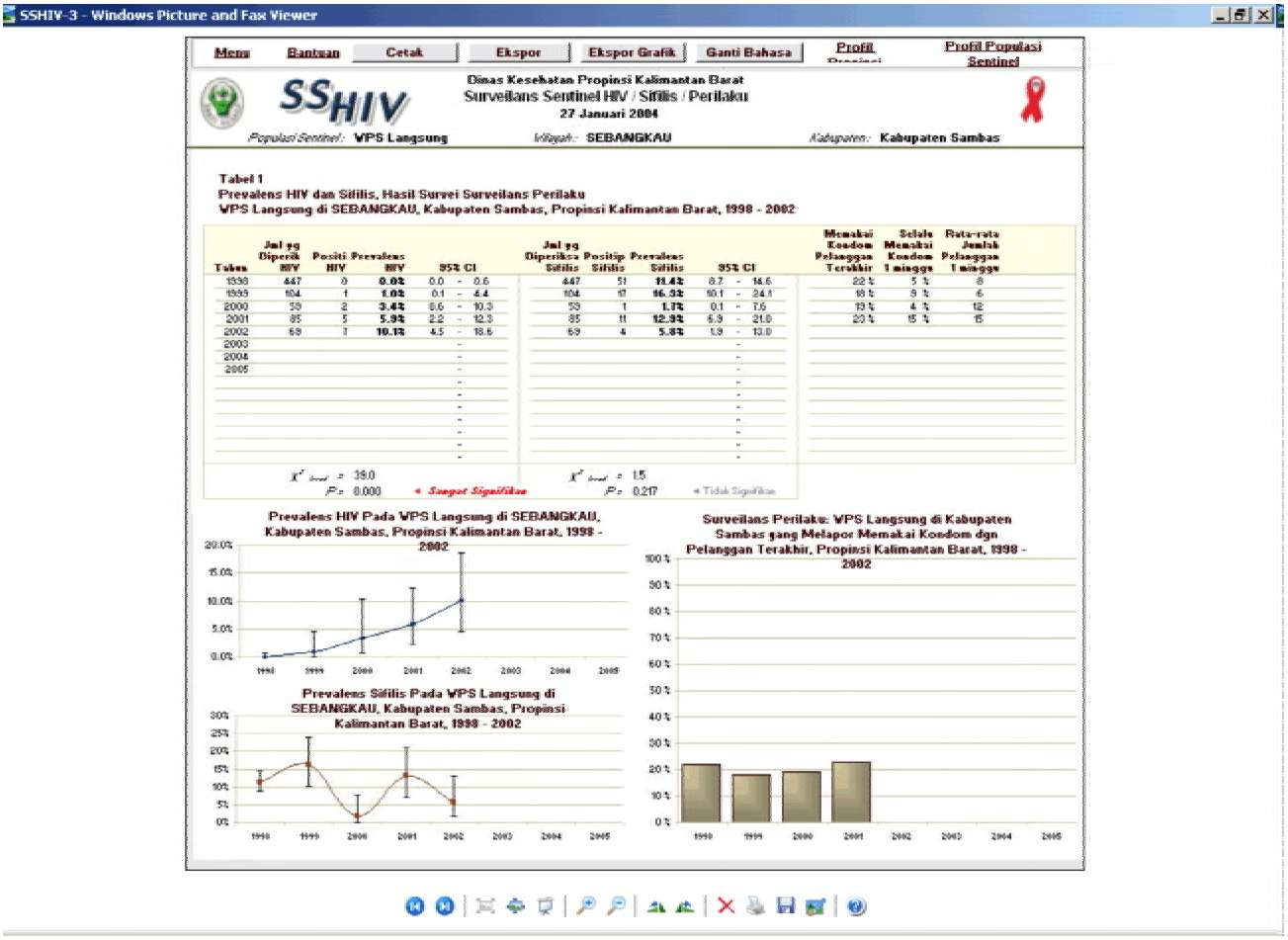
Several informatics activities will be supported by PEPFAR. USAID, CDC, the Health Resources and Services Administration (HRSA) and John Snow International have written a concept paper on strengthening national health information systems. Site teams will be visiting PEPFAR countries to review existing information technology strategies and to recommend future directions and activities.

Within CDC GAP there are an informatics team consisting of systems analysts, programmers and statisticians and a handful of in-country informatics units in Botswana, Thailand, Uganda and Zimbabwe. There are several information system resources that GAP has supported, including a concept paper on facility-based patient information system, an inventory of HIV care and treatment information systems, a list of core data elements for patient and clinic management of ARV programs and databases built in EpiInfo to support PMTCT programs, ARV care and general program management. CDC has also developed software packages, including EpiInfo, which is for database management and analysis of epidemiologic data; EZ-Text, which allows analysis of structured qualitative data; AnSWR, which allows analysis of unstructured qualitative data; and patient-flow analysis, which provides time-process analysis to improve clinic management of patient flow. EpiInfo is the jewel in the crown. It is free-ware and downloadable; is designed for health information; allows form creation, data entry, analysis and report generation including mapping; has training materials and user support; has a large user population and existing applications for problem solving; involves low effort and fast start-up and is consistent with WHO AFRO's integrated disease surveillance system.

Ms. Elizabeth Pisani of Family Health International described the Indonesian experience with health informatics.[15] In Indonesia, the development of a new data management system was driven by the chaotic decentralization of public health functions, including HIV control programs. There was no secure funding for surveillance, a poor understanding of data quality, poor interpretation of data, no data transfer, no institutional memory leading to loss of data trends, no use of data at any level and no training at the district level where all decisions had to be made. To meet this challenge a group from the Ministry of Health, AusAID, the Macfarlane Burnet Institute and Family Health International developed the SSHIV software to both control and drive data quality. Its purposes were to increase data reporting from both HIV serosurveillance and behavioral surveillance, impose limits on data (e.g., sites, populations, sample sizes), encourage compliance with existing testing protocols, identify a minimal national system and to provide opportunities for widespread training on fundamental principles of surveillance to those who were actually doing the surveillance activities. SSHIV has a number of important design features, such as automatic back up, extensive help files, logic checks and warnings and exportability to Excel and .dbf formats, and reporting-generating capacities including reports in nationally standardized formats, reports on international indicators such as the United Nations General Assembly Special Session (UNGASS) indicators and reports in Indonesian and English. An example of an SSHIV screen is shown in Figure 2. SSHIV allows some flexibility to meet local district-level needs but is not so flexible that central control of core data elements can be lost.

Ms. Kimberly Marsh of CDC described CDC's new training module on electronic data management and analysis for HIV sentinel surveillance.[16] WHO and CDC guidelines have both recommended specific approaches for collecting, managing and analyzing data, but there is a limited capacity at country level for implementing best practices and using computing tools and a critical need for high quality HIV sentinel surveillance data. To meet this need, CDC developed a computer-based course in 2002 and 2003. The course objectives were to introduce best practices for systematically collecting, managing, processing and reporting survey data and to use EpiInfo for Windows 2002 for forms, analysis, statistics, maps and graphics. The course is intended for epidemiologists and statisticians, last 3.5 to 5

Figure 2. SSHIV spreadsheet screen, Indonesia.



days, utilizes a case-based approach and focuses at least initially on HIV sentinel surveillance in generalized epidemics using three years of ANC data from a fictitious country. The course content is shown in Table 6. Future plans include modifying the course to a train-the-trainers format and to develop modules for concentrated epidemics, behavioral data and other circumstances.

Dr. Shabbir Ismail of CDC GAP-Ethiopia spoke about piloting the CDC training course in Ethiopia.[17] The objectives of the course were to teach students to design data collection and entry forms, design data entry screens, develop check codes, conduct basic descriptive analyses and generate regional and national reports. Potential participants were selected from the Ministry of Health and regions and then chosen on the basis of basic computing skills, prior training in epidemiology and statistics, work with HIV/AIDS-related data and willingness and readiness to process local surveillance data and on a recommendation from the regional health bureaus. The 30 participants included regional surveillance coordinators (physicians, health officers and nurses) and statisticians and came from the Ministry of Health, regional health bureaus, Addis Ababa University and CDC GAP-Ethiopia.

The training extended over five days and emphasized hands-on training; each participant had a personal computer. Course elements included an orientation to EpiInfo 2002, developing data collection forms, creating data entry screens with Make View, writing check codes, single and double data entry, simple

Table 6. Content of CDC training module on electronic data management and analysis.

Designing easy-to-use data collection and electronic data entry forms
Developing simple and complex check code to validate data entry
Overseeing and performing data entry
Developing and documenting data cleaning and database storage strategies
Conducting simple exploratory analysis for data cleaning purposes
Performing simple and complex descriptive analysis
Developing clear and concise national and regional reports

data analysis, reporting writing and mapping. Future plans will involve providing students personal computers with EpiInfo 2002 already installed to take back home with them, to encourage the use of the system to process local data for the 2003 sentinel surveillance round and routine morbidity data, to provide training courses to other regions, to provide refresher courses and to initiate electronic data processing, transfer and feedback at the local level.

Update 5. State-of-the-Art Sampling for Hidden Populations: Time-Location and Respondent-Driven Sampling

Dr. Tobi Saidel provided an overview of the limitations of conventional probability sampling methods for hidden populations, described two main alternative strategies (time-location sampling [TLS] and respondent-driven sampling [RDS]) and answered questions.[18] Methods exist for conducting high-quality surveys with high-risk and hidden populations; however, there is insufficient capacity to conduct these surveys on a consistent basis. "Hidden" populations are populations with high-risk behaviors for whom no sampling frame exists and who, because their behaviors may not be socially sanctioned, are often reluctant to have their identities known. The most common examples of hidden populations include CSWs, IDUs, MSM and migrants. For these populations, conventional household cluster sampling methods are typically inadequate because of the small sample size of the "hidden" populations, respondents' potential reluctance to reveal non-sanctioned behavior and the lack of stable presence of relevant populations in households. Additionally institutional settings, such as schools and factories, where conventional cluster sampling can be done, are unlikely to have sufficient representation from these populations to make sampling in these types of venues a feasible option. To address these problems, TLS and RDS have recently been developed for probability sampling of "hidden" populations.

Methodologically, TLS relies on clusters of potential participants defined by a time and location dimension, for instance, areas where CSW congregate during evening hours. A random sample of potential clusters (e.g., two-hour time intervals from 7:00 PM to 11 P.M. in each of the areas for seven nights per week) is chosen, and all or a part of the sample in that time-location cluster is interviewed. Since in most cases the absolute size of the population being sampled is not fixed, selecting samples with probability-proportion-to-size methods should be avoided. The first-stage sample consists of a simple random sample or a systematic random sample of the time-location clusters. The second-stage sample consists of all potential respondents or simple random sample of eligible participants who are physically in the location during the time interval chosen. The length of the time interval depends on the expected volume of contacts at the site. These should be the same in all locations; if different time intervals are chosen for different sites, the data need to be weighted to create a composite estimate.

The strength of TLS is that it extends probability-sampling methods to "hidden" populations that congregate in accessible places. However, its limitations are that it reaches only the most visible subset of these high-risk populations, it requires high quality mapping, it can be difficult to ensure the randomness of the second-stage sample and repeat attendees at the same or multiple sites may interfere with the randomness of the method. This method has been used in Bangladesh to sample IDUs, MSM, male and female CSW, long-distance truck drivers and rickshaw drivers; in Cambodia to sample MSM; in India to sample MSM, female CSW and taxi drivers; and in Laos to sample female CSW and truck drivers.

RDS, the other strategy discussed, in principle improves on TLS. RDS is essentially chain-referral sampling that starts with a set of "seeds" or members of a "hidden" population purposely chosen based on an understanding of the target population's network. It attempts to overcome lack of a sampling frame by using these seeds to recruit no more than three new participants from his or her network. A system of dual incentives is used to encourage participation, and recruitment waves continue until the sample size is reached. This method produces asymptotically unbiased population estimates, as measured by the ratio of Horvitz-Thompson estimators,[19] and its primary strength is are its ease of access to hidden populations.

The most commonly used form of chain-referral sampling is snowball sampling. Although this method can be used to access hidden populations and is easily implemented, it has several limitations. These are that the final sample depends heavily on the set of seeds chosen (since seeds with large personal networks can dominate the sample), parts of the chain can be masked if seeds are reluctant to reveal the identity of their contacts, contact information of new participants may be of poor quality and, in essence, this method results in a non-probability convenience sample. RDS, although similar to snowball sampling, has several mechanisms built in to overcome the limitations of regular snowball sampling. RDS limits the number of recruits per recruiter to a maximum of three, which encourages a longer referral chain by minimizing the ability of a person with large personal networks to dominate the sample. Given a long referral chain, usually three to six waves of recruitment, the composition of the sample will stabilize regardless of the initial seeds. That is, composition of the sample will not change significantly after a certain number of waves of recruitment. In general, the greater the homophily – the likelihood of a participant recruiting others similar to himself or herself – the greater the number of waves that will be needed to reach equilibrium. This convergence around the population parameters is consistent with Markov chain theory. RDS utilizes several population parameter estimates to compensate for undue influence of the initial seeds and dampens the effect of the size of personal networks.

There are also several unanswered questions about RDS as it applies to HIV/AIDS surveys. First, how do we view the epidemiological importance of different subgroups within a "hidden" population? Is the more visible subset, for instance, MSM who congregate in bars, at higher risk of transmitting and acquiring infection than those who are more hidden? Secondly, can RDS produce a nationally representative sample, or is it only useful in smaller geographical settings? Thirdly, there are a series of questions that involve field operations. How well will RDS work outside the United States? Although formative research is not theoretically necessary, it will likely be necessary in some situations to pick the best initial seeds. If formative research becomes necessary, will RDS actually be less expensive than TLS? How well will it work in situations where the behavior in question is highly stigmatized or socially repressed? There is some experience with RDS outside the United States, for instance, in sampling IDU in Nepal, attempting implementation among female CSW in East Timor and among IDU in Georgia, and a number of other studies are being planned.

Discussion

The discussion session provided clarification of some of the methodological issues raised. In response to a question of how RDS is used to estimate population sizes, RDS by itself does not give population size estimates; however, it could either be used as a multiplier or as one arm of a capture-recapture study. Regarding monetary incentives in areas where exchange of money is considered culturally inappropriate, there has not been a lot of experience to date but using non-monetary gifts as incentives may work, although more research is necessary to determine appropriate incentives. Another question asked about the need to conduct separate, intensive studies that define hidden populations in order to describe the homophily of the population; experience and prior knowledge of the population are necessary and that data can be analyzed along the way.

Where and when are these newer methods necessary? They are, after all, difficult to implement in the field, and getting the incentives right is thorny. How much prevention should be delivered along with surveillance, and, if these methods are used to uncover hidden populations for service delivery, how useful will the surveillance data be? RDS adapted for prevention should probably be used only when no other methods are available, and initial prevention efforts should concentrate on the most visible segments of the "hidden" population where most of the risk likely occurs, although there is no empirical basis for this assumption. The experience in Indonesia when using RDS for delivering prevention messages was that the investigators were overwhelmed with participants, which caused a strain on minimally available resources, services, and staff.

Another possibility is a hybrid methodology, using RDS for initial assessment and epidemiologic mapping and then switching to TLS or venue-based methods for repeated measures. However, creating a distinction between the use of these methods for surveillance and the use of them for delivering prevention services is artificial and may be short sighted. Capture-recapture has been used successfully in Brazil to estimate size of HIV-infected population and size of population of persons living with AIDS, and there are plans to use this method for estimating the population sizes of MSM and IDU. RDS had also been used in Brazil for estimating HIV prevalence among IDU and for understanding their counseling, testing, care and treatment needs.

Do national AIDS control programs have the methodological expertise and funding necessary to undertake and analyze these complex behavioral methods? This type of expertise often exists in national statistical bureaus rather than in ministries of health. Another option, Priorities for Local AIDS Control Efforts or PLACE methodology, was also brought up. This five-step methodology focuses on places rather than individuals and more specifically on high-priority areas for local HIV control efforts. Areas of high transmission are identified, and key informants are asked to provide information regarding venues where new partnerships are formed. Investigators then confirm the sites and interview patrons at the sties. This method can be used both for surveillance and targeted prevention activities; there is experience with its use in Africa, Asia, Latin America and the Caribbean.

Update 6. Estimation and Projection Tools

Dr. Timothy Brown of the University of Hawai'i East-West Center discussed UNAIDS' EPP and recent developments and future changes in its use.[20] The goal of EPP is to improve national capacity to develop estimates and projections. It was developed to fit trends in surveillance, provide short-term (i.e., five-year) projections, reproduce real-world epidemiologic trends and be useful to the national program without a lot of additional training. Twelve training workshops on EPP were held in 2003. An example of a projections page from EPP is shown in Figure 3.

Changes are currently being considered in EPP, and the strategy is one of incremental improvement rather than complete rewriting in order to minimize training requirements. Two issues that will be addressed in the newer version of EPP are turnover in high-risk populations and adjustment for the addition of new surveillance sites. In concentrated epidemics, there is a lot of mobility into and out of high-risk populations, and the base EPP assumption of a closed population does not hold. For example, female CSW are generally engaged in sex work for about 10 years and then re-enter the general population. Also certain high-risk populations may have higher mortality than others, for instance, IDU, and former HIV-infected members of high-risk populations may show up in general population surveys, such as former CSW in ANC surveys. To address these concerns, a new parameter that assumes persons are in high-risk populations for a period of time (1/d) has been introduced to model turnover. This is shown schematically in Figure 4. This provides better fits to several actual epidemics.

Figure 3. EPP projections page, Botswana.

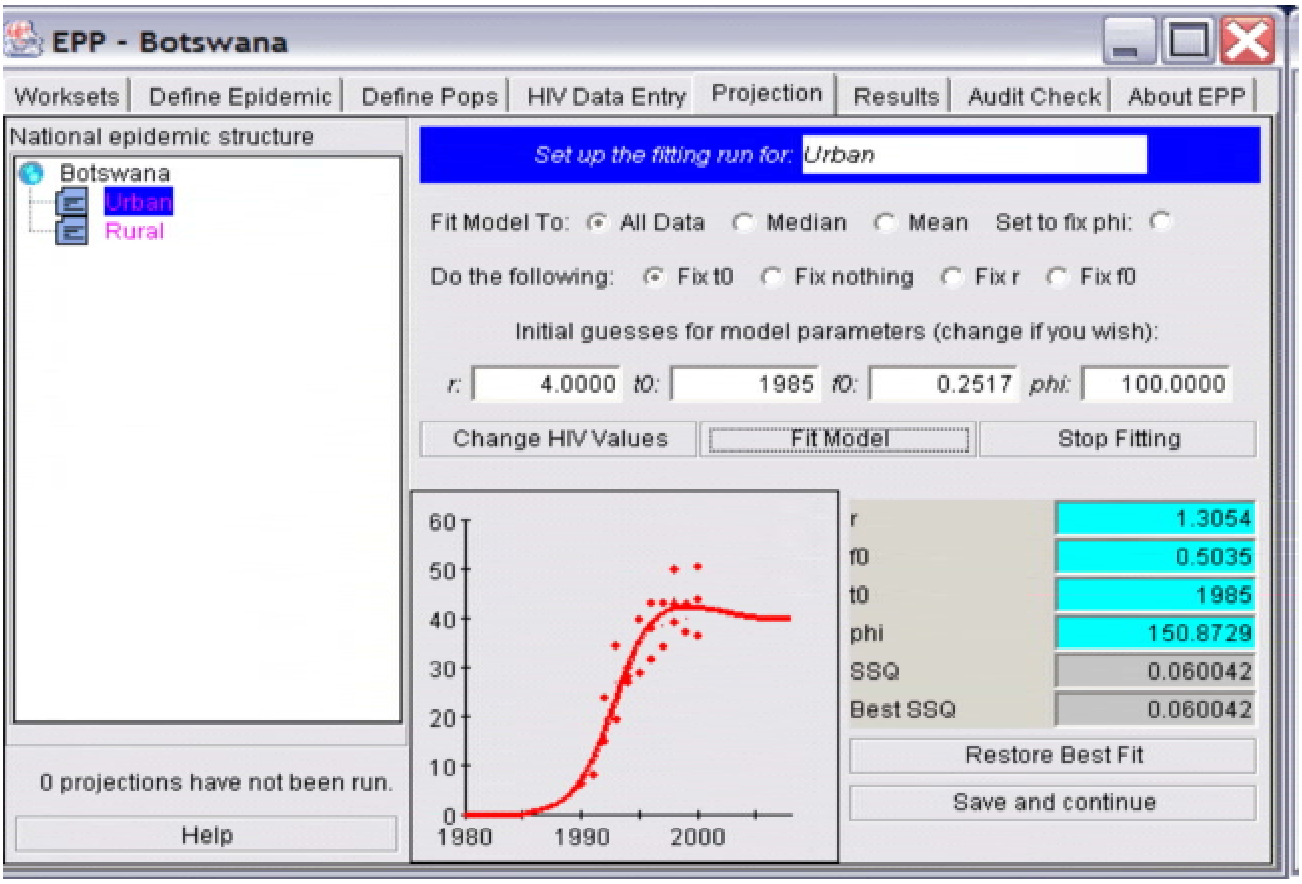
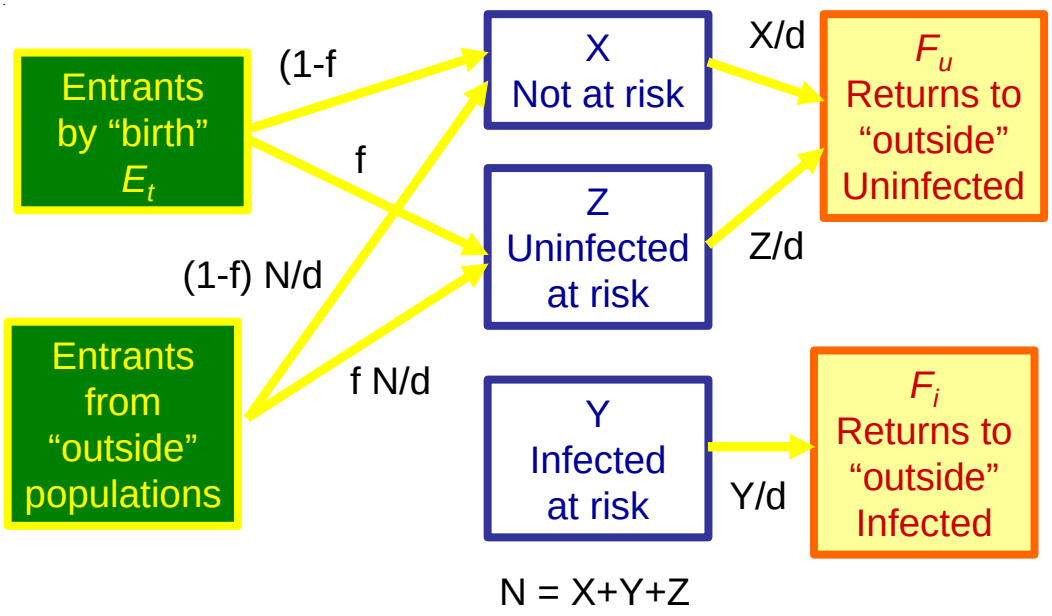


Figure 4. EPP model with turnover.



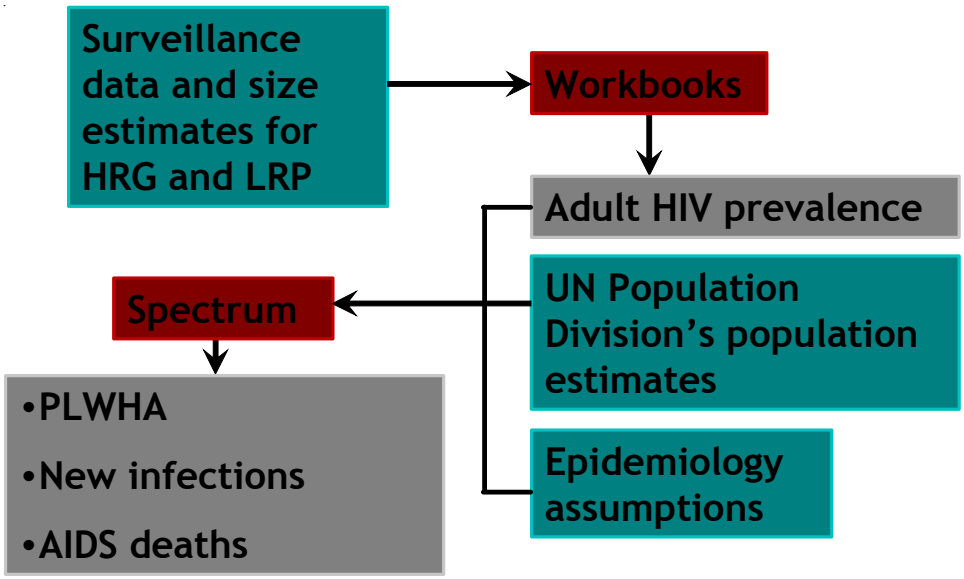
The addition of new surveillance sites often will bring down the overall prevalence estimates because sites with lower-risk populations are generally added after sites that represent higher-risk populations. For example, Ethiopia added rural sites where prevalence rates were lower than those in urban areas. A leveling parameter will be introduced into EPP to deal with this, which fits trends for each site independently while assuming that the trajectories of the fitted curves for each site are the same. Future parameters that will be considered include ARV treatment effects, a shift to maximum likelihood instead of least squares optimization, allowing for demographic parameter changes over time and exploring programmatic impacts on transmission rates.

Three additional points were raised by the audience. The first concerned how to determine a duration parameter for MSM since this is not likely to be a behavior that one exits. The way to deal with this is to identify the period during which high-risk sexual behavior occurs rather than to focus on any male-male sex. The current difficulty in determining this duration is lack of data. The second issue concerned the effect of adding lower risk sites and the change in effect based on the size of the additional populations. This can be dealt with two ways in EPP. Each site can be fit independently and then assigned the proportion of the population that the site represents (this is done in some countries) or the population associated with each site can be specified and the overall national impact can then be calculated. The final topic of discussion was the importance of allowing the model to vary by parameters other than the ones discussed, such as educational level. The intent of EPP is to remain a simple model (it has five parameters including duration). However, additional parameters can be added in countries where such data exist. The method involves stratifying the data by that variable, such as educational level.

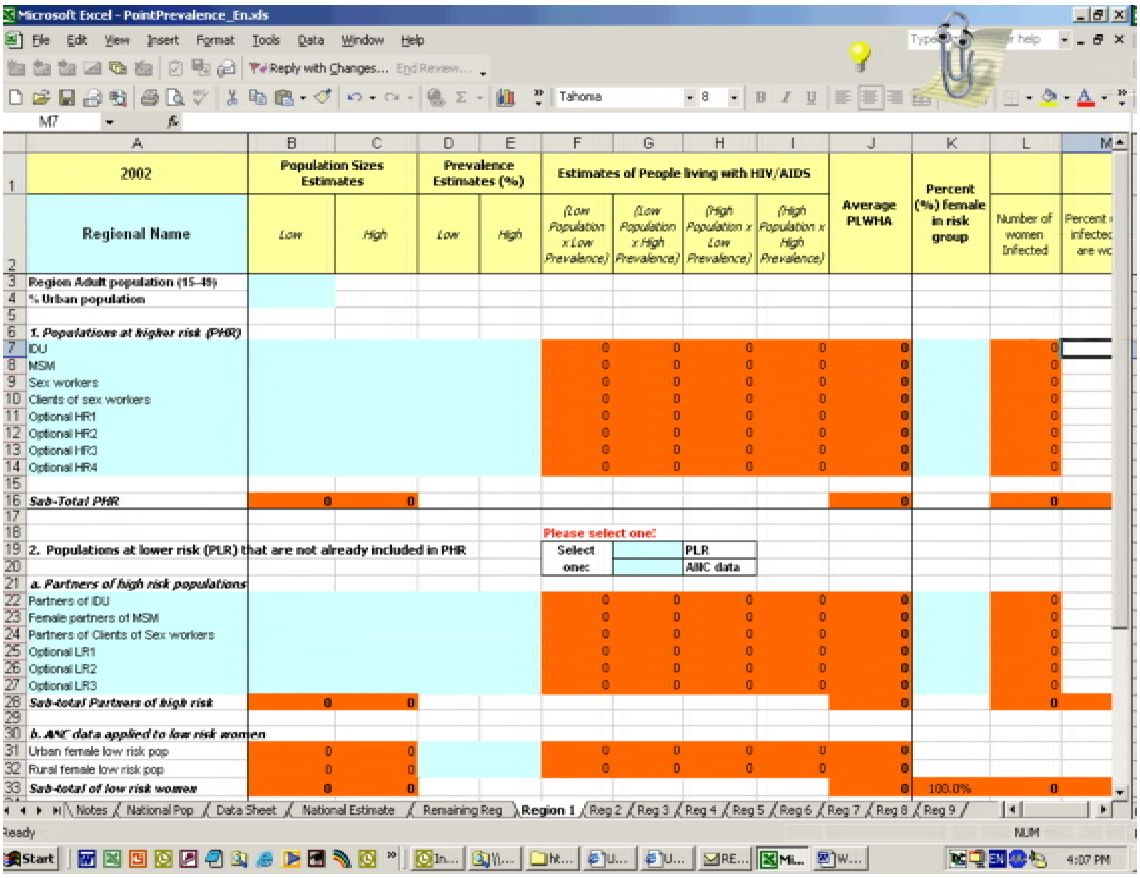
Ms. Karen Stanecki of UNAIDS spoke on two other tools used for estimates and projections, Workbook and Spectrum.[21] Workbook and Spectrum are both software packages that can estimate a variety of epidemiologic parameters. Workbook is the simpler tool and gives adult point prevalence estimates in low-level and concentrated epidemics. It takes inputs from biological and behavioral surveillance data, including size estimates for high- and low-risk populations, and uses curve-fitting techniques. It essentially performs the same function that EPP does in generalized epidemics.

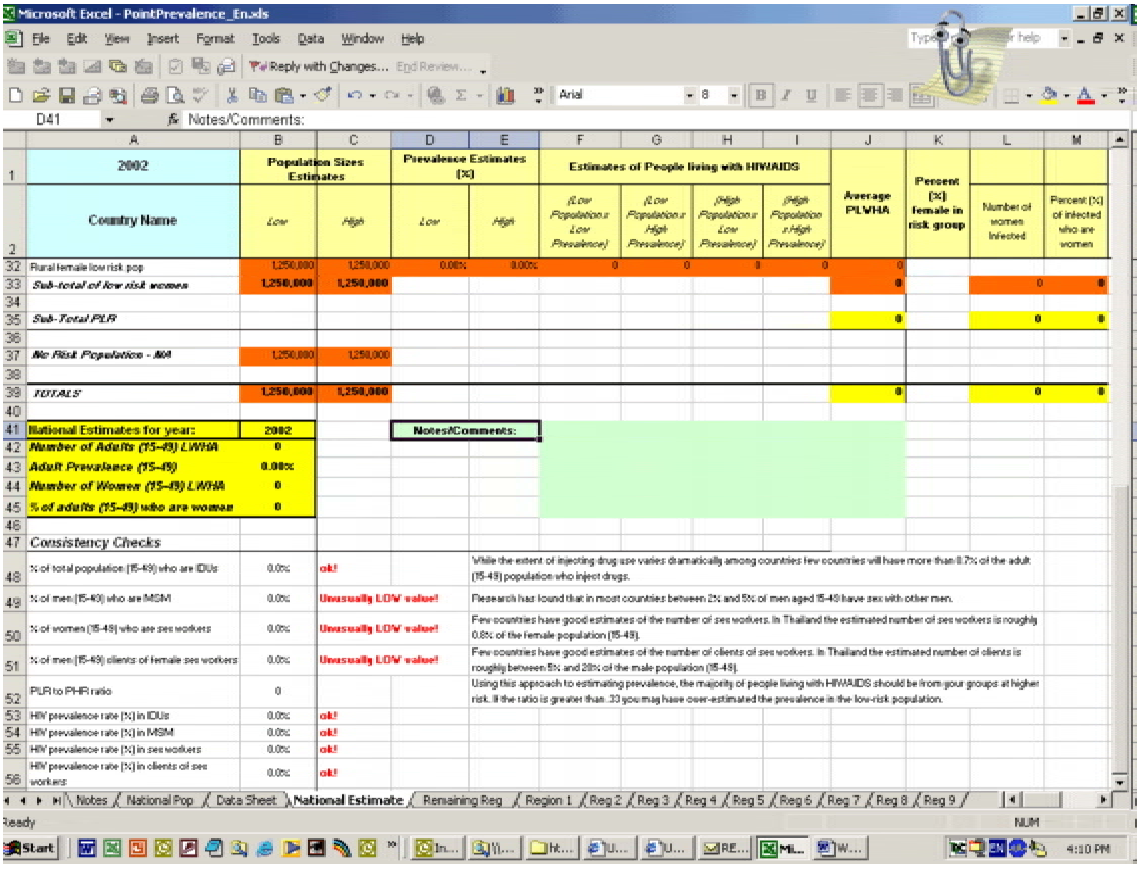
Spectrum is the more complex tool; its inputs include adult HIV prevalence (from Workbook or EPP), population size estimates from the UN Population Division and a variety of epidemiologic assumptions. Its outputs include the numbers of persons living with HIV and AIDS, the number of new infection and the number of deaths due to AIDS. Figure 5 gives an overview of Workbook and Spectrum in low-level and concentrated epidemics, and Figures 6 and 7 are actual spreadsheets from Workbook. Spectrum software is available on the Futures Group web site (http://www.futuresgroup.org).

Figure 5. Overview for low-level and concentrated epidemics.



Figures 6 and 7. Workbook spreadsheets.





For generalized epidemics ANC data are the sole input, and EPP is used instead of Workbooks to produce adult point prevalence estimates (Figure 8). The epidemiologic assumptions are:

- The female-to-male ratio increases up to 1.3:1 in generalized epidemics
- Fertility is 50% higher in 15-to-19-year-old women and 20% lower in all other age groups
- The mother-to-child transmission rate is 32%; this can be modified based on country-specific estimates
- Median adult mortality is 9.0 years overall, 8.6 years for males and 9.4 years for females because of the earlier age at which females are infected

Recently, Spectrum has been updated in a variety of ways. It has an updated child survival curve. It directly calculates the percentage of children born to HIV-infected mothers from adult ANC data and perinatal transmission rates. Its life tables have been updated based on the 2002 United Nations Population Division's revisions. Finally, the female-to-male ratio has been increased from 1.2 to 1.3 in generalized epidemics. New indicators that are now estimated by Spectrum include the number of new infections, the number of HIV-infected women, the number of persons needing ARV drugs, the numbers of persons on ARV drugs and the numbers of new orphans, both in total and by age.

Dr. Neff Walker of UNICEF discussed errors, ranges, uncertainty, bounds and plausibility bounds in HIV estimates.[22] Potential errors exist at several levels when using ANC data to estimate HIV prevalence in the general population. These include the ANC estimate itself, the ANC to general population adjustment, the adult survival estimates due to AIDS and other causes, curve fitting and epidemiologic trajectory modeling, population estimates, sex ratios, vertical transmission probability and child survival estimates due to AIDS and other causes. In order to deal with error, it is necessary to

Figure 8. Overview for generalized epidemic.

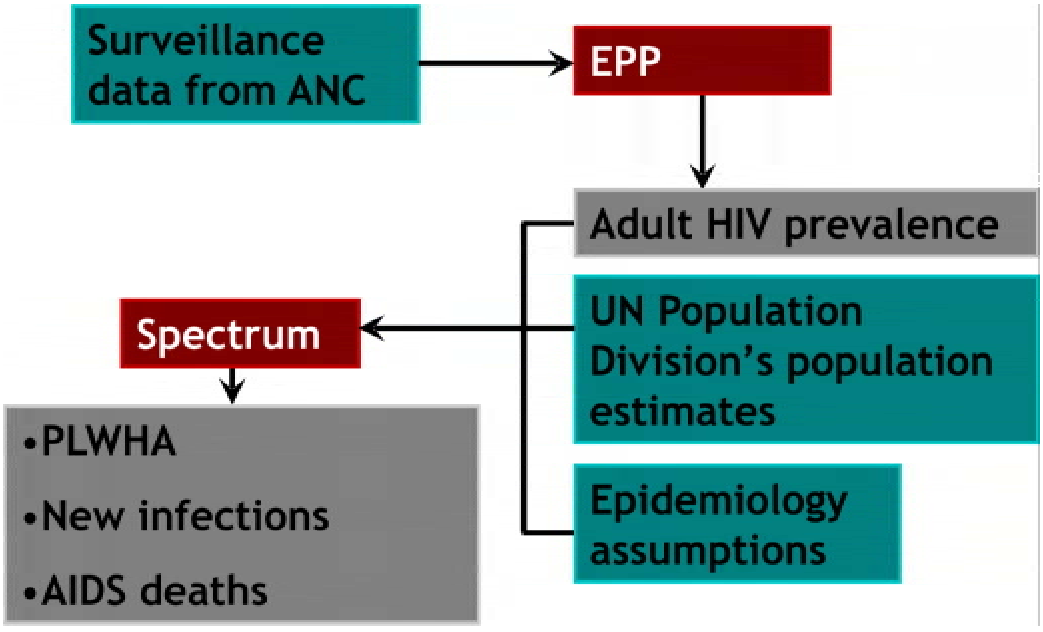


Table 7. Assumptions and errors in adult HIV prevalence estimates in generalized epidemics.

Parameter	Base estimate	Error
ANC prevalence		±2%
ANC:general population prevalence	1:1	SD 0.28
Adult survival	Median 9 years	SD 1 year with Weibull
Population size	UN population estimates	
Sex ratio	1.3 female:1 male	SD 0.25
Mother-to-child transmission probability	32%	SD 5%
Child survival	39% at 5 years	SD = double Weibull

SD, standard deviation

identify the steps and assumptions used in making the estimates, to develop an estimate of error for each step and assumption and then to combine individual errors into an overall estimate of error using a parametric bootstrap approach. Assumptions and errors inherent in using ANC prevalence data to estimate adult HIV prevalence are shown in Table 7. There are additional multiplicative errors in estimates of incidence, prevalence and mortality in children to be cognizant of. Future work will include running bootstrap programs on a series of countries that vary in prevalence levels and amounts of data, completing analyses for additional sources of variance for estimates for children and investigating plausibility bounds by comparing them to independent data sources.

Dr. Peter Ghys of UNAIDS discussed comparing sentinel surveillance based on estimates to survey-based results in constructing national estimates for HIV prevalence[23] and building on work published in 2003.[4] In 2001 methods for estimating HIV prevalence in generalized epidemics included:

- Curve-fitting approaches using all available data over time to develop an estimate of prevalence for pregnant women in urban and non-urban areas
- Adjusting median HIV-1 prevalence in non-urban areas down by 20% because of under-representation of remote rural clinics
- Assuming HIV-1 prevalence in pregnant women is a good proxy for prevalence in all adults aged 15 to 49 years
- Calculating the national estimate of HIV-1 prevalence by weighting urban and rural areas
- Assuming the female-to-male ratio of HIV-1 prevalence grows to 1.2:1
- Calculating the number of people living with HIV and AIDS (both men and women) and other statistics from the national prevalence estimate

While ANC prevalence corresponds to the prevalence among males and females in the community, ANC sentinel surveillance typically underestimates the community prevalence among women and overestimates it in men. For example, in Yaoundé, Cameroon, HIV prevalence among ANC attendees was 5.5%, while in population-based surveys it was 7.8% in women and 4.1% in men. Similarly in Ndola, Zambia, HIV prevalence among ANC attendees was 27.3%, while in population-based surveys it was 31.9% in women and 23.2% in men.

The basic limitations of estimates derived from ANC sentinel surveillance data are threefold. First, the prevalence equivalence of ANC and general populations may not apply equally well in all countries, but, on the other hand, there is a growing body of studies that support this assumption, including the Zambian DHS (ANC prevalence was 19.5% while the DHS estimate was 18.9% in an analysis of DHS clusters situated near ANC sites) and a cohort study in Kisesa, Tanzania. Secondly, with the exception of South Africa, ANC-based estimates suffer from the insufficient inclusion of rural sites in the surveillance system in most countries; however, many countries have recently expanded their sentinel surveillance systems to include more rural sites. Finally, any adjustments that aim to account for the under-representation of smaller rural sites are necessarily crude.

In recent years national surveys have become available in a number of countries, including the DHS in Mali, the Dominican Republic, Zambia and Kenya and the Young Adult Survey in Zimbabwe and other surveys in Burundi and Niger. These types of surveys are of most value in high-prevalence epidemics and are definitely not useful for measuring HIV prevalence in low-level and concentrated epidemics.

Compared to the HIV prevalence estimates in these surveys, prevalence estimates based on ANC surveillance data have been higher in most countries. A limitation of national surveys is that non-response rates may be high, including a combination of refusal and not at home, averaging 24% in Zambia, 38% in South Africa and 26% in Kenya. Rates differ with women more likely to participate than men and rural populations more likely to participate than urban populations (Table 8). In addition participation rates vary widely between provinces, and in serial prevalence studies, such as in Kisesa, participation rates in rural males and urban males and females have fallen.[24] Travel is an especially important issue to consider in non-response rates. Data from Yaoundé, Cameroon, suggest that prevalence of HIV in men is directly associated with duration of travel in the past 12 months.[25] Finally, reasons for non- response vary and can be either more pronounced among persons with higher risk of HIV or those with lower rate of HIV (Table 9).

Table 8. Response rates and seroprevalence by sex and region of residency, Zambia, Kenya and South Africa.

Country	Coverage rates (%)				Prevalence (%)			
	Male		Female		Male		Female	
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural
Zambia	67	80	80	87	19.2	8.9	26.3	12.4
Kenya	58.1	76.4	66.2	81.6	7.6	3.5	12.3	7.5
South Africa	58		67					

Table 9. Possible relationship between HIV prevalence and non-response.

HIV higher in non-responders	HIV lower in non-responders
Single person household	Young people away at school
Traveling associated with higher HIV risk	High risk perception and HIV fear
Absence due to HIV-related morbidity and mortality	At home secondary to HIV morbidity
Fear of learning HIV-positive serostatus	
Prior knowledge of serostatus	

Recommendations for research include examining non-responders who are able to be interviewed in the next round of cohort studies and responders from prior rounds who are unable to be interviewed in future rounds. In DHS a possible solution is also a specific repeat of surveys among those who were absent during the regular data collection period. Additionally, the characteristics of those who decline HIV testing are being explored in the Kenya DHS and should be explored in future surveys, as should the characteristics of those absent during data collection. Finally, comparing the female-to-male ratios for HIV prevalence, AIDS cases and excess mortality may help explore non-participation bias.

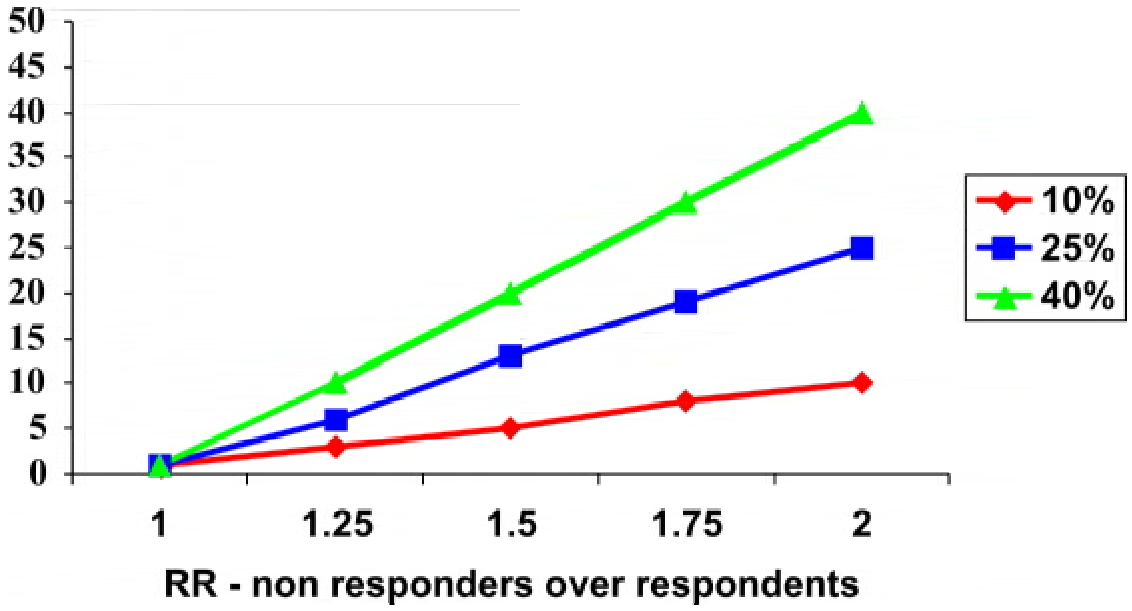
Seven steps were recommended for reconciling antenatal-clinic based prevalence estimates and those derived from national population-based samples:

- Compare HIV prevalence among pregnant women in ANCs and in surveys
- Compare HIV prevalence between urban survey areas and urban ANCs
- Compare HIV prevalence between rural survey areas and rural ANCs
- Compare HIV prevalence between ANCs and for both sexes combined for nearby clusters in the population-based survey
- Compare rankings of HIV prevalence by geographic areas (e.g., provinces or regions) for survey and ANC data
- Assess the level of non-response in the surveys data by selected key variables that have a strong association with HIV prevalence: by sex and age groups and by urban/rural residence
- Analyze and adjust for the effect of survey non-response bias on the prevalence estimate by assuming that non-responders have the same prevalence as survey participants or, if there are good reasons to assume that the relative risk of HIV infection is higher among non-responders (e.g., urban males), adjust using higher rates of infection.

The relationship between non-response rates and underestimation of HIV prevalence is shown in Figure 9.

In the media the question has been raised whether UNAIDS and WHO should lower their estimates by some 15%, as suggested by comparisons of previous ANC-based estimates with estimates from national surveys. This is already happening to some extent with downward revision of adult prevalence estimates in many countries. In the regional EPP workshops held in 2003, among the most important clarifications was the reclassification of ANC sites that had previously been considered as rural to urban. The surveillance system is also expanding, bringing more rural sites into the system. Additionally, the new national surveys provide new information on HIV prevalence, including in rural areas and among men, although the HIV prevalence from these surveys needs to be given appropriate weight following careful consideration of non-response and any bias it may introduce. The net effect of the above factors was the reduction of the UNAIDS/WHO 2003 estimate of the number of HIV infections in sub-Saharan Africa from 29.4 million in 2002 to 26.6 million in 2003.

Figure 9. Effect of relative risk of non-response by underestimation of HIV prevalence at different prevalence levels.



SESSIONS AND WORK GROUPS

Session 1. Measuring Recent HIV Infection

Dr. Steve McDougal of CDC discussed principles and validation of assays for estimating HIV incidence from cross-sectional studies.[26] Incidence can either be defined as the proportion of seronegative individuals who seroconvert during a defined period of observation or as the proportion of positives identified in a cross-sectional study that has markers of recent infection (Figure 10). Mathematically, cross-sectional incidence can be expressed as:

$$\text{Incidence} = \frac{(365/\text{window period}) \times (\#\text{ who test incident})}{\#\text{ at risk}} \times 100$$

or

$$I = \frac{(365/w)N_{incident}}{N_{seronegative} + (365/w)N_{incident}/2} \times 100$$

where I is incidence, w is the window period, $N_{incident}$ is the number of persons tested whose tests have evidence of recent infection and $N_{seronegative}$ is the number of persons tested who are seronegative.

Figure 10. Cross-sectional versus longitudinal incidence measurement.

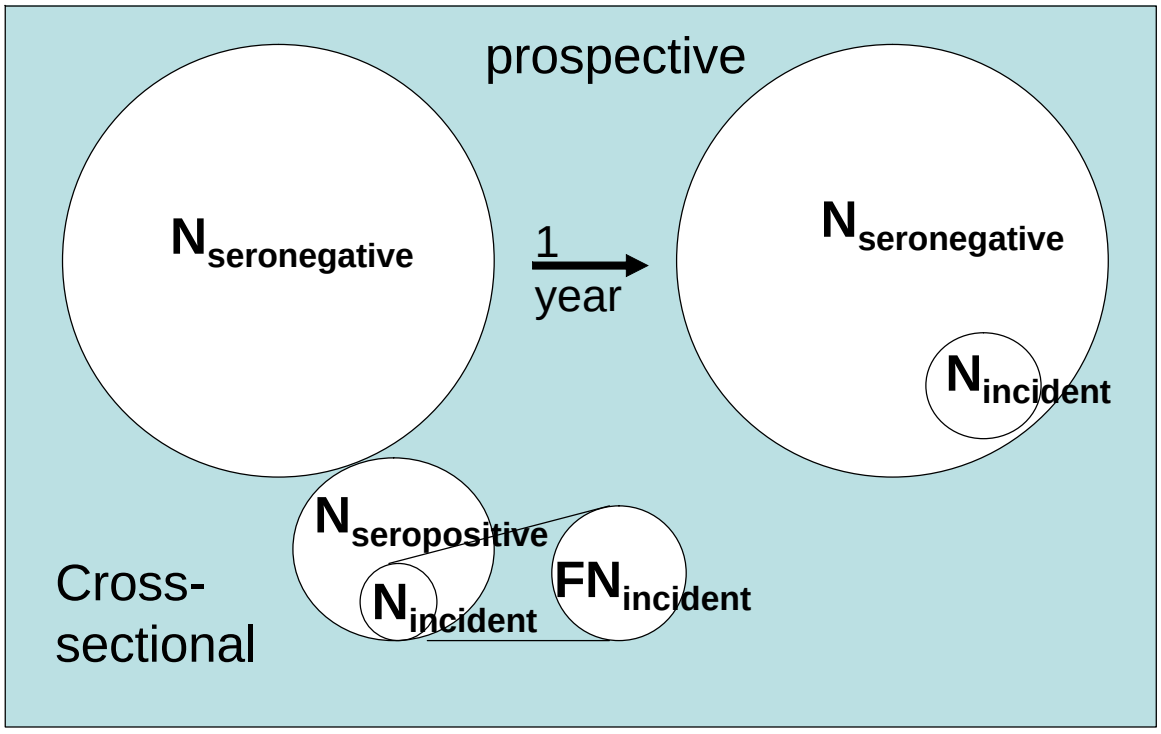
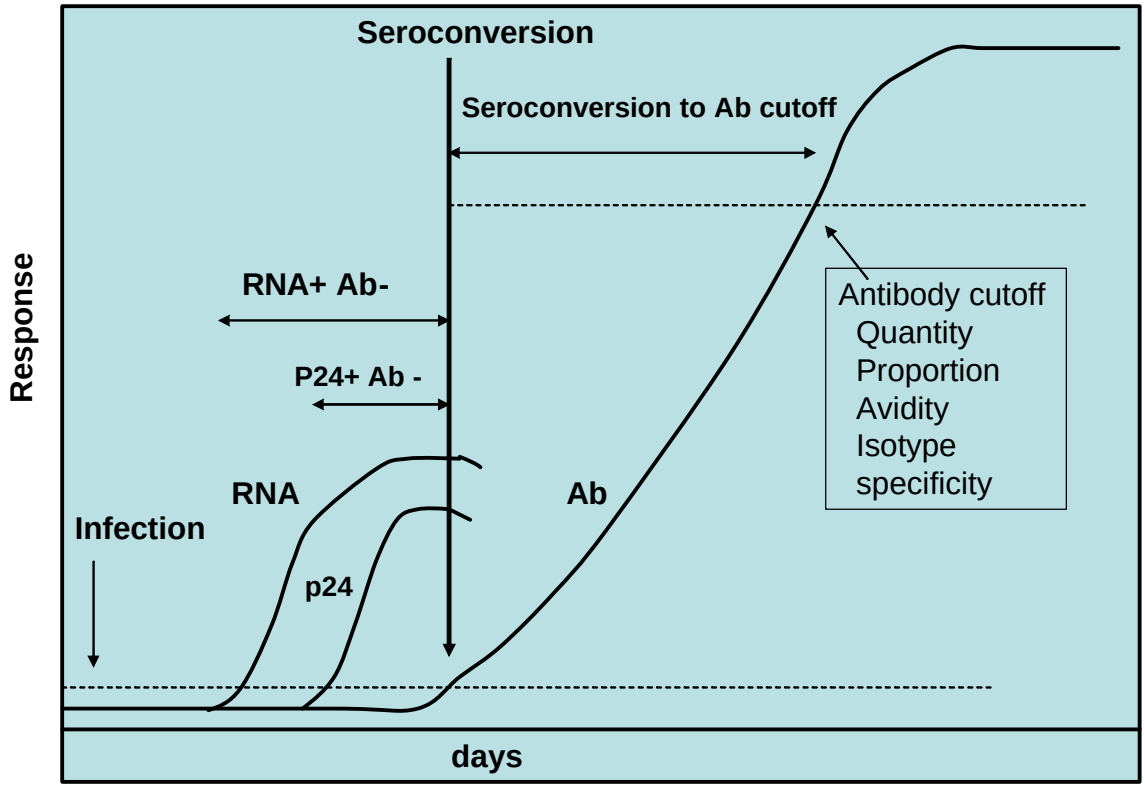


Figure 11. Antibody, RNA and antigen patterns in early HIV infection.



The ideal assay for recent infection would have a distinct interval of relatively uniform duration; would be universally positive in recent infection and negative later in infection (or vice versa); would be unaffected by virus subtype, mode of transmission, therapy, the presence of opportunistic infections or AIDS, age, sex or race; and all else being equal would have a relatively long window, all else being equal. The longer the window period, in general, the lower the error. As shown in Figure 11, incidence can be measured prior to antibody conversion, using RNA or p24 antigen, or post-antibody conversion by quantity, proportion, avidity or isotype specificity.

A variety of assays has been proposed to measure recent HIV infection (Table 10). All rely on the standardization of the window period (w), which is done by examining panels of sequential specimens from recently infected individuals whose approximate date of seroconversion is known. The interval between specimens should be sufficiently short so that a reliable regression analysis over the "threshold-to-cutoff" range can be generated. To measure the window period, one plots the assay results versus the intervals between specimens and then uses regression analysis to determine the time from assay threshold to assay cutoff from the mean of individual subjects' regressions, from the regression of all plotted data and from coordinates that optimize correct classification. Additional validations that are ongoing include the effects of viral subtype, opportunistic infections and AIDS, therapy, age, sex and race on test performance and the false positive rate in established infection and the false negative rate in recent infection. These validations are done in longitudinal cohort studies where the assays can be used in cross-sectional samples of study populations and then independently verified using conventional measures of incidence. Post-test adjustments may need to be made to incidence estimates based on frequency of testing for STARHS, sensitivity, specificity and the proportion of incident specimens in the tested specimens. Secondary or confirmatory testing can also be done with another incidence assay.

Table 10. Assays for recent HIV infection.

		Window interval (w)		
Assay	**Tests for**	**From**	**To**	**Duration**
HIV RNA	Plasma RNA	RNA +	Seroconversion	19 days
HIV p24 Ag	Plasma p24	P24 +	Seroconversion	14 days
STARHS	HIV Ab titer	Seroconversion	Titer cutoff	130 days
BED-capture EIA	HIV Ab/total IgG	Seroconversion	Ab proportion cutoff	160 days
Avidity	HIV Ab avidity	Seroconversion	Avidity cutoff	Variable
Affinity	HIV Ab affinity	Seroconversion	Affinity cutoff	Variable
IgG3 isotype	IgG3 anti-HIV Ab	Seroconversion	Undetectable IgG3 Ab	Undetermined
Anti-HIV p31	anti-HIV integrase	Seroconversion	Detection of anti-p31	70 days
CD4	CD4 levels			

How can these incidence tests be used in surveillance settings? Some ways include comparing incidence between subgroups of the same population, comparing incidence over time in the same population, comparing incidence rates between different populations and extrapolating incidence data to national incidence estimates.

Dr. Bernard Branson of CDC spoke on the use of STARHS for estimating incidence and covered the principles of STARHS testing, the basis for assay calculation, incidence calculations and the assays purported non-utility for individual results.[27] STARHS is a pair of HIV EIA antibody tests with difference performance characteristics and is based on the principles that as seroconversion progresses, antibody titers increase as does antibody affinity. Figure 12 shows the relationship between HIV antibody level, time since infection and the two points at which HIV antibody is measured in STARHS. The Vironostika EIA gives a window period of 170 days for subtype B infection (95% CI, 162-183 days).

The performance of STARHS is quite precise with stringent incubation timing (±1 minute) and stringent temperature requirements (±1°C). For the more-sensitive EIA, there is a 1:75 dilution, a 90-minute specimen incubation period and a 35-minute conjugate incubation period; for the less-sensitive (detuned) EIA there is a 1:20,000 dilution, a 30-minute specimen incubation period and a 30-minute conjugate incubation period. Small variations in any of these parameters may result in considerable test-to-test variability. As a practical matter, however, it is difficult to achieve such stringent requirements. Less sensitive EIA procedures include screening of all positive EIA with standardized optical density <2.0, which are then reconfirmed in triplicate from new dilutions of the same specimen. Other steps include a calibrator, a negative control, a high-positive control and a low-positive control. In real life, the less sensitive EIA produces a range of values, as shown in Figure 13.

Figure 12. Window period and STARHS.

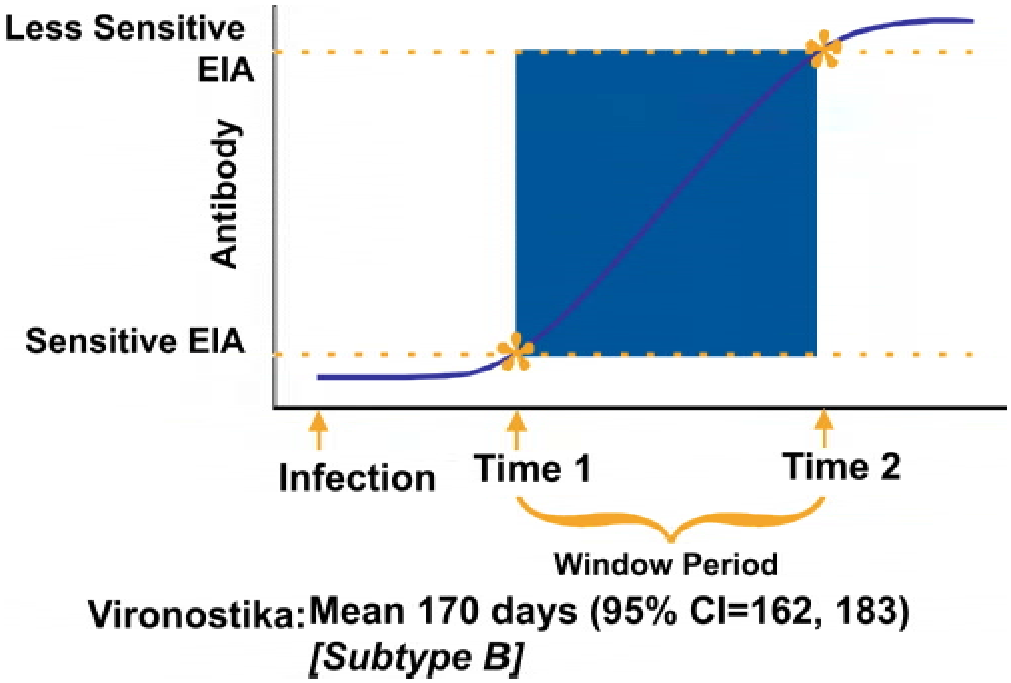
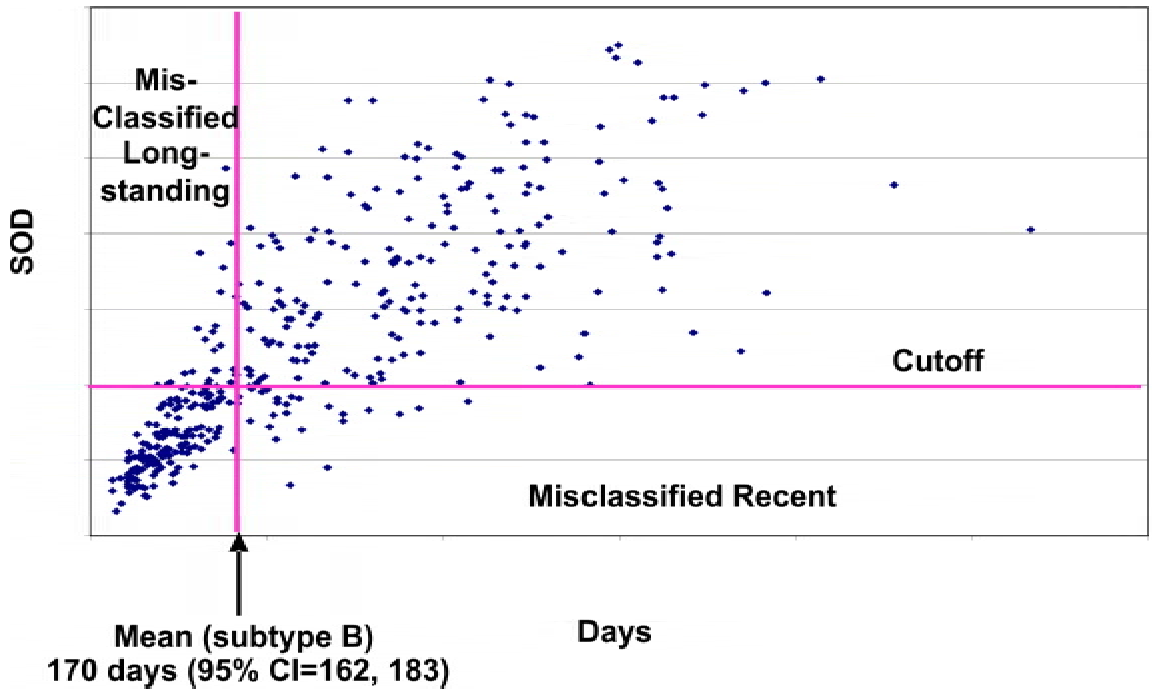


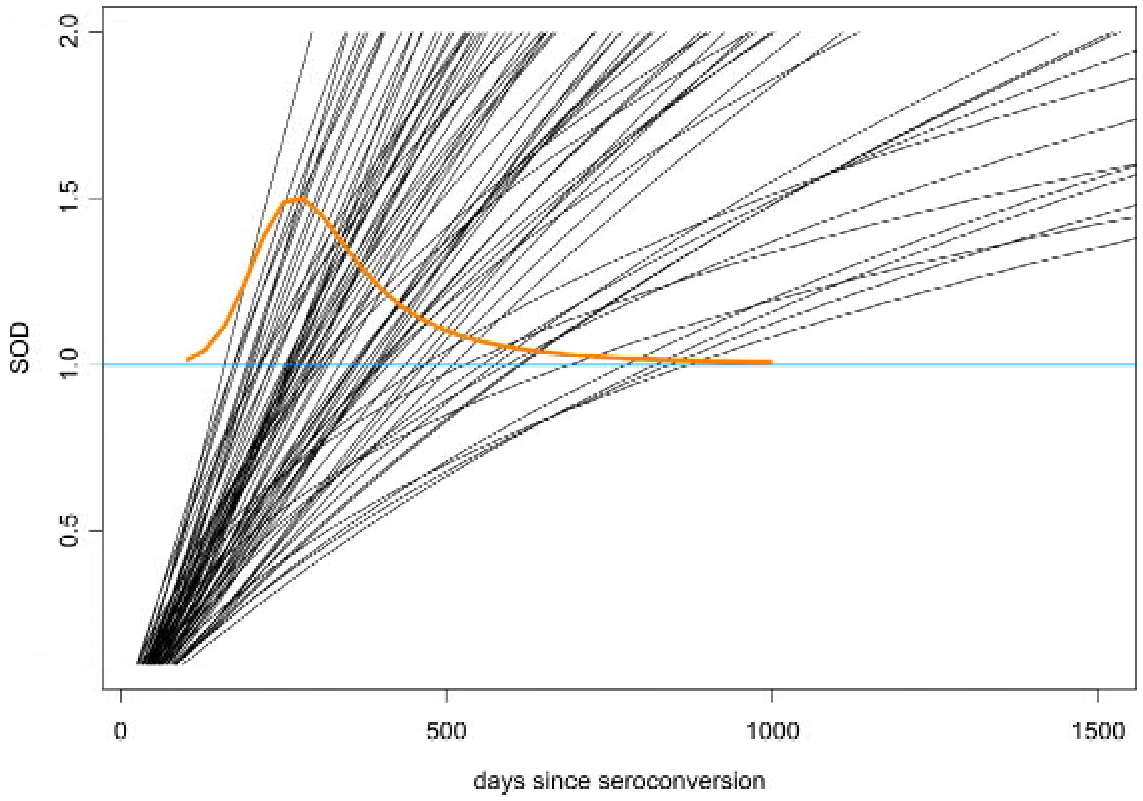
Figure 13. Window period estimates: incidence.



These are actual data from STARHS performed on 60 known seroconverters; the x-axis represents days from seroconversion and the y-axis the Vironostika-less sensitive EIA standardized optical density. At a standardized optical density cutoff of 1.0, the mean window period for this group of patients is 170 days. The specimens in the lower left corner – below the cutoff – are from recent infections (less than 170 days). There are, however, false positives (specimens with a standardized optical density below the cutoff, from persons who seroconverted more than 170 days ago) and false negatives (specimens with a standardized optical density above the cutoff, from persons seroconverted less than 170 days ago). The reason STARHS is useful for estimating incidence at the population level is that the number of false-positives is approximately equal to the number of false-negatives. Thus, they "cancel" each other out. However, the number of misclassifications is not trivial, and each of the individuals represented in the grey boxes would receive an incorrect interpretation. Figure 14 shows this variability in a different way. Each curve in the figure represents STARHS results for one person. The x-axis represents days since seroconversion. Standardized optical density on the y-axis increases with time after seroconversion. The point where each curve crosses the cutoff of 1.0 is the window period (in days) for that person. The probability distribution of the windows is superimposed, in red. The mean for this population is at 170 days, but the window periods for different individuals range from 63 days to 404 days. A considerable number of individuals have window periods greater than 170 days.

With the Vironostika EIA different HIV subtypes have different window periods. Subtype B has a window period of 170 days (95% confidence interval [CI], 145-200 days), subtype B' has a window period of 239 days (95% CI, 208-287 days) and subtype E has a window period of 356 days (95% CI 318-402 days).

Figure 14. Distribution of individual window periods.



Trying to interpret STARHS results for individual patients is complicated, both by the variability in the time that antibody develops in different seroconverters and by the variability in the results of the less-sensitive assay. Given this variability, while the mean window period of 170 days is used in formulas to calculate incidence from aggregate data from a population, for individuals broader results should be given. By moving the vertical cutoff in Figure 14 from 170 days to 1 year, almost all false negatives (individuals who are indeed recent seroconverters but are not identified by the test) are eliminated. For an individual with a standardized optical density <1.0, an interpretation is that they probably seroconverted in the last 12 months. An individual with an SOD of one or greater may or may not have seroconverted more than one year ago. Fortunately a variety of other incidence assays are on the horizon, including a the HIV-1 plus O successor to Vironostika, the BED capture assay, the avidity index and the IgG subclass assay.

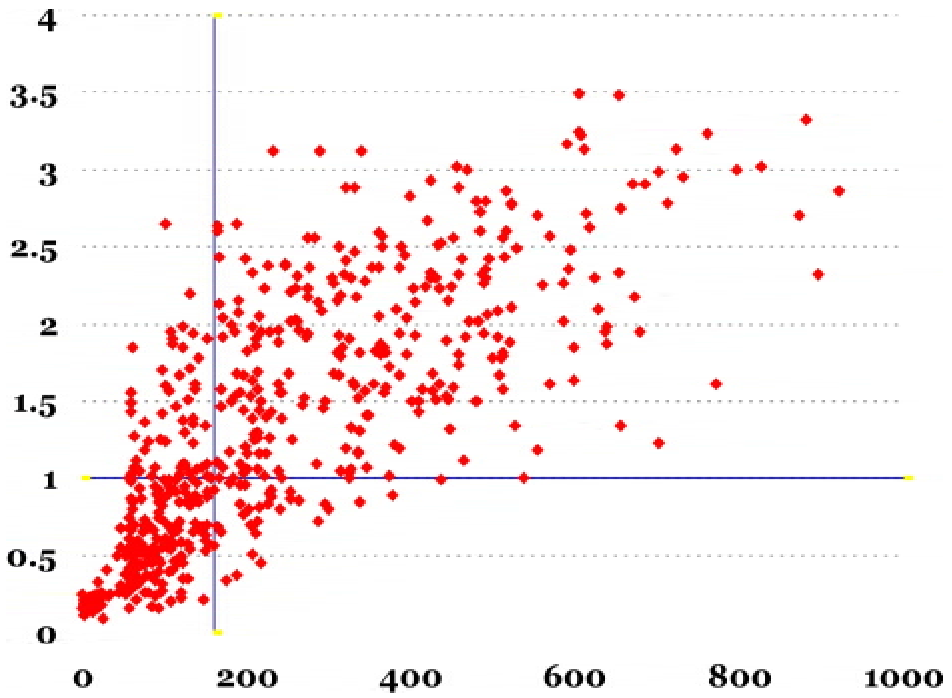
In conclusion, the current less-sensitive assay used for STARHS is investigational and giving results to individuals requires an FDA-approved protocol. Second, the less-sensitive and other alternative assays need to be validated with a larger number of seroconversion panels to better establish what their results might mean, both for better estimates of incidence and, potentially, for providing results to individuals.

Dr. Bharat Parekh of CDC discussed one of the newer incidence assays, the BED-capture EIA, which has the distinct benefit of being able to identify recent seroconversion independent of viral subtype.[28] The BED-capture EIA was designed to have a single window period regardless of subtype, to be able to be performed with standard laboratory equipment and to be more robust, easier to perform and less variable than STARHS. A 2001 publication assessed a wide variety of potential new assays for distinguishing recent from long-term HIV infection.[29] The most promising of these is the IgG-capture BED EIA, which measures the increasing *proportion* of HIV-IgG after seroconversion.[30] It incorporates a multi-subtype synthetic antigen (gp41-IDR) to permit equivalent detection of antibodies to B, E, D and other HIV-1 subtypes (hence, "BED"). It is performed at a convenient specimen dilution of 1:100 and, thus, does not require labor-intensive dilution process; moreover, the assay is not affected by variation in dilution as long as the proportion of HIV-IgG and non-HIV-IgG remains the same. In an initial evaluation involving US and Thai B, B' and E specimens with 67 from 22 BB' subtype B panels, 518 from 90 Thai seroconverters (104 of these were from 18 Thai B seroconverters and 414 from 72 Thai E seroconverters) and 37 from other studies. In the assay optical density values were normalized by dividing the specimen optical density by the calibrator specimen optical density to minimize inter-run variations, and seroconversion was assumed to have occurred at the midpoint between the last negative and first positive specimens. As seen in Figure 15, these specimens yielded a range of normalized optical densities that correlate well with time since seroconversion.

Since these initial evaluation five additional cohorts from the Netherlands, Kenya, Ethiopia, Zimbabwe and India, which encompass subtypes A, B, C and D, have also been evaluated with similar results. The window period is a function of normalized optical density cutoff in these experiments and ranges from 153 days, when a cutoff of 0.8 is used, to 167 when 0.9 is used to 191 when 1.0 is used. With the 1.0 normalized optical density cutoff performance is slightly better than STARHS with 4.1% of specimens misclassified as compared to 4.36% for STARHS.

The BED-capture EIA has also been evaluated in several thousand patients in cross-sectional cohorts from Thailand, Uganda, Ethiopia, Cambodia and the U.S. Among IDU in Thailand the BED-capture EIA was used to identify recent infection among 113 (19%) of 594 seropositives and to establish that younger IDUs had a higher rate of recent infection than older users and that marriage and employment

Figure 15. Changes in normalized optical density after seroconversion, US and Thai B, B' and E subtypes.



were both associated with lower rates of recent infection.[31] In Cambodia the BED-capture EIA assay was used to assess recent infection in a variety of sentinel surveillance populations, including women attending ANCs, CSWs, indirect sex workers and police officers. Incidence was high but falling in CSWs and indirect sex workers, especially in the central providences. In the PACTS study at Emory University in Atlanta, BED-capture EIA was used to estimate HIV incidence in pregnant women from 1991-92 to 1997-98 and was found to be declining from about 2.8 per 1000 woman years to about 1.7 per 1000 woman years. In the Wonji area of Ethiopia in a community cross-sectional study involving approximately 2,000 participants, 48 were found to be HIV-infected, and 5 of those were positive by BED-capture EIA. This equated with an incidence rate of 0.47 per 100 person years. In the same area, a cohort of factory workers was found to have a similar incidence, 0.41 per 100 person years.

In sum, the BED-capture EIA is a new, subtype-independent assay, with mean window period of 153 days at a normalized optical density of 0.8 or 191 days at a normalized optical density of 1.0 for detecting recent HIV-1 infection. The assay is designed to work in populations with divergent HIV-1 subtypes and can be an important tool for measuring incidence worldwide. The format of the assay ensures ease of dilution, less labor and high reproducibility. Scale-up will allow more GAP and other countries to access the reagents.

Dr. Christopher Pilcher of the University of North Carolina at Chapel Hill discussed the use of HIV-RNA assays for identifying recently infected individuals and the North Carolina public health follow-up programs that have been developed to use this information.[32] Acute retroviral infection, a period of infection defined as the first 30 days following initial transmission, is recognized clinically less than

50% of the time, but is a period of extreme infectiousness starting at approximately one week post transmission. In the Rakai study 48% of all infections observed were attributable to transmission in the first five months following initial infection,[33] and blood and genital compartment viral loads peak at three to four weeks. There is a clinical opportunity to avert transmission to regular sexual partners and children and possibly to improve host immune control of HIV with a short-course of ART[34] by identifying and intervening with patients with very early HIV infection.

HIV RNA becomes measurable in serum at seven days post infection and remains present in the serum for several months. As shown in Figure 16, it precedes the appearance of p24 antigen, the onset of symptoms or HIV antibody. However, testing for HIV RNA is expensive, with each test costing approximately $34 USD, is limited to laboratory facilities capable of measuring RNA and has a false positive rate of about 1%. The positive predictive value varies depending on the prevalence of RNA-positive samples in a population from around 85% if 5% of specimens are RNA-positive to 9% if only 0.1% are positive. One way to lower cost is to pool specimens, as blood banks do in the United States. Individual specimens can be screened for HIV antibody using standard methods and HIV-antibody-negative specimens pooled in five groups of 10 specimens and screened in a single 50-specimen pool for RNA. Positive pools are retested to determine which individual specimen is positive.

In North Carolina's Screening and Tracing of Active Transmission (STAT) program, these methods have been applied to specimens from 110 VCT sites across the state. Individuals who test positive for HIV RNA are rapidly notified by disease intervention specialists who link them to clinical care and partner counseling and referral services. Data are collected on social and sexual networks with active HIV transmission in real time and systematically analyzed to characterize transmission patterns and networks. From October 2002 to November 2003, 117,753 individuals were tested confidentially in North Carolina. Seven hundred fifty-five (0.7%) tested positive for HIV antibodies. Of these 130 (17%) were positive by STARHS, and 23 (4%) were positive by HIV RNA. Of the 23 STARHS-positive patients, 22 were started on ART, including one pregnant woman; 12 of these went into clinical

Figure 16. Acute HIV infection timeline.[35]

trials. These 23 individuals named 39 partners of whom 20 are known to have been tested. Clinically, none of the 23 was suspected of having HIV prior to testing; seven had acute retroviral syndrome by history or physical, six more developed acute retroviral syndrome within the week following RNA testing and 10 were asymptomatic throughout except for eight with STIs. The median viral load at detection was 209,183 copies per ml, and the highest was 38,000,000. From a laboratory standpoint the assay was able to detect RNA levels as low as 1,171 copies per ml despite 100-fold dilution in screening pools. There were two false positives out of 22,315 specimens when pooling was done manually and none out of 95,279 when pooling was done robotically. The specificity was greater than 0.9999, and the positive predictive value was 1.00 (95% CI 0.74, 1.00). Laboratory cost was $2 USD per specimen.

In network analysis, 11 likely transmitters were identified of whom three were core transmitters infecting two or more individuals. Ten of these 11 had previously diagnosed HIV infection, but only three had disclosed their HIV infection to their acutely infected partner. Nine were in long-term relationships with index cases. Risk factors included sex between men in 11 of 22 infections with known risk factors, multiple anonymous partners in four, commercial sex work in five, crack cocaine in eight and other drugs and alcohol in 10. Five individuals had been recently released from prison. Two cases occurred in college students in the same town; this led to early detection of an HIV outbreak in colleges in the area and new CDC and state programs targeting this population.[36]

HIV RNA testing has now been taken to Malawi. There, pooling is done by hand with a 12-channel AlphaPette® pipetter. Cost is lowest when pools of 10 are used. In a pilot study, 1,360 consecutive male sexually transmitted disease and dermatology outpatients were tested at Lilongwe Central Hospital using a serial HIV testing algorithm with rapid testing for HIV antibody and RNA testing on pooled specimens. Of 1,361 specimens, 553 (41%) were HIV antibody positive; 28 (5.0%) of the remaining 774 negative specimens were HIV RNA positive. Of these 28 HIV antibody-negative HIV RNA-positive specimens, 24 had acute HIV testing, two had HIV antibody missed by rapid testing and two had indeterminate status with HIV RNA less than 10,000 copies per ml. The median viral load among those with acute infection was 1,258,925 copies per ml, as opposed to 26,302 with established infection. Twenty-three of the 24 acutely infected patients were from the sexually transmitted disease clinic; the single patient from the dermatology clinic had trichomoniasis. Eleven (46%) of the patients had acute retroviral syndrome, and an additional five (21%) had inguinal adenopathy associated with genital ulcer disease. Thus, 2.5% of men with acute sexually transmitted diseases in Malawi had antibody-negative acute HIV infection; they represented 4.5% of all HIV antibody-negative men and 5.0% of all men with detectable HIV infections. These individuals were extremely infectious with viral loads up to 2.4 billion copies per ml, but most had clinically unapparent acute infections. In the STI clinic, genital ulceration and inguinal adenopathy were strong predictors of acute HIV infection.

The Acute HIV Infection Study has now been started in Malawi, whose purposes are to determine the prevalence of acute HIV infection among patients with STIs, to identify the sociocultural and behavioral antecedents of HIV infection in this population and to correlate these results with PLACE methods in Lilongwe. Secondarily, it seeks to assess the performance and cost effectiveness of p24 antigen testing in comparison with HIV RNA as additive laboratory procedures in HIV VCT; to describe clinical, behavioral and demographic factors associated with acute HIV infection; to assess viral load in blood and genital secretions in these patients and to examine the etiology of genital ulceration associated with acute HIV infection. To date, 836 participants have been enrolled in the study of whom 320 (38.3%) are HIV-antibody positive. Of the 516 HIV antibody-negative participants, 13 (2.5%) are HIV RNA

positive. All 13 have been located and donated genital secretions. Sixty HIV-negative controls and 22 controls with established HIV infection have also been recruited. The median viral load was 1,000,000 copies per ml with a range of 9,049 to 10,951,872 copies per ml. Seven (41%) of the 13 had detectable p24 antigen. In summary, STI clinics harbor large numbers of acutely HIV-infected individuals in high-prevalence areas; whether comparable numbers of acutely infected patients could be found in other settings is unknown. In situations where PCR testing is possible, these infections can be accurately and efficiently detected using pooled HIV RNA testing. While less cost efficient than the technically simpler p24 antigen assay, it is more sensitive. The role of heat-dissociated p24 antigen testing, which may improve its sensitivity, is a matter for additional research.

Finally, the identification of acute HIV infection presents new opportunities to avert transmission. By targeting acute HIV testing in high-yield clinical settings, by using central processing of specimens for improved cost efficiency and by increasing capacity for partner referral and counseling, network notification and data gathering, individual-level disease control programs are possible in resource-constrained settings.

Dr. Guy Gershy-Damet of the WHO-AFRO discussed potential uses of measuring recent HIV infection in Africa.[37] In Africa the most common measure of the HIV/AIDS epidemic is HIV prevalence, and in most African countries the system used to obtain prevalence data is HIV sentinel surveillance among pregnant women attending ANCs. There were 625 ANCs supported by WHO-AFRO participating in HIV sentinel surveillance in 2002, and an additional 400 in South Africa. However, HIV prevalence data do not distinguish between those who acquired HIV infection very recently and those who were infected a decade or more ago.

A measure of HIV incidence would help complete the picture of current trends, but measuring HIV incidence is expensive and complicated. Two possible low-technology proxies for incidence are repeat HIV antibody testers and cross sectional prevalence data from 15-to-24-year-old women attending ANCs. Incidence data can be used for a variety of things:

- To mobilize political commitment, especially of decentralized government agencies and local stakeholders
- To advocate and target activities for population groups and areas
- To monitor and evaluate programs
- To allocate resources and conduct short-term planning

Discussion

Several clarifying points were made. A first question was on the purpose of capturing non-HIV antibody in BED-capture EIA and whether it was possible to use CD4 counts to identify recent infection. In BED-capture EIA, total antibody needs to be captured for the denominator used in the calculations. Regarding CD4 counts, it is not really possible to infer anything about CD4 at an initial visit because CD4 counts fall rapidly in initial infection before normalizing at a set point around four to six months post infection. Dr. Pilcher was asked why he avoided using the word incidence. He answered that because he was examining a selected population rather than a random sample of a population he did not believe that he could infer incidence from his rates of recent infection. In response to another question regarding other easy incidence measure that can be found in existing HIV surveillance data, the panel responded that it was as yet unknown if the assays discussed in the session would prove to be more useful for local control efforts that seroprevalence in young pregnant women. A question was asked about standardized optical densities and the need to standardize cutoff points. These are arbitrary cutoffs, and window periods are a function of standardized optical densities. For surveillance calculations, longer window periods are desirable, but this needs to be balanced against the need for shorter window periods if the goal is initiation of earlier therapy. The observation was made that when laboratory methods mature, the temptation will be to use them for measuring incidence in ANC attendees. However, because of decreased sexual activity during pregnancy, using pregnant women may underestimate true population incidence.

Another line of discussion was around using incidence measures for monitoring and evaluation. The first question dealt with the distinction between calculating exact incidence and monitoring incidence trends and that misclassification is negligible when calculating incidence but may be a problem when examining associations. The response was that for the purposes of monitoring and evaluation, the focus needs to be on defined populations. The problem with HIV RNA and p24 antigen tests is that HIV-negative specimens need to be rescreened plus the window period is short with a resultant high chance for error. If the purpose is identifying individuals, for instance for public health control programs or early initiation of therapy, STARHS has a low positive predictive value in comparison to HIV RNA. Finally, a point was made about evaluations using incidence and the need to include behavioral data when examining time-dependent incidence data.

Work Group 1 reviewed the issues discussed in Session 1.* They were asked to discuss a series of questions dealing with the measurement of incident HIV infection (Table 11). Their discussion focused largely on three points: QA, development and evaluation of laboratory methods for evaluating recent infection and using these methods in epidemiologic surveillance. There was agreement that it is critically important to diagnose recent HIV infections to monitor changes in incidence resulting from new initiatives such as WHO's 3 x 5 initiative and PEPFAR. However, the work group felt that existing tests were not ready for implementation and that there was an urgent need for additional resources to develop new tests and evaluate and deploy existing tests.

The work group concluded that measurement of recent infections has two broad purposes, population incidence rates, which are best measured by antibody tests, and individual recent infection, which is best measured by RNA and p24 tests. The group felt that both assays required operational research to assess appropriate population groups and issues regarding implementation and that surveillance programs at the international and national levels required capacity building to select appropriate populations and interpret results. The work group's recommended goals and objectives are summarized in Table 12.

* Dr. Stefan Wiktor, facilitator; Ms. Sheila Jain, rapporteur; Ms. Kimberly Marsh, presenter; Dr. J. Steve McDougal, lead author. Other work group members were Drs. Achara, Branson, Davis, Demby, Gershy-Damet, Martin, Parekh, Pilcher and Rayfield, Mr. Crippen and Mss. Mulenga and Suvimon.

Table 11. Work Group 1 discussion questions.

1. Which laboratory methods can be applied most readily and most efficiently in what parts of the world?
2. Are there existing samples that can be used to validate tests? If so, where are these panels? Are there anticipated future panels?
3. What samples can be used to apply incidence tests for public health surveillance?
4. What is the role of rapid test/dried blood spot?
5. What lessons have we learned from doing incidence testing for surveillance in different countries?
6. Given the impression of the incidence assays, are there minimal sample sizes or prevalence rates that should be used to guide the application of incidence assays?
7. What samples should be used to provide for a representative sample. How does application of incidence assays vary by type of epidemic? For example, in a generalized epidemic, should an incidence assay be applied to specimens collected from a DHS? What sampling methods should be applied to concentrated and low level epidemics?
8. What other information needs to be collected about the population that can potentially influence bias?
    - Frequency of testing (VCT), testing history, reasons for testing
    - Risk behaviors, timing of recent infections
    - Is population skewed by acute events
    - False positives from long term survivors
    - AIDS patients on treatment
    - Sexual risk behavior, sexual activity patterns of pregnant women
9. Are ANC populations appropriate for incidence measures? Would application of incidence assays to ANC data help in validating the use of prevalence trends in the youngest women as a proxy for incidence?
10. Are new incidence measures ready for “prime time”, in terms of:
    - Test parameters – accuracy, sensitivity, specificity
    - Application in various epidemiologic settings
    - What other criteria are necessary for it to be ready for prime time?
    - How do we build local capacity to these tests
11. What are the issues in building local capacity?
12. What ethical issues should be considered in applying incidence assays?

Table 12. Goals, objectives and activities, Work Group on Recent HIV Infection.

Goal 1: Promote the development of new tests to measure recent HIV infections

Objective 1.1: Increase the amount of funding available for test development; this would include identifying less expensive easier-to-use tests and specimen collection methods that would be applicable in resource-poor countries.

Activities:

- Identify possible existing research funds at U.S. National Institutes of Health, CDC
- Advocate for new funds from stakeholders (United States government, Gates Foundation, etc.)
- Conduct evaluation of dried blood spots for use in testing for recent infections

Goal 2: Promote validation and implementation of existing tests to measure recent infections

Objective 2.1: Facilitate evaluation of tests by establishing a collection of serum panels containing samples from persons with known dates of seroconversion; these panels should include all major HIV subtypes

Activities:

- Develop contract to fund collection of samples (recipients: US universities and country programs)
- Obtain cross-sectional samples from observational incidence cohorts
- Advocate for additional resources to expand number and diversity of panels for comprehensive test validation

Objective 2.2: Support the production, assessment of feasibility of use, and field evaluations of these tests in resource-poor countries

Activities:

- Fund and assist test validation: acceptability of methods, local capacity
- Fund production of non-commercial tests (BED assay) for evaluation purposes
- Assure that quality standards are maintained as test production is expanded
- Promote linkages and provide training to epi-surveillance staff (technical assistance providers and in-country staff) on issues around measuring incidence

Objective 2.3: Develop guidance and standardized procedures for in-country evaluation and deployment of tests for recent infection

Activities:

- Organize meeting to share experiences from initial field evaluations (Ethiopia, Malawi, Thailand, South Africa, Zimbabwe)
- Conduct operational research to identify appropriate population groups for incidence testing:
  a. Assess representativeness of population group to explain possible biases
  b. Characterize factors in tested groups that may impact generalizability of results at the population level
- Organize technical meeting to develop guidelines based on results of operational research for deployment:
  a. Define which tests for which populations
  b. Develop appropriate sampling framework
  c. Assess country capacity
- Develop QA systems

Session 2. General Population-Based Surveys

Dr. Ann Way of ORC Macro spoke on non-response issues in population-based surveys.[38] HIV testing has been done as a part of DHS or the AIDS Indicator Survey in a number of countries in Latin America and sub-Saharan Africa. In the late 1990s, an HIV/AIDS module was introduced in the DHS surveys. More recently, HIV testing has been incorporated in some countries into these surveys (called DHS+). Key elements of HIV testing in DHS+ surveys include a target population of 15-to-49-year-old women and 15-to-54-year-old men; informed consent; free VCT; provision of AIDS educational materials; and use of venous blood, salvia or dried blood spots for HIV testing. Results from these studies conducted in the Dominican Republic, Kenya, Mali and Zambia are shown in Table 13.

In addition to sampling methodology and approaches to HIV testing, there are a series of critical questions related to non-participation bias, which are critical to interpreting the results. This can be summarized by three key questions that needed to be answered in interpreting the seroprevalence results from these surveys:

- Who did the survey miss?
- How much does it matter that they were missed?
- What can we do to address coverage issues?

There are different ways in which the sample selection process can contribute to persons not being sampled, that is, "missing". Specific groups can be excluded from the sample frame, for example, persons in prison, in the military, away at school, in refugee camps or homeless. The sampling frame can be out of date, and there can be errors or other problems with the household listing or selection or in identifying eligible respondents. In addition to the sampling framework, there are multiple reasons why, once the sampling frame is chosen, an interview may not be completed. These include no competent person at home, refusals, the dwelling not being found, the household being absent, the dwelling vacant or the address not being a dwelling, the dwelling having been destroyed and others. As shown in Table 14, the proportion of interviews completed, the household response rate (the proportion of interviews completed of eligible dwellings) and the proportion of eligible men and women who completed the survey varied. There are many factors that will or could influence this. Some are inherent to the survey itself, like the sampling frame, the preparation of the survey, community mobilization, the training and supervision of interviewers and services provided; others can be cultural or religious in nature and still others that are entirely independent of the survey itself. In any case, careful preparation should be undertaken in order to ensure maximum participation and minimum bias. Especially noteworthy in these four surveys were the higher participation rates among women compared to men, much of which is due to men's absence from the household (Table 15) and higher participation in urban dwellings versus rural households. Refusal rates were lowest where Orasure® was used, as in the Dominican Republic, or where combined with anemia testing, as in women in Mali.

With regard to differential non-participation, missing persons matter only if they are systematically different than persons included in the survey with respect to HIV status. To address coverage rates, the DHS is documenting sample design and response rates and calculating sampling errors, supporting a special assessment of the impact of non- response on HIV seroprevalence data and reviewing HIV testing data-collection procedures, especially for males.

Table 13. HIV seroprevalence rates, DHS

	Dominican Republic, 2002	Kenya, 2003	Mali, 2001	Zambia, 2001-02
Women, 15-49	0.9	8.7	2.0	17.8
Men, 15-49	1.1	4.5	1.3	12.9
Total	1.0	6.7	1.7	15.6

Table 14. Participation rates in DHS, Dominican Republic, Kenya, Mali and Zambia.

	Dominican Republic	Kenya	Mali	Zambia
Households sampled	35,013	9,865	13,717	8,050
Interviews completed (%)	77.5	86.8	89.9	88.5
Household response rate (%)	97.9	96.3	97.9	98.2
Response rate among eligible women (%)	92.8	94.0	94.9	96.4
Response rate among eligible men (%)	80.5	85.5	83.8	88.7

Table 15. Participation rates by sex, DHS, Dominican Republic, Kenya, Mali and Zambia.

	Dominican Republic	Kenya	Mali	Zambia
Women				
Tested (%)	89.0	76.3	85.2	79.4
Refused (%)	6.5	14.4	8.6	15.7
Absent (%)	4.5	8.6	6.2	3.0
Number eligible	12,514	4,302	4,556	2,689
Men				
Tested (%)	80.9	70.0	75.6	73.3
Refused (%)	6.6	13.2	14.4	14.9
Absent (%)	13.5	15.4	10.9	8.1
Number eligible	14,456	3,924	4,302	2,418

Dr. Lawrence Marum of CDC GAP-Kenya spoke on logistical issues involved in the 2003 Kenya DHS.[39] There were five logistical challenges encountered in the survey:

- Coordination of field teams & partners
- Participant access to HIV results
- Balancing access, anonymity and autonomy
- Sample and data handling issues
- Community mobilization and support
- Individual participation and consent

The 2003 Kenyan DHS was the fourth conducted in Kenya but the first that included a full HIV/AIDS module and a seroprevalence survey. The survey was intended to measure Kenya's progress in meeting targets for the National HIV/AIDS Strategic Plan, and to validate sentinel surveillance results from ANCs. In the 1998 survey, only 15% had been previously tested but 65% of those who had never been tested were interested in learning their HIV status. The survey was a sample of 400 clusters with 8,889 households. The household and women's questionnaires included modules on AIDS, tuberculosis, malaria and domestic violence and anthropometric measurements for children. The survey included, for the first time, clusters in the remote, sparsely populated areas of the northern part of Kenya. There were 17 field teams covering 12 major language groups. In half of the households, all men aged 15 to 54 and all women aged 15 to 49 were interviewed and asked to provide capillary blood from a finger stick, collected on filter paper and dried in the field. VCT was organized according to national guidelines in all areas except Nairobi, which had nearly 40 certified VCT centers at the time of the survey. Two counselors were assigned to each team to provide services in temporary locations in the community during the survey. The teams had logistic challenges traveling throughout the country during part of the rainy season. In remote areas in the north they sometimes had to sleep in the vehicle or in tents, and one team hit a land mine while traveling in a convoy, killing the security officer.

Each of the 17 teams had a field supervisor who oversaw three sub-teams with different functions – an interview team of four female and one male interviewer and one editor, a health care worker who collected blood spots and the two counselors. There was only a single driver and vehicle per team, which tended to hamper efficiency in the field. A district statistical officer did the initial mapping of selected houses and planned the approach to each cluster. Overall there were 17 field team supervisors, 88 interviewers, 17 editors, 20 health workers and 35 VCT counselors assisted by 74 district statistical officers. Centrally, six staff from the Central Bureau of Statistics were responsible for overall supervision, coordinating the interview sub-teams and often transporting data and dried blood spots back to Nairobi. Six laboratory staff from CDC and the Kenyan Medical Research Institute ensured quality of dried blood spot collection, drying and storage and provided logistical support to the counselors. There were also six counselor supervisors, four staff that provided financial coordination and four others who provided general supervision.

The survey had many partners and donors, including the Central Bureau of Statistics of the Ministry of Planning and National Development, ORC-Macro, the Kenyan National AIDS/STD Control Programme of the Ministry of Health, the Kenya Medical Research Institute and CDC. USAID, the United Nations Development Programme, the U.K. Department for International Development, UNICEF and CDC were all donors. Despite thorough planning, coordination could have been improved through more frequent meetings, a long-term schedule of joint supervisory visits and a single mechanism for supplying money to the field, agreeable to all donors.

Improvements that could be made include a second full-time vehicle per team so that counselors are not dependent on District AIDS Coordinators for logistic support, better initial training of team leaders so that they have a better understanding of the roles and special needs of the VCT counselors and health workers, better links with community and district leaders and improving the efficiency of financial transfers with a single mechanism. A final note was that cellular telephone links were critical for communication.

A second discussion focused on balancing access, anonymity and autonomy in participants and the importance of ensuring that HIV test results were available to participants and to their communities. The survey's goals were to preserve participant autonomy, to ensure them proper information and easy access to counseling and testing and to preserve their anonymity so that their personal information was protected. The five questions considered were:

- What type of sample and test strategy?
- Who will collect the sample?
- Will results be anonymous or confidential, linked or un-linked?
- How, when and where will participants learn their HIV status?
- How will the integrity, anonymity and quality of this information be maintained?

To meet the ethical requirement of providing HIV results to the survey participants while preserving confidentiality and autonomy, survey organizers first considered using rapid HIV tests in parallel to provide results in the home for consenting adults but were concerned about preserving confidentiality in crowded village homes and protecting participants from coercion or violence. This left the option of referring patients to VCT sites for blood draws and counseling. However, despite rapid scale up of VCT in Kenya, it was felt that referring participants to existing VCT sites would not be adequate as half of the districts and at least 250 of the enumeration areas did not have easy access to a site. Referral turned out to be useful only in Nairobi. For the bulk of the survey, a third option was chosen, which included adding two VCT counselors to each of the other 16 teams. These counselors set up a temporary VCT site in or adjacent to the enumeration cluster and provided services for both participants and others in the community. They remained there until the final callbacks in the enumeration areas were completed, usually one week. In each district and enumeration area, the team leader, the counselors and district and local leaders selected the site. Importantly, both participants and other members of the local community could use the temporary site.

The health workers obtained informed consent from those selected for dried blood spot testing and explained that there would be no linkage between their name and the blood test result. A brochure was given to participants to explain about why it is helpful to learn HIV results and the process of VCT. They were also told where they could get VCT services in their village during the time the study team was in the area but also that they could learn their HIV results through two tests done by the counselor in less than one hour. A voucher would ensure that the testing was free, and they could also go to any of the other testing sites in the province, which were listed in an insert given with the brochure. The brochure, voucher and insert were also provided to households not selected for dried blood spot testing.

The facilities and equipment were simple and included a table and three chairs, which were requested from the local leaders. The counselors carried all other supplies and equipment in backpacks, including forms, logbooks, condoms, a penis model and a sharps container. Two test kits were done in parallel by

finger stick, as is the national standard. A third rapid test was used as a tiebreaker if the first two were discordant. For every tenth client a filter paper specimen was collected for later validation in the central lab.

In all 10,089 individuals, including both participants and non-participating community members, received their results from mobile voluntary testing and counseling sites. Of the 10,089, 6,617 were male, and 3,472 were female. Prevalence in the mobile sites among men was 5% and among women 13%, which was similar to those participating in the survey among men (4.5%) but higher among women (8.7%). Even when there were pre-existing nearby sites, some attendees stated a preference for counselors from outside the community. Cost was less than $20 per client who learned their results, about a third higher than fixed VCT services.

A third area with many logistical implications relates to the type of sample collected for HIV testing. With venous blood, as was done in Zambia, multiple tests such as syphilis and *Herpes simplex* virus type 2 were run, but there were logistical challenges, such as phlebotomy in the field, how to promptly separate serum and refusals specifically because of phlebotomy. Dried blood spots, which were chosen in Kenya, offer advantages in the field and were acceptable to most participants. Filter papers are dried overnight and may remain at room temperature for a month, allowing collection every few weeks, but there are limits to the type of tests that may be run, and long-term storage takes significant space. Oral fluid collection systems such as Orasure®, which was used successfully in the Dominican Republic, also offered advantages but required shipment for testing in the United States. In future surveys in Kenya, rapid tests (oral or whole blood) may be utilized in the field, though this was ruled out in this survey because of the difficulty in maintaining privacy and confidentiality in a small or crowded household.

Handling laboratory data to assure confidentiality also included some logistical issues. A bar code on the sample and interview control form provided a temporary link. The dried blood spot and questionnaires were logged in at the Central Bureau of Statistics with only a bar-code identifier, and the dried blood spots were transferred to CDC and the Kenya Medical Research Institute. Samples were eluted and tested first with the Vironostika EIA, then all positives and 10% of negatives re-tested with the Enzygnost EIA and discrepant specimens tested by Western Blot. Laboratory and interview data were stored in separate physical locations at the Central Bureau of Statistics and CDC offices within the Kenya Medical Research Institute. Only after household cluster and district identifiers were removed, ORC Macro used the control forms to create a merged file with the laboratory results. Control forms are housed in a third protected location and will be destroyed after final merger of the de-linked data.

Mr. James Muttunga of the Kenya Medical Research Institute then discussed community and participation issues in the Kenyan DHS survey. Adequate publicity, ownership and support of communities are necessary for survey acceptance, especially where stigma is high. This is best accomplished with the support of provincial and district administrators and political and civil society leaders, who in turn look for top-level political support and national publicity before assenting. Local chiefs should be informed through these leaders, but they should also be approached directly before the team begins work in the community to secure “community consent”. Field operations should be put on hold until suspicions among community members are cleared to avoid community refusal, as individual acceptance is dependent on community approval. With improved community mobilization and better publicity rates of refusal and missing fell from >20% to about 10%, and rates of finding women and men at home also improved from the first to the third and fourth months of the survey.

Overall, 24% of eligible women and 30% of eligible men were not tested. The higher rate of not being tested in men (15%) compared to women (9%) was due to an inability to locate them for the survey despite three callback visits. These rates were especially significant in urban residents, where less than 60% of men were tested. Five percent of eligible men and women were interviewed but not tested. This may be an organizational error because there was only one health worker on each team, and one recommendation was that there be a second health worker per team so there is no time lag between interview and blood taking. Refusal rates were 14% for women and 13% for men, with higher refusals in urban areas. The survey found a 1.8:1 female-to-male HIV seroprevalence ratio with some differences among regions. Participation bias, especially among the men who were never found and the men and women who refused, is a definite possibility in the survey and will be examined closely when behavioral and sociodemographic data are linked with HIV results.

Other issues affecting participation included confusing testing conducted as part of the survey with testing at the mobile VCT sites, community prevalence and knowledge of people with AIDS, cultural beliefs about not giving blood samples to unknown persons and the negative influence of witchdoctors and traditional healers.

In conclusion, population-based HIV prevalence surveys provide a more balanced estimate of national and regional estimates and validate sentinel surveillance. However, logistical issues in successfully fielding and completing one of these surveys are daunting, and piloting, pre-testing and training are critical and must precede the main surveys to identify problems and refine the field operations. An important part of this is the early sensitization of sampled households and individuals by the survey team and the involvement of provincial administrators and local leaders. Surveys must be publicized through public meetings and mass media communication and need top level government and political support to promote acceptance. In approaching a community, survey teams should gauge how local leaders understand the survey's objectives because participants need to see support from their leaders to support and participate in the survey. Field operations should be put on hold until suspicions among community members are cleared to avoid community refusal as individual acceptance is dependent on community acceptance. Ideally, sample collection should include screening for multiple diseases and not solely HIV to reduce the stigma associated with HIV testing. A unique feature of this survey, the mobile VCT sites, appeared to be generally acceptable and even preferred by some. Some communities had high stigma and low uptake whereas others with higher prevalences had an overwhelming response, demonstrating an unmet need for VCT. The mobile sites allowed more than 10,000 participants and their neighbors to learn their HIV status anonymously, with quality counseling and confirmed test results. The mobile VCT met both met the ethical requirements for survey and provided an important service to these communities.

In the analysis phase of the study, some additional technical issues remain. These include how to adjust estimates for urban and slum cluster areas with high refusal and absence rates, how to adjust estimates for high-risk groups that refuse blood samples and how to adjust the household estimates to account for youths 15-20 years who are in school during the survey. It may be necessary to provide addition weighting from some of these data to improve on the national and regional estimates.

Mr. Lovemore Kaetano of the Tropical Disease Research Centre in Ndola, Zambia, discussed field experiences from the Zambian DHS.[40] The Zambian DHS was conducted in 2001 and 2002 and was designed to provide information on population, family planning, maternal and child health, child survival,

HIV/AIDS, STIs, reproductive health and nutrition. It was comprised of 9,803 randomly selected 15-to-49-year-old women and 15-to-59-year-old men, who were questioned about their background and health-related issues such as reproductive health and family planning. Other information relevant to policy makers and health planners was obtained through administration of a structured questionnaire. The objectives of the survey were to collect up-to-date information on fertility, infant and child mortality and family planning; to collect information on health-related matters related to mothers and children; to generate information for decision making by health policy makers and planners; and to document current epidemics of STI and HIV/AIDS through use of specialized modules.

Interviewers administered questionnaires to men and women in households. Other personnel included laboratory technicians, nurses, field supervisors, field editors, drivers and auxiliary staff. Personnel were trained with particular attention to ensuring adherence to survey protocols, observance of ethical issues, sound data and blood collection techniques and accurate specimen processing and testing. Roles of the survey staff were as follows:

- Interviewers facilitated the identification of eligible survey participants from selected survey clusters and interviewing all eligible survey participants
- Nurses administered the informed consent and collected blood samples from survey participants
- Laboratory technicians processed blood samples, tested specimens for syphilis by rapid plasma reagin (RPR) and prepared dry blood spots for HIV testing at reference laboratory
- Supervisors provided overall supervision for the survey team
- Drivers transported survey staff and materials for use in the survey to selected mapped areas

Laboratory specimens were processed in the field and stored in liquid nitrogen for three to four weeks before being transported to Ndola. Field laboratory equipment included liquid nitrogen tanks, blood collection instruments, RPR test kits, a hand centrifuge, camp chairs and table, cool boxes with cool packs and a four-wheel-drive vehicle.

Each of the nine provinces in Zambia had a full DHS team, and bigger provinces, such as Copperbelt, Northern and Lusaka Provinces, had two teams. The sample was based on standard enumeration areas, the lowest administrative unit in Zambia* and was stratified into urban and rural districts. Each primary sampling unit, or cluster, required a minimum requirement of 85 households. The number of clusters in each district was not allocated proportionally to the total population due to the need to present estimates by each of the nine provinces. Based on the level of non-response from the 1996 survey, to achieve this target, approximately 8,200 households were selected. In each province there was a minimum target of 750 completed interviews, distributed proportionately among urban and rural areas.

The sample was selected using a stratified two-stage cluster design of 320 clusters, 100 in urban and 220 in rural areas. Once the number of households was allocated in each province by urban and rural areas, the number of clusters was calculated based on an average sample coverage of 25 completed interviews among women 15 to 49 years. In each urban or rural area in a given province, clusters were selected systematically with probability proportional to the number of households in each cluster. The sampling was felt to be excellent largely because of the complete coverage of the very recently conducted 2000 census and experience with the 1996 DHS.

* Zambia is divided into nine provinces, which are in turn divided into 72 districts, 150 constituencies, 1,289 wards, 4,400 census supervisory areas and 16,400 standard enumeration areas. Census supervisory areas and standard enumeration areas were developed during the 2000 nationwide census.

Challenges were multiple and included:

- Blood collection, which was being done for the first time in many areas and needed to be explained carefully to help participants understand the objectives of the study
- Accessibility to remote areas, some bordering on the impassable
- Logistical issues such as procurement of sufficient supplies for the survey
- Training of the survey staff
- Financial constraints given the huge budget of the survey
- Maintenance of the cold chain for the serum/plasma collected for syphilis confirmatory testing at reference laboratory
- Storage of temperature sensitive RPR syphilis testing kits
- Performing RPR testing in field laboratories
- Ensuring that the data were correctly entered
- Refilling liquid nitrogen tanks that were used for sample storage and transportation to reference lab

Secrets to success included hard work and commitment, team work, governmental and political will, communication at all levels to solve emerging issues and problems and good leadership.

Dr. César Cárcamo of the Universidad Peruana Cayetano Heredia spoke on a household-based general population survey of risk behavior, HIV and STI in Peru.[41] This survey was conducted by university-based groups at the Universidad Peruana Cayetano Heredia, the University of Washington and Imperial College in partnership with the Peruvian National Institute of Statistics and Informatics, the Peruvian STD and HIV Control Program in the Ministry of Health and the United States Naval Medical Research Center Detachment in Callao, Peru. Funded by the Wellcome Trust, this was a community-based randomized trial to test the impact of a hybrid STI and HIV prevention intervention. The intervention included strengthening pharmacy- and clinician-based syndromic management of STIs,[42,43] screening and treatment of STIs coupled with condom promotion[44] and social marketing of condoms for casual and commercial sex.

As part of a baseline assessment for the trial, data on STI prevalence and risk behaviors and the structure of sexual networks were collected through a general population survey. Twenty-four (80%) of the 30 Peruvian cities with populations greater than 50,000 inhabitants were selected for the survey. In each city, a random two-stage cluster household sample of 250 men and 250 women and a consecutive sample of 50 male sexual partners and 50 female sexual partners was selected in each city. This was done by first conducting a census in the selected clusters to identify households with eligible members, selecting a random sample of households with at least one eligible member and within the selected households selecting the eligible member with the most recent birthday. Inclusion criteria included men and women from the ages of 18 to 29 years old who lived with sex partners 18 years of age or older and who had been residents of the selected city for at least six months prior to the survey. Consenting participants completed a face-to-face demographic questionnaire and a self-administered sexual behavior questionnaire. Approaches to assure participants of the confidentiality of their data and hence better responses included a "voting booth" for taking the self-administered questionnaire, bar codes for questionnaire identification and a locked bag for turning it in once completed.

Participants were asked to provide blood or, if unwilling, oral fluid. Men were also asked to provide urine, and women were asked to provide self-administered vaginal swabs or, if unwilling, urine. Serum

samples were used to detect syphilis and HIV, oral fluid samples to detect HIV using OraSure®, urine for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* using the Roche Cobas Amplicor NG/CT® PCR and vaginal swabs for *N. gonorrhoeae*, *C. trachomatis*, *Trichomonas vaginalis* and bacterial vaginosis using Roche Cobas Amplicor NG/CT® PCR, InPouch TV® and Gram stain to determine Nugent's score.

Of 16, 867 persons eligible to participate, 15,259 (90.5%) agreed to. Additionally, 2,347 (88.1%) or 2,663 sex partners agreed to participate. Questionnaires were returned by all but 176 (1.2%) of the participants. Eighty-four percent provided blood or oral fluid, 87% of men provided urine and 84% of women provided a vaginal swab or urine. Median age at first intercourse was 18 years for women and 16 years for men; women had a median of one lifetime sex partner, and men had three. Twenty-eight percent of sexually active men and 12% of sexually active women reported initiating sex within one month of meeting their last partner. Thirty percent of women and 15% of men reported believing that their last sex partner had another sexual partner. For 33% of men but only 6% of women the last sexual partner was reported to be a casual partner, and 88% of these women and 76% of these men reported that they did not use condoms consistently with casual partners. Forty-four percent of women reported having had intercourse with a female CSW, and 55% reported that they did not use condoms consistently with CSWs. Only 3% of women reported exchanging sex for money or favors with their last sexual partner. With regard to same sex behavior, 12% of men reported ever having had sex with another man, and 6% reported having had sex with another man in the past 12 months. Sixty-eight percent of these men reported not using condoms consistently with male partners.

STI and HIV prevalence rates are shown in Table 16. Rates of chlamydia were highest among 21-to-25 year olds. Risk factors for syphilis among the 55 men who tested positive were older age, having any of the last three sexual partners male and low educational level and for the 52 women older age and low educational level. Risk factors for the 17 men with gonorrhea included having any of the last three sexual partners male, unprotected sex with a female CSW and low educational level. Risk factors for HIV among the 22 men who tested positive were having any of the last three partners male and for the three females having been paid for sex by any of the last three sexual partners. Risk factors for the 399 women who tested positive for chlamydia included younger age, having a new sexual partner in the past 12 months and low educational level. Lastly, risk factors for trichomoniasis in the 308 women who tested positive were having a new partner in the past 12 months and low family income.

Table 16. STI and HIV prevalence rates by gender, Peru

	Women	Men
Syphilis	0.9% (0 -3.4)	1.0% (0 -5.2)
Gonorrhea	0.8% (0 -2.5)	0.3% (0 -1.3)
Chlamydia	6.8% (3.4 -11.4)	4.0% (1.1-7.9)
Trichomonas	5.2% (1.3-15.4)	NA
Bacterial vaginosis	25% (10-37)	NA
HIV	0.1% (0 -0.4)	0.4% (0 -1.9)

Ranges among cities in parentheses. NA, not applicable

In conclusion, this baseline survey documented a number of risky sexual behaviors among sexually active Peruvians including a high frequency of sex with CSW, a low frequency of condom use with casual partners and CSW and a high percentage of men having unprotected sex with men. Overall, HIV is more frequent in men and chlamydia is more frequent in women. This was the first general urban population random household sample with comprehensive STI and behavioral measures to be conducted in Peru and demonstrates that such studies are feasible and will have high participation rates.

Factors contributing to its success included collaboration of multiple institutions, the participation of the National Institute of Statistics and Informatics, university participation, careful attention to training and supervision, participation of local resident health professionals as interviewers, providing participants with information and confidentiality protections such as self-administered questionnaires, voting booths and locked bags.

Discussion

In response to a question about levels of mistrust, item non-response and the potential for computer-assisted interviewing techniques, Dr. Way said that there was typically not a high level of refusal on behavioral questions. Also there had been some experimentation with computer-assisted interviewing, but it increased costs markedly in large surveys. The point was made that the UNAIDS epidemic classification system should be used when planning surveys. General population surveys are needed only in generalized epidemics, and there should be clear guidelines about when to use general population surveys. Dr. Way responded that DHS was under pressure to include HIV testing in low-prevalence countries, but their basic stance is not to do it unless there is a generalized epidemic. Additionally she said that DHS recommends doing the HIV unit only once and not repeating it. A question was asked about the cost of HIV testing in the DHS. Dr. Way replied that if testing for anemia is already being done, the costs are minor for training and equipment except for scaling up community-based VCT, as was done in Kenya, and testing for syphilis, as was done in Zambia. Dr. Marum added that out of a total budget of $2.2 million USD for the Kenyan survey, which did not include testing for anemia, VCT cost approximately $200,000 USD and health workers cost an additional $150,000 USD, or together less than 20% of the overall cost of the study. Dr. Kaetano added that syphilis testing in Zambia led to much higher costs. Dr. Marum was asked about the percentage of survey participants that also accessed the mobile VCT sites in Kenya. While there were not consistent data from the mobile centers, he estimated that about 25% of participants also accessed VCT.

Regarding the discordance between rates measured in the Kenya DHS and those estimated from ANC data, Dr. Marum responded that there the general population rates both nationally and by province were fairly close to estimates based on ANC serosurveillance. The new information was on the female-to-male ratio, which was measured at 1.8:1, which may mean that there are fewer infected males. A comment was made that in the UNAIDS four-city study, the female-to-male ratio in Kisumu was 1.5:1. Another comment was made about problems with the media release of the Kenyan data, but the survey was supportive of estimates for prevalence in women derived from sentinel serosurveillance but not in men. A further comment was made that the Kenyan DHS will contribute to callibration of HIV estimates from ANC serosurveillance.

Another group of questions dealt with community concerns and how institutional review boards dealt with community concerns. In addition, a question was raised regarding the level of field laboratory support that was provided in this study where counselors who provided field VCT services also conducted HIV testing for the survey. Dr. Marum responded that surveys provided for individual consent; however, in communities that did not support the survey, response rates were low. In response to a question regarding the level of support provided for VCT services, Mr. Muttunga noted that a team of supervisors from Nairobi were assigned to study teams and reviewed specimen collection procedures and VCT services to ensure that the HIV test never left the presence of the client during the VCT procedures. Mr. Kaetano mentioned that in Zambia they experienced few problems in specimen collection because counseling was detailed, one-on-one with a trained nurse, with benefits of the procedures fully explained to participants. Further, he remarked that collaborations with other agencies and community awareness of national surveillance programs were effective in mobilizing the community to participate in the survey.

Dr. Peter Ghys of UNAIDS commented regarding the use of general population-based surveys in low-level and concentrated epidemics. Costs were not only financial but also in the confusion caused by the data created, and clear recommendations are needed about when to use this method. The generalized epidemic threshold (>1% seroprevalence in women attending ANCs) might not be the threshold at which general population-based surveys become useful; it may actually be higher. Finally, he summarized the presentations by saying that the DHS was not so great for making HIV estimates in men. Dr. Txema Calleja of WHO added that there were some data in a recent study in Cameroon that suggested seroprevalence was five times higher in men absent from the home and traveling for more than one month. Those absent may be populations with higher risk behaviors such as the military, long-distance truck drivers and businessmen.

Work Group 2 focused on the issues discussed in Session 2.[*] It was asked to discuss a series of questions dealing with the utility and conduct of general population-based surveys (Table 17).

Table 17. Work group 2 discussion questions.

1. At what expected prevalence are general population based surveys useful (or when is the prevalence so low that this type of survey is not worth the effort)?
2. What are the costs of these surveys?
3. Should test results be returned to participants and how?
4. What data are needed to interpret bias (e.g. what do you need to know about non-respondents or those who refuse testing)?
5. What sampling strategies are most useful?
6. How can these data be used to adjust national estimates?
7. How frequently should these surveys be done?
8. What are the best laboratory procedures to avoid cold chain problems, minimize costs, be simple to collect and have some type of QA?
9. How much data can be linked to HIV test and how can confidentiality be best protected?

[*] Dr. Txema Calleja, facilitator, presenter and lead author; Dr. Andrea Kim, rapporteur. Other work group members were Drs. Cárcamo, Kirungi, Masupu, McNaughten , Mukthar, Pun-Chinarro, Somi and Way; Professor Pandey and Messrs. Bicego, Kaetano, Magis and Muttunga.

Work Group 2's discussion initially focused on the utility and use of population-based surveys, which the participants felt need to be assessed carefully by countries. National HIV population-based surveys are not part of the surveillance system but rather close gaps in HIV surveillance data (e.g., male-to-female ratios; urban-to-rural distributions). If countries do decide to implement population-based surveys, core indicators should be provided to facilitate the implementation of the survey.

There was general agreement that HIV population-based surveys should be conducted in countries with generalized epidemics. It was also felt that the threshold of 1% used for generalized epidemics was too low to recommend population-based surveys. However, there was no agreement as to which level of infection to use, although some proposed that population-based surveys could be useful if ANC prevalence rates are 5% or higher.

There was also general agreement that, whenever possible, HIV population-based surveys should be linked to individual questionnaires like in Kenya and Peru as these surveys can provide much richer information regarding risk for HIV. However, they need to be done in ways that assure anonymity and confidentiality. There was a consensus that HIV sentinel surveillance systems should be evaluated regularly, taking into account different information sources for HIV serology in the country, including national HIV population-based surveys and data from VCT and PMTCT programs.

National HIV population-based surveys contribute to a more accurate estimate of HIV prevalence in the country, but it is important to calibrate survey results with HIV sentinel surveillance data. Community participation and mobilization are key elements to increase response rates in population-based surveys, and how countries address this should be explicitly documented. Specifically, a clearer understanding of absence in population-based surveys and its relation to HIV prevalence is needed. Analyses on

In a question and answer period following the presentation of these recommendations, a question was asked about whether countries could do these surveys on their own or not. Dr. Calleja answered that they needed to be familiar with the surveys but were not in a position to make decisions regarding appropriations. A second series of questions were asked about the appropriateness of general population-based surveys in low-level and concentrated epidemics. It was pointed out that non-response bias will have a larger effect in low-level and concentrated epidemics than in generalized epidemics and that the need in low-level and concentrated epidemics is to focus on high-risk groups. Quantitative recommendations on non-response bias need to be generated. A question was asked why not have recommendations to conduct one national baseline behavioral survey without HIV data in low-level and concentrated epidemics. In higher-level epidemics these could be repeated every five years and be augmented by behavioral surveillance in high-risk populations. He ended by pointing out the need to link scientists in national AIDS control programs with appropriate behavioral science expertise.

absence and refusal should be conducted on population-based surveys that have already been implemented.

The work group's recommended goals and objectives are summarized in Table 18. Some recommendations were to undertake specific actions to understand better the results of the new

Table 18. Objectives and activities, Work Group on General Population-Based Surveys.

Objective 1: To have a better understanding of HIV epidemiology in a country

Activities:

- If countries are going to implement HIV population based surveys, they need to revisit sentinel surveillance data
- Document field experiences in national population-based surveys from countries that have already conducted population-based surveys
- Assess if the country needs to undertake a national HIV population-based survey to balance the costs (both financial and non-financial) and benefits of surveys
- Document the issues in conducting HIV national population-based surveys to ensure standards of quality and develop guidelines for ensuring quality
- Document field experiences in community mobilization based on country's experiences
- Document field experiences on the number of health personnel needed to be trained for population-based surveys
- Conduct population-based surveys in countries with relatively high prevalence of HIV. Results from HIV population-based surveys have extreme variations in low prevalence settings. The survey should be adequate to the situation of the country.
- Determine the age criteria of participants based on the objectives of the survey; should be a minimum of 18 years
- Combine surveys with HIV serology if appropriate
- Evaluate which population-based sampling strategy is more adequate and cost effective for the country
- Consider oversampling strategies if information is needed for specific groups (e.g. youth, hidden populations, geographical areas)
- Develop appropriate testing algorithms appropriate for the types of samples (e.g., serum, saliva, dry blood spot)
- Undertake an ethical review process of the protocol by national institutions
- Undertake further analysis on absent or non-response participants
- Calibrate the results of HIV population-based surveys with sentinel surveillance, especially in rural areas
- Undertake a comprehensive analysis of all existing HIV surveillance data in the country
- Report a minimum core of information needed to understand the meaning of the data (e.g. how many tested, accepted, non-response, QA of lab testing, quality management systems)
- Increase national capacity to conduct and analyze HIV population-based surveys
- Develop training modules on the analysis of data
- Use qualitative studies to understand non-response issues
- Ensure community participation and mobilization to increase response rates
- Store samples for possible future testing for other biomarkers
- Ensure the highest quality of survey. Better to have no survey than a bad survey.
- Compare HIV sentinel surveillance among ANCs to HIV population-based surveys

Objective 2: To collect information to monitor national strategic plan and evaluate achievements regarding national and international targets

Activities:

- Combine HIV population-based surveys with behavioral components and other possible indicators as needed
- Facilitate access to the survey data for interested parties upon request
- Facilitate timely access to the survey results for national institutions and international agencies
- Develop a communication package to maximize the information collected from the HIV population-based survey
- Complete the reports with interpretation and meaning of the data and provide guidance on how to use this information
- Ensure that the data collected is pertinent and adequate to evaluate the response for National AIDS programs
- Use HIV population-based results to improve the precision of the HIV estimates
- Ensure that HIV population-based surveys have prevention components integrated into their design

population-based surveys, while others were made as general recommendations for countries that intend to undertake HIV population-based surveys.

Session 3. Linking Behavioral and HIV Surveillance

The first speaker was Ms. Basia Zaba of the London School of Hygiene and Tropical Medicine who spoke on methodological issues and practical experiences in measuring sexual behavior and HIV trends.[45] HIV sentinel surveillance and behavioral surveillance are different. They have different approaches and different problems. Sentinel surveillance is mainly based in facilities, aims to be nationally representative, is repeated annually, collects minimal background data, uses anonymous unlinked testing and has international standards of design and conduct. In contrast, behavioral surveillance is based in households, schools, hot-spots and snowball samples; the investigator is lucky to get anyone to participate; they are cross-sectional in design; they collect rich background detail and the instruments vary. Sentinel surveillance has one series of questions and problems that it must face about representativeness of facilities and subjects; behavioral surveillance has another set. How do you get people to tell the truth? What aspects / timing of behavior should be measured? Is partner or network information needed?

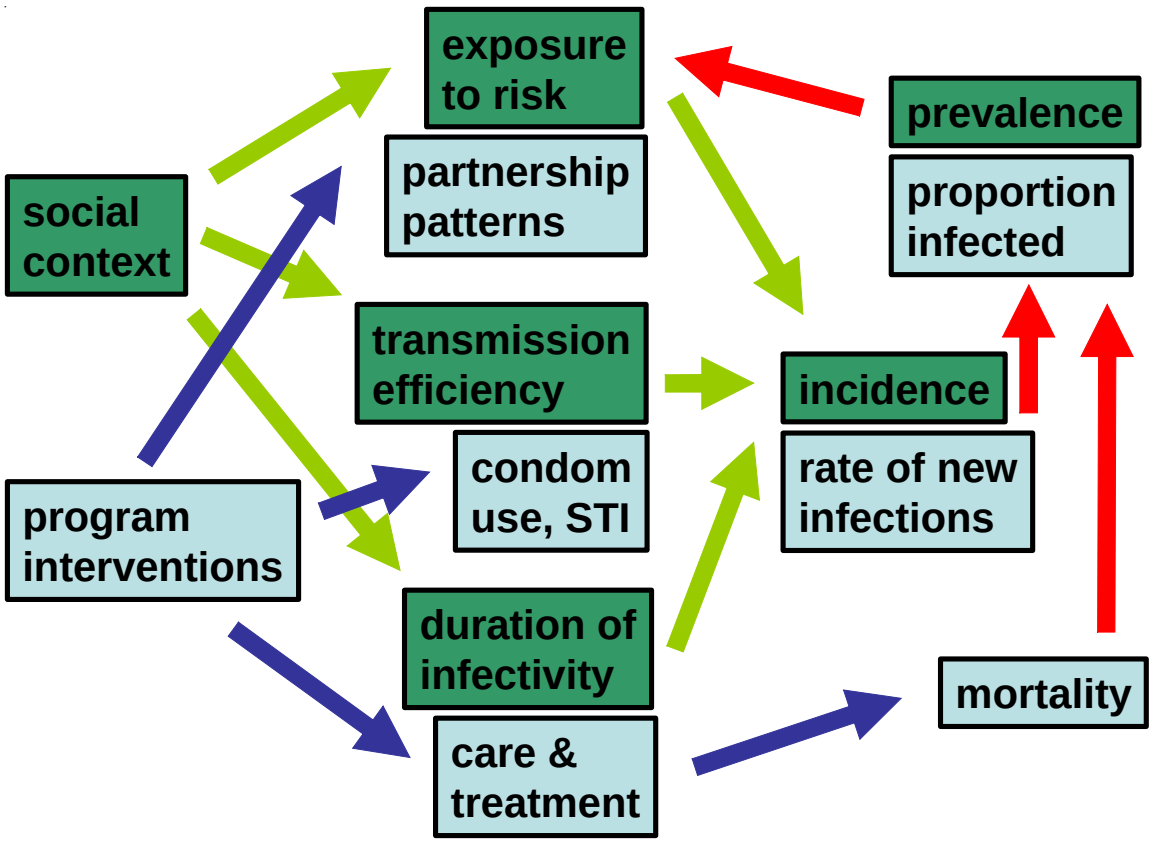
Linking biological and behavioral surveillance, or "triangulation", provides mutual support from shaky foundations, dispels other people's myths, guides interventions and strengthens advocacy. The data are complementary; behavioral data help explain the spread of HIV. However, reverse causality and confounding can obscure true links. This is because triangulation relies principally on community-level linkages that make use of different data sources collected at different times, and which can be affected by selection effects and coverage of different sources. The ideal solution, linking data at the

individual level, involves simultaneous collection of biological and behavioral data and is expensive, difficult and ethically challenging. The bottom line is that surveillance is the wrong tool for theoretical research. Linking data at the level of individual through the simultaneous collection of biological and behavioral data, the relationship between behavioral antecedents and HIV status can be seen. In contrast, when data are linked at the community or facility level using different data sources, the relationships that can be seen are that programs are associated with outcomes, and average behaviors are associated with HIV prevalence.

Time scale is important in linkage studies. Recent behavior, such as number of partners in the last year or condom use at the last sexual intercourse, leads to current status, i.e., prevalence. Lifetime behavior, such as age at first sex, also leads to current status, i.e., HIV prevalence. Behavior change leads to change in status or prevalence as measured over two or more rounds of data collection. In each case the critical issue is to identify behaviors that occurred before infection.

A causality model of HIV transmission can combine elements of social context and program interventions as the most distal factors, which in turn was influenced by risky exposures, itself a function of partnership patterns, transmission efficiency (including condom use and STIs) and duration of infectivity (which is presumably affected by care and treatment) to produce incident cases, prevalent cases and mortality.

Figure 17. Causality model of HIV epidemic dynamics.



The focus of our measurements, prevalence, is fairly removed from the factors influencing transmission and is itself influenced by things we do not measure, such as mortality (Figure 17).

Given the complex nature of HIV transmission, links can be obscured. For example, a sexual partner's past and current behavior is as important as that of the interviewed person. Because of the probability of choosing an infected partner as prevalence rises, background prevalence may be more important than individual behavior as a determinant of HIV status. Also epidemic momentum may have much larger effect on community prevalence than changes in sexual behavior. Better behavior can, in fact, look bad. For instance if an HIV-infected person starts using condoms, there will be a strong association between condom use and HIV infection. If casual discordant partners get married, there will be a finding that discordant couples have more frequent intercourse. These are both examples of "indicator tyranny". In particular, national-level indicators need nationally representative surveys, but even then some surveys cannot measure UNGASS indicators. In fact, UNGASS and ABC indicators are in fact not the best measures of behavior change. An example of this is in data from Tanzania, where the proportion of virgins is buried in UNGASS indicators.

In conclusion, there were some straightforward recommendations: choose the right indictors, repeat rounds to measure change, allow for background prevalence and focus on recent infections. A feasible recommendation is to link biological and behavioral data at the level of the individual. Finally, asking about partner behavior and linking individuals' behavior between rounds is research, not surveillance, and should only be pursued in a research context.

Mr. Mark Urassa of the National Institute for Medical Research in Mwanza, Tanzania, discussed HIV prevalence and sexual behavior trends in an ANC setting in northern Tanzania.[46] A series of studies undertaken in the Kisesa ward in the Mwanza region of Tanzania, which borders Lake Victoria, include a cohort study of factory works from Mwatex, conducted between 1991 and 1996, the Kisesa community-based cohort, begun in 1994 and still ongoing, and an extended ANC surveillance experiment conducted in Mwanza and Magu from 2000 to 2003. In the ANC experiment, baseline data were collected in 2000 and 2001 and follow-up data in 2002 and 2003. The survey was based on a 100% sample of women with a first-time ANC visit during a three-month period in each year. Unlinked and anonymous testing was done on residual syphilis serologies using dried blood spots. VCT was available nearby, and there was no PMTCT program in place yet. The standard sentinel serosurveillance questionnaire was modified to included clinic attendance, current residence and mobility, socioeconomic background, pregnancy history, marital history, sexual behavior in the last 12 months, partners' sexual behavior, family planning use and signs and symptoms of STIs. Overall 7,052 women were tested in both rounds, 3,197 at baseline and 3,855 at follow up.

HIV prevalence was lowest in rural areas, next lowest in urban areas and highest in roadside areas and cities. There was a small increase in prevalence between rounds except in Mwanza city, where there was a small decline. Among women less than 25 years old, median age at first sex was 16.5 years at both baseline and follow up, and having ever used a condom increased from 13.0% to 16.1% between the rounds. On multivariate analysis risk factors for HIV infection among women less than 25 years old included having a mother who had non-monogamous sexual partners, ever having used a condom and living in a roadside area, town or city compared to a rural area. Being sexually active for less than one year was significantly protective. Interestingly, socioeconomic factors were not significantly associated with HIV risk when residence was controlled.

In conclusion, although women attending ANCs are prepared to answer questions about sexual behavior, the relationship between sexual behavior indicators and HIV prevalence at the clinics was not clear-cut. In comparing ANC results with results from the Kisesa community-based survey, HIV prevalence levels were in close agreement, but higher levels of non-monogamous partners were reported by women in the ANCs than in community. A possible explanation is that unmarried mothers often marry after the baby is born. A plausible relationship was found between individual sexual behavior and HIV status, and there were no significant clinic-level relationships.

Dr. Txema Calleja of WHO spoke on operational issues related to linking behavioral and biological surveillance.[47] The European Commission has funded second-generation HIV/AIDS surveillance activities from 1999 to 2003 with a goal of improving the sustained production, collection, analysis and interpretation of HIV/AIDS, STI and risk behavior surveillance. Projects have been funded in Burkina Faso, the Dominican Republic, Mexico, Mozambique, Myanmar, Nigeria, Tanzania and Vietnam. The projects have been specifically designed to reach in-country consensus on strengthening HIV surveillance through the development of a national plan. There is an emphasis on country ownership as opposed to a package and on testing through pilot studies. The projects include national AIDS control programs, local partners, the UN, bilateral donors and other agencies, such as FHI and CDC. Another emphasis has been sustainability either through national funds or external funds for monitoring and evaluation.

In each country, protocols were developed for both biological and behavioral components of second-generation surveillance. Design-phase issues included unequal quality of protocols, with biological surveillance protocols generally being better than those for behavioral surveillance, insufficient plans for analysis and triangulation, an overly lengthy process, the lack of continuity and limited expertise at the national level. As a result, there were some delays and difficulties in implementation due mainly to administrative issues, limited expertise or experience in the country. On the good news side, HIV surveillance based in ANCs was relatively easy, and the protocols improved. However, for behavioral surveillance, there was a lack of tools and instruments and a lack of expertise in national AIDS control programs. There was a persistent imbalance between the behavioral and the biological components of second-generation surveillance; most of the time the two components ran separately, and triangulation was not performed. A further issue was timing between behavioral questions and HIV serology.

Nevertheless, synergies were created, such as capacity building workshops, or used, including cooperation with other national or international institutions, use of common material, monitoring and evaluation and others. The project provided good opportunities for improving existing systems or upgrading experience, including the first experience in population mapping in behavioral surveillance in Latin America and the Caribbean. Also the project was able to accomplish innovations in some countries and overall was able to boost HIV surveillance act ivies within the framework of second-generation surveillance.

In conclusion, the second-generation surveillance concept was accepted and disseminated. Overall, countries' systems were reinforced despite the limited technical capacity for behavioral surveillance in countries' national AIDS control programs. However, in the context of limited resources, it is difficult to sustain interest and participation of all parties throughout the entire process. Nonetheless, there seems to be an interest in developing a more integrated analysis of different data sources in countries. Finally, the context of surveillance is in continuous evolution. There are new demands for information, such as UNGASS indicators, and alternative or additional proposals from international agencies, which will need to be implemented. In countries with concentrated epidemics, sustainability is more uncertain

in terms of financial resources, and sustainability of surveillance systems in general remains an issue as most of funds are provided by donors in many countries. The need remains, however, for a reliable behavioral surveillance system and links between individual-level biological and behavioral data.

Ms. Emma Slaymaker of the London School of Hygiene and Tropical Medicine discussed results of behavioral and biological surveillance in Tanzania, Nigeria and Burkina Faso from the second-generation surveillance project.[48] In these three countries in 2002, 114 clinics and 32,683 women participated in ANC serosurveillance; at the same time, data were collected from 25 behavioral surveillance survey sites and 16,983 respondents. In this study, representative data were obtained from areas around ANC catchments, as the sample sizes from the national surveys were too small to do these analyses. As these sub-samples were not designed to be representative of a wider area, it is difficult to compare behavioral surveillance system results with other survey results without weights or other information. The questions in the behavioral questionnaire were modified from the FHI model with some omissions. The same questions were not always asked in the ANC and behavioral surveillance system surveys, including using different categories for marital status and no information on current or recent pregnancies. There were two research questions:

- Are women tested in ANCs representative of all women in their area, and does this change over time?
- Do levels of risk behavior differ between sites with high HIV prevalence and sites with low prevalence?

In Burkina Faso there were three sites for comparison. HIV prevalence was similar at the three sites, but there were some differences in knowledge and behavior. In Nigeria there were 16 sites for comparison. HIV prevalence varied from 1% to 15%, and risk behaviors similarly varied widely. However, there was no pattern of variation in HIV prevalence and behaviors or knowledge. In Tanzania there were six sites for comparison. The sociodemographic characteristic of young women attending ANCs and surveyed in the behavioral surveillance sites were different. Sites in Mtwara had many high-risk behaviors, and one site in Dodoma had a high-level of commercial sex. HIV prevalence was highest in one Mtwara site and one Dodoma site. Syphilis prevalence did not follow the same pattern, however.

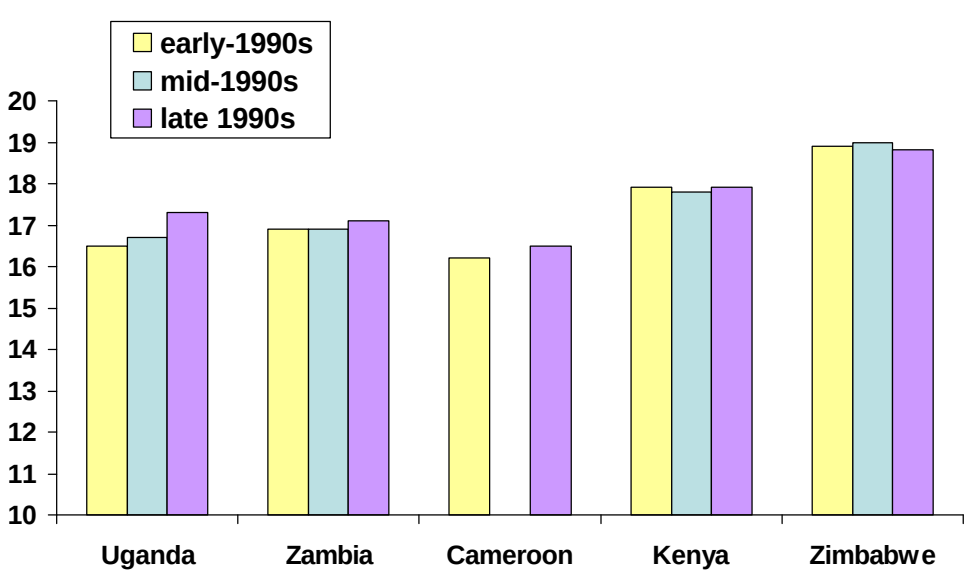
While there was some evidence of correlation between HIV prevalence and risk behaviors, it was not obvious. Possible explanations for this are that second-generation surveillance is designed to interpret trends, and there is no reason why prevalence and behavior estimates should be associated at one point in time. Additionally, there may have been differences in data quality between different sites. Tanzania is the only country where antenatal catchment areas are explicitly defined for the behavioral surveillance system target population, but more data points may be needed for analysis, more like the 16 available in Nigeria.

Dr. Priscilla Akwara of ORC-Macro presented results from the first phase of the ABC Study.[49] The purpose of the ABC Study is to examine how abstinence, reducing the numbers of non-monogamous partners and using condoms may have affected HIV prevalence in three countries where prevalence appears to have declined (Uganda, Thailand and Zambia) and in three others where there is little evidence of much decline (Cameroon, Kenya and Zimbabwe). This is a secondary data analysis project and uses data from DHS surveys conducted in Cameroon in 1991 and 1998; in Kenya in 1989, 1993 and 1998; in Uganda in 1989, 1995 and 2000; in Zambia in 1992, 1996 and 1998; in Zimbabwe in 1988, 1994 and

1999; WHO Global Programme on AIDS survey conducted in Uganda in 1989 and 1995; a sero-behavioral survey conducted in Zambia in 2000; and published data from Thailand.

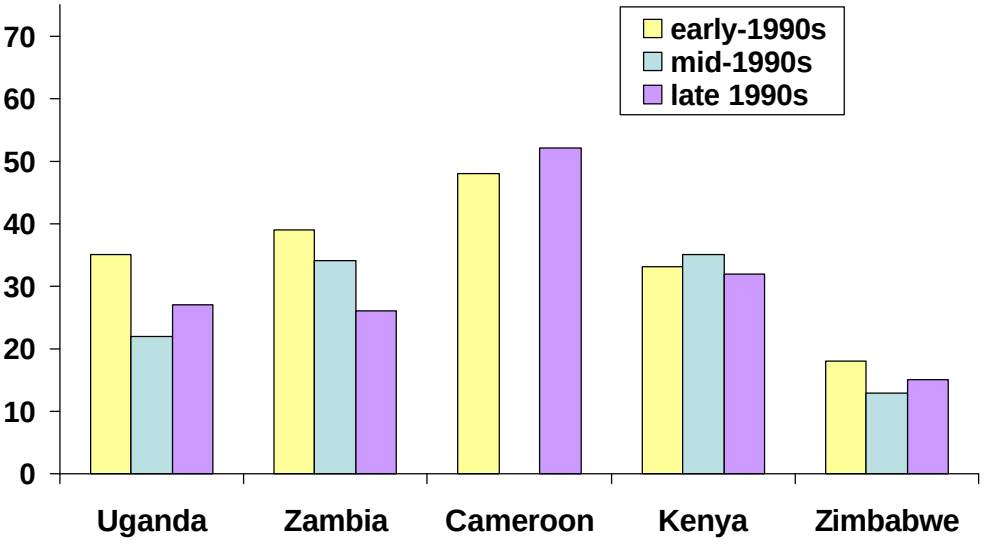
Median age at first intercourse among 15-to-24-year-old women increased by approximately one year from the early 1990s to the late 1990s in Uganda and by approximately 0.5 years in Zambia without similar change in Kenya or Zimbabwe (Figure 18).[50] Similar results were seen among 15-to-24-year-old men. There were also decreases in the percentage of never-married 15-to-24-year-old women old who had had sex within the past year (Figure 19) in Uganda and Zambia but not in Cameroon, Kenya or Zimbabwe.

Figure 18. Median age at first intercourse among women 15-24 years old, Uganda, Zambia, Cameroon, Kenya and Zimbabwe.



Results from survival analysis indicate a ~1 year increase in Uganda and a ~1/2 year increase in Zambia, no significant increases in Kenya or Zimbabwe. Zaba et al, 2002

Figure 19. Percentage of never-married women 15 to 24 years old who had sex in the past year.



Between the 1989 and 1995 Global Programme on AIDS surveys in Uganda, a number of behavioral indicators changed markedly among men, including declines in more than one sexual partner, in two or more sexual partners among single men, in extramarital sex and three or more sexual partners and increases in condom use. Condom use by men increased from the mid to late 1990s in Uganda, Zambia and Zimbabwe and from the early to mid 1990s for paid sex in Thailand.

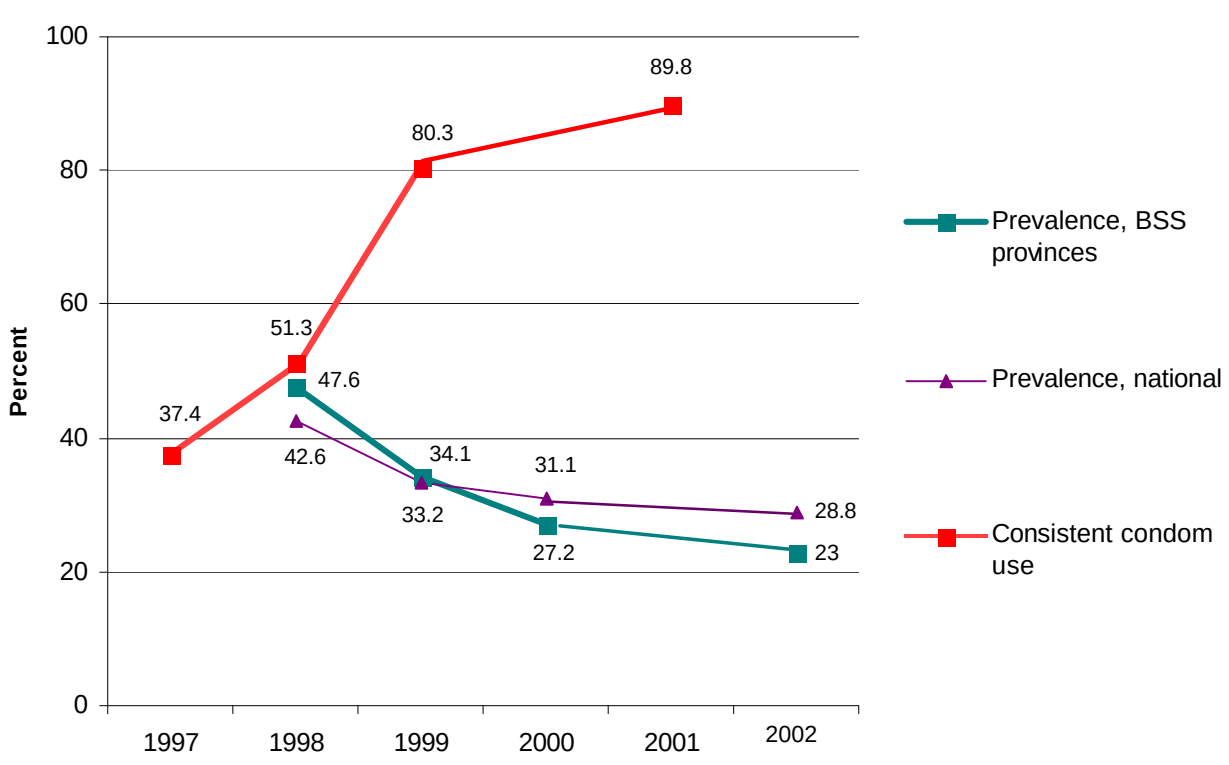
In conclusion, there is evidence of a decline in premarital sex among women and men in Uganda in the early 1990s and in Zambia throughout the decade. There is also evidence of declines in extramarital sex among men in the early 1990s in Uganda, but not later, and in the late 1990s in Zambia. At end of decade, highest levels of non-regular partnerships were found among men in Cameroon, followed by Zimbabwe and Kenya. Condom use with non-regular partners has increased in all countries with the highest rates among men in Zimbabwe and Uganda. In Uganda and Zambia, there is also evidence for a reduction in non-regular and multiple partners, increases in the age of sexual debut among both men and women and greater use of condoms with non-regular partners. Reductions in non-regular and multiple partners occurred in Uganda in the early 1990s when the decline in HIV incidence was much greater. Condom use in Uganda, while low in the late 1980s, also increased throughout the 1990s. Thus, while trends in sexual behavior within countries are consistent with trends in HIV prevalence, differences in patterns of high-risk sexual behavior across countries are not fully sufficient to explain differences in HIV prevalence.

Dr. Heng Sopheab of the Cambodian National Center for HIV/AIDS, Dermatology and STDs spoke on biological and behavioral trends in general and risk populations in Cambodia.[51] HIV was first detected in Cambodia in 1991 and the first AIDS cases reported in 1993. In 2002 there were an estimated 157,500 persons living with HIV in Cambodia, making it one of the highest prevalence countries in Asia. There have been nine rounds of HIV sentinel surveillance since 1995 and six rounds of behavioral surveillance since 1997. There were special STI surveys done in 1996 and 2000. Crude HIV prevalence in 2002 was 28.8% among direct sex workers, 14.8% among female indirect sex workers, 8.4% among tuberculosis patients, 3.1% among police officers and 2.8% among ANC attendees. Prevalence in direct sex workers has fallen from 42.6% in 1998 to 28.8% in 2002, with a greater decline in women less than 20 years old. Prevalence among indirect sex workers has been somewhat more stable, declining from 19.2% in 1998 to 14.8% in 2002, again with more marked declines among women less than 20. Prevalence among urban police officers has declined from 6% in 1998 to 3.1% in 2002.

Behavioral surveillance has indicated an increase in always using condoms with clients from 1997 to 2001 both among direct (to 90.9%) and indirect (to 56.3%) sex workers. Among men in 2001, reported prevalence of always using condoms with sex workers has increased to 78.8% to 86.7% depending on subgroup sampled. Sex with CSW in the past year has also fallen with 32.8% of military, 32% of police and 17.8% of moto taxi drivers reporting this risk in the 2001 survey. Changes in behavior have temporally corresponded with decreases in HIV prevalence among direct sex workers (Figure 20).

There is also a similar trend among indirect sex workers and urban police. Similar condom-use trends among brothel-based sex workers have also been associated with lower prevalence of syphilis, gonorrhea and chlamydia. During this same time period the adjusted HIV prevalence among ANC attendees has remained relatively stable between 2.56% in 1997 and 2.73% in 2002. This, however, is merely the stable part of a precipitous rise in prevalence among women attending ANCs beginning in 1991. Using EPP, adult prevalence among 15-to-49-year-old Cambodians has decreased from 3.3% in 1997 to 2.6% in 2002.

Figure 20. HIV prevalence and consistent use of condoms among direct sex workers in behavioral surveillance system provinces and national HIV prevalence, Cambodia, 1997-2001.



In conclusion, the prevalence of HIV among ANC women has been roughly stable in Cambodia for the past three to four years. At the same time, prevalence continues to decline among direct and indirect sex workers but not among urban police officers where it appears to be leveling off. According to the best available models, the number of new infections per year has been declining while the number of deaths per year has been increasing, and thus a combination of decline in incidence and mortality are responsible for the declines in national prevalence.

Discussion

In opening the discussion session, Dr. Boerma made five points:

1. *Monitoring behavior trends is essential but linking at the population level needs to be done cautiously. Using prevalence as a proxy for incidence, using ANC prevalence as a proxy for general population prevalence and the difficulties inherent in sampling and measuring sexual behaviors all create noise that make linking difficult.*
2. *From the perspective of second-generation surveillance, it is better to have bad behavioral survey data than none at all. The purpose is to measure trends. As long as misclassification is constant over time, trend data should be interpretable.*
3. *Efforts to monitor trends in the same population are not worth it for generalized epidemics but are worth it for low-level and concentrated epidemics.*
4. *A limited number of indicators are used for program design and monitoring but more indicators are needed for evaluation. Qualitative results are generally disappointing.*
5. *To evaluate trends and programs, monitoring and evaluation need to be integrated with surveillance.*

In the question and answer period, Ms. Pisani made the point that when using surveillance data for monitoring and evaluation, questions will arise, such as is rising incidence associated with prevention failure or treatment success? A question was asked of Ms. Zaba about the ideal frequency of surveys. While some advocate for biennial or triennial surveys, she felt that every five years with more sites would be adequate. There was disagreement with Dr. Boerma's third point, feeling that general population surveys are both feasible and worthwhile periodically. Ms. Zaba advocated expanding ANC questions to include questions about the baby's father, such as was the mother living with the father and was he the same father as her other children's. It was also pointed out by a participant that this created ethical problems with the unlinked anonymous testing format. It was suggested that in low-level and concentrated epidemics behavioral surveys need to be done with somewhat greater frequency and that studies in these epidemics based at the individual level need to be further linked to data on exposure to prevention programs. It was recommended that these data need to be examined over time because the prevention effect is cumulative.

A participant noted that declines in HIV incidence in Cambodia as measured by BED-CEIA were consistent with increased condom use. There was a discussion of using prevalence among women less than 19 years old attending ANCs as a proxy for incidence. Another participant pointed out the implications of the data for programs is equally important in generalized epidemics and that prevention effect may not be due to discrete programs. He concluded that what was needed was to look at the right indicators. One participant from Zambia pointed out that in Zambia 26.2% of couples were discordant; he felt strongly that the prevention message needs to focus on getting tested. The session finished with one participant expanding on Dr. Calleja's point about lack of capacity in national AIDS control programs for behavioral surveillance. With the strong possibility of treatment optimism as ART becomes available, this participant felt that developing the capacity now for behavioral surveillance is important; if we wait for prevalence changes, it will be too late to intervene.

Work Group 4 focused on the issues discussed in Session 3.* They were asked to discuss a series of questions regarding linking seroprevalence to behavioral data in surveys (Table 19).

Table 19. Work group 4 discussion questions.

1. What factors need to be considered when interpreting findings from both prevalence and behavioral surveys?
2. Are there ways to assess if risk occurred before infection or if risk occurs at same time of HIV testing?
3. What is the role of STIs in linking HIV prevalence and behavioral surveillance data in populations? Can STI surveillance be added to these surveys?
4. Besides assessing risk behaviors and HIV results, can we look at other behavioral data collected in surveys to assist with prevention planning or treatment, such as HIV testing behaviors or use of health care services?
5. What are the recommendations for 2nd generation surveillance in the various types of epidemics? How can this be used to monitor and evaluate prevention programs?
6. Are there settings in which collection of prevalence, incidence and behavioral data should be collected at the individual level, as has been proposed for monitoring in antenatal women?
7. Should behavioral surveys ideally contain biological measures, and if so, which ones?
8. In what types of epidemics is it worthwhile to link behavioral and biological surveys? Should this link be examining data collected from different surveys or should one survey that collects both behavioral and biological data be used? How does this affect costs? What logistical, political, and ethical issues need to be considered?
9. How does behavioral surveillance differ for people who know their HIV serostatus, versus those who do not? What effect does treatment have on their attitudes toward behavior? What questions should be routinely considered as we enter an era of wider treatment? How does the prevalence of infection affect the interpretation of behavioral data?
10. What methods should be used to build capacity at local level?

* Ms. Basia Zaba, facilitator and presenter; Mr. David Plate, rapporteur. Other work group members were Drs. Sabin, Akwara, Saidel, Bhattacharya, Baganizi, Brown, Mugurungi and Wokle; Mr. Urassa and Mss. Sinclair and Slaymaker.

Work Group 4's discussion centered on the question of why biological and behavioral data should be linked. An underlying premise was to make use of existing data and data collection systems rather than making recommendations for new ones. Linking is useful to explain epidemic trends but not to establish causality. In concentrated and generalized epidemics the different surveillance activities conducted raise different linkage issues. In terms of outcomes, the work group felt that other STIs were important to include if they are of short duration, treatable and common. However, in order to assure treatment, surveys should make use of rapid methods. A final point of discussion was that surveillance is different from monitoring and should be driven by national requirements not program evaluation needs.

The work group identified two objectives:

- Ensure surveillance can contribute to an understanding of epidemic dynamics
- Encourage data linkage for triangulation and integrated analysis

In concentrated epidemics, the group recommended that regular nationally representative household-based risk behavioral surveys be carried out without biological markers but with program exposure questions and used as a source for estimating size of high-risk groups and background levels of risk behavior. They also recommended continuation of ANC-based HIV sentinel surveillance and adding screening and treatment for other appropriate STIs. They suggested conducting facility-based surveillance of high-risk groups (e.g., STI clinics and prisons) with probability-based cluster surveys. Where acceptable, they recommended doing biological surveillance in the same sample and linking at the individual level, both for convenience and to identify correlates of risk. In situation where biological surveillance is not acceptable in high-risk groups, they suggested giving treatment tokens and monitoring receipt at neighboring treatment centers.

In low-level and concentrated epidemics they recommended carrying out regular nationally representative household-based risk behavior surveys with questions on program exposure and ANC attendance. Some of these will be benchmark surveys with HIV and appropriate testing for STI and used to calibrate national HIV prevalence estimates, to obtain national level risk behavior indicators and to identify and measure size of high risk groups. They also recommended continuing ANC-based HIV surveillance and adding screening and treatment for other appropriate STIs and also contextual questions, such as residence, parity and marital status, in order to monitor changes associated with prevention of the mother-to-child transmission programs. They specifically felt that PMTCT programs offered a rich set of behavioral data that should be exploited. Finally, they recommended identifying one or two higher risk or vulnerable groups that are feasible to use for regular sentinel surveillance. A goal is to strive for widely distributed geographic clusters, but not necessarily representativeness.

With respect to encouraging data linkage for triangulation and integrated analysis, the work group suggested comparing risk behavior data from any available source, such as program monitoring, cohort studies and other research activities, with risk behavior survey and surveillance data. They also suggested comparing biomarker data from other available sources, such as blood donors, VCT programs and research studies, with survey and surveillance data. They recommended using qualitative data to enrich interpretation of trends in risk behavior and HIV prevalence data and using models to link behavioral and biological trends and to estimate incidence. Finally, they noted that data should be analyzed to look for lagged links between behavior change and later epidemic trends, allowing for background prevalence levels in ecological analyses. The work group's recommended goals and objectives are summarized in Table 20.

Table 20. Objectives and activities, Work Group on Linking Biological and Behavioral Surveillance.

Objective 1.1: Ensure surveillance can contribute to understanding of epidemic dynamics in low-level and concentrated epidemics

Activities:

- Carry out nationally representative household-based risk behavior surveys without biology but with program exposure; use to estimate high-risk group size and background risk level in general population
- Continue ANC-based HIV surveillance, add screening and treatment for other STIs, choosing appropriate infections for particular epidemiological context
- Supplement risk behavior surveillance of high-risk groups in facilities (e.g., STI clinics, drug rehabilitation centers, prisons) with probability-based cluster surveys
- Where acceptable and convenient do biological surveillance (HIV and selected STIs) in same sample and link at individual level to enhance analytical possibilities, e.g., to identify correlates of risk, or perform incidence analysis when that becomes possible.
- Where biological surveillance is not acceptable in high-risk group sample, give treatment tokens and monitor their receipt at neighbouring treatment centers

Objective 1.2: Ensure surveillance can contribute to understanding of epidemic dynamics in generalised epidemics

Activities:

- Carry out regular nationally representative household-based risk behavior surveys with program exposure, HIV testing history and ANC attendance (name facility). Incorporate benchmark HIV measurement less frequently (including rapid STI tests if appropriate). Use the surveys to calibrate national prevalence estimates, obtain national level risk behavior indicators, identify high risk groups and estimate their size
- Continue ANC-based HIV surveillance in nationally representative facility sample, add screening and treatment for other appropriate STIs, add contextual questions (residence, parity, marital status, etc.) in order to monitor possible client population changes if facility joins PMTCT program (especially as a pioneer). Exploit potential to move to rich behavior data collection in PMTCT program context
- Identify one or two higher-risk or vulnerable groups (based on risk behavior survey) that it is feasible to use for annual sentinel surveillance (behavior, maybe biomarkers also), such as military recruits, taxi drivers, domestic workers, bar staff. Strive for widely distributed geographic clusters but not national representativeness

Objective 2: Encourage linkage for triangulation and integrated analysis

Activities:

- Compare risk behavior data from any available source (program monitoring, cohort studies, and other research activities) with risk behavior estimates from survey and surveillance data
- Compare biomarker data (HIV and STIs) from any available source (blood donors, VCT, research studies) with biological data from surveys and surveillance. Encourage experimental incidence measurement studies in (or close to) surveillance populations
- Use qualitative data (e.g. key informant interviews, situation analyses, formative research) to enrich interpretation of trends in risk behavior and biological data
- Use models to link behavioral and biological trends and to obtain incidence estimates, for the whole population in generalized epidemics and high-risk sub-populations in concentrated epidemics
- Allow for background prevalence levels in multi-level ecological analyses that look for lagged links between behavior change and epidemic trend a few years later

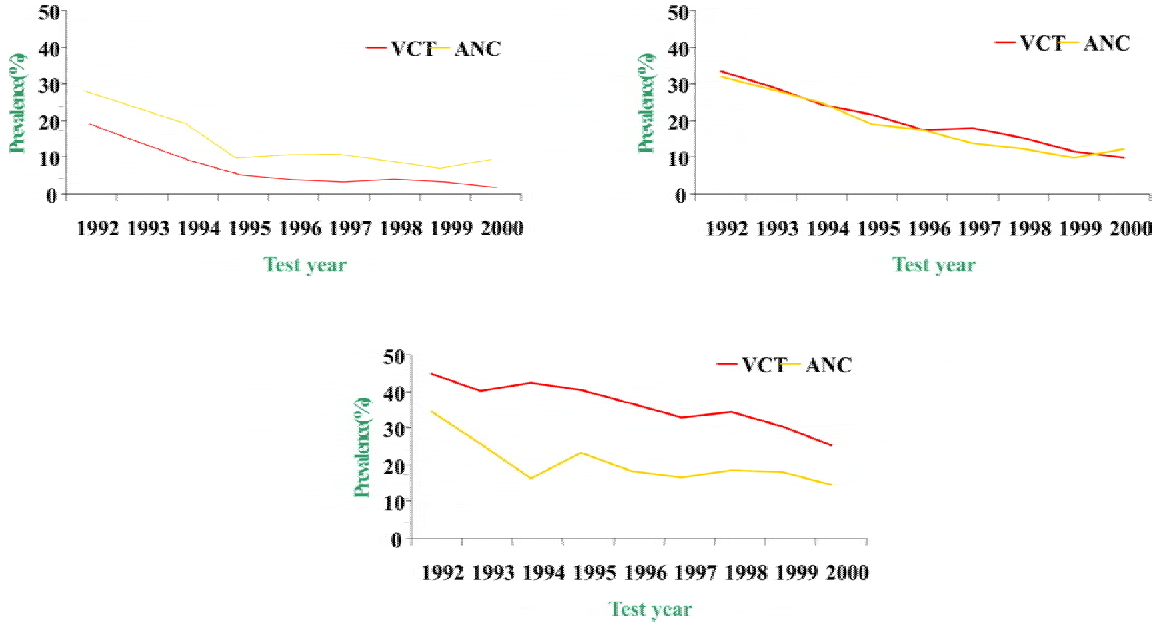
Session 4. Use of VCT and PMTCT Data for Surveillance

Dr. Frank Kaharuza of CDC-Uganda discussed the Ugandan experience with using VCT data in HIV surveillance.[52] The Ugandan HIV/AIDS surveillance system uses data from 25 sentinel ANC sites, from tuberculosis and STI patients, from population-based cohorts in Rakai and Masaka and from programmatic sources, such as blood donors, VCT and PMTCT programs. Data from VCT sites, or "interventional surveillance" data, are routinely used to monitor HIV/AIDS interventions and are now being evaluated as a supplement to traditional surveillance data. VCT provides large amounts of data at little or no additional cost, though this is counterbalanced by likely selection biases. To use these data they need to be comparable across sites and over time, collected in a standardized way and adjusted for differences in testing algorithms.

In Uganda, VCT services are in high demand; 70% of the population wants to know its HIV status. There are 160 testing sites nationwide providing confidential testing. These include five stand-alone and 74 integrated sites managed by the AIDS Information Centres, the first of which was opened in 1990. AIDS Information Centres are the largest providers of HIV testing services in Uganda, having provided over 700,000 tests since 1992.

In this study data from 201,741 clients visiting an AIDS Information Centre were included; clients were excluded if they reported illness or were widowed. Trends in HIV prevalence and the shift in age of peak HIV prevalence were assessed. Basic demographic characteristics changed minimally over time. The overall prevalence declined from 23% in 1992 to 13% in 2000, with prevalence among men declining from 17% to 9% and prevalence among women from 31% to 17%. No prevalence declines were noted in men over 40 years or in women over 30 years of age. As shown in Figure 21, HIV prevalence trends in VCT consistently underestimated prevalence in 15 to 19 year olds, were superimposable for 20 to 24 year olds and consistently overestimated prevalence in those 25 years old and older. There was also a shift in peak age for HIV prevalence from 25 to 29 years for women in 1992 to 35 to 39 years in 2000 and from 35 to 39 years to 40 to 44 years in men. During this time period, prevalence at peak age also declined from 42% to 36% among women and 27% to 22% among men.

Figure 21. VCT and ANC HIV prevalence trends, Kampala, Uganda, 1992-2000.



There are a number of potential biases inherent in using VCT data from the AIDS Information Centres. First, VCT data under-represent teenage boys and men and women over 40 years old and over-represent teenage girls and 30-to-39-year-old men and women. Additionally, some demographic factors, such as marital status, education and area of residence, are not distributed as in the general population. The coverage may also not be national, and there have been changes in participation over time in terms of the proportion of ill clients, testing of couples and the reasons for seeking testing, such as marriage and ARV treatment. Finally, other VCT sites need to standardize the information collected on their forms to make their data more usable. On the other hand, VCT data from AIDS Information Centres have a number of advantages. They are robust and provide data for men and older women. Key data variables are collected in a standardized way at the AIDS Information Centres, such as age, sex, urban versus rural site, marital status, reason for test and testing history. Additionally, by using data only from stand-alone VCT centers, of selection bias due to patients seeking testing because they are ill is largely avoided.

Another future and potential VCT data source may be "home-based" VCT, also pioneered in Uganda. No comparison of this data source to ANC surveillance data is yet available. Here, consent for testing and blood collection are carried out at the client's home. Testing is carried out at a central location, and counseling is offered at home or at a referral site with the option for individual or couples counseling. Historically, home-based counseling and testing had very low uptake. However, after introducing home-based testing options, a substantial increase in the proportion of clients accepting VCT was observed. In one survey carried out by CDC in Buzika, a rural community east of Kampala, 3,338 community members (94% of total) were enrolled in home-based VCT. Of these, 3,323 (99%) consented to HIV testing, and 93% of these were tested. Ninety-nine percent preferred to receive their test result and counseling at home rather than at the local study clinic or a referral site. In Tororo in eastern Uganda, 4,128 (99%) of 4,159 household members agreed to HIV testing, and 4,055 (98%) received results. Ninety-seven percent preferred and received counseling in their homes. Notably, 35% of married HIV-infected clients had an HIV-uninfected spouse.

Several concerns exist, however, about using home-based VCT data in national serosurveys. They are costly and may be unsustainable in the context of the national scale-up plan for VCT. There is possible participation bias, and there are concerns about maintaining confidentiality. Home-based testing involves a more complicated protocol, and at the end it is an untested model in the context of national serosurveillance. However, cost estimates have turned out to be the same for home-based and voucher system approaches, and both build capacity through training of VCT personnel. More research is needed to assess the feasibility of home-based VCT for national serosurvey, its effects on survey participation and the ability to maintain confidentiality in home-based settings.

In conclusion, VCT data are an important source for HIV surveillance in Uganda. Some, though not all, biases inherent in these data can be adjusted for. Research on home-based testing has important programmatic implications, and VCT and PMTCT programs may wish to consider home-based testing. Interventional surveillance will be important in the scale up of VCT, PMTCT and care programs, and we should ensure the maximum utility of these data sources.

Dr. Tanarak Plipat of the Thai Ministry of Public Health compared two reporting mechanisms for ANC-based HIV prevalence data.[53] The Thai HIV serosurveillance system was originally established in 1989 across 14 provinces, but within a year had been expanded to a nationwide system. Based mainly on unlinked anonymous testing, it included ANC patients and several other groups. In 1995 the

system was revised to use VCT data where available, to collect data from district hospitals and individual records and data on age once per year in June. In 2003, unlinked anonymous testing of women attending public hospital-based ANCs was discontinued, and the public hospital part of the system is now based entirely on voluntary testing. ANC data are now drawn from clinic logbooks and include age, parity, race, HIV status, syphilis status and individual data.

PMTCT was implemented in 2000 in Thailand. The Perinatal HIV Intervention Monitoring System is based on aggregated reports from all public hospitals and summarizes data elements from ANC and 30 delivery room logbooks. The ANC population monitored through this system is the same as that monitored in the ANC HIV sentinel surveillance system and overall captures about 60% of all pregnant women in Thailand. Nearly 100% of facilities report to both systems. The delivery room system includes women delivering in public hospitals who have had HIV testing done either during antenatal care or at delivery. Only aggregated data are reported. The delivery room system captures about 75% of all pregnant women in Thailand, but it excludes women whose pregnancies were not completed or who delivered outside of hospitals (fewer than 5% of all births). Results from the three different systems are shown in Table 21.

ANC-based sentinel serosurveillance and antenatal HIV testing data from the Perinatal HIV Intervention program correlate well; the correlation is less robust for delivery room data. There is some evidence of referral bias as non-hospital-based clinics do not report but often refer HIV- infected women to hospital-based clinics, which do report. There is also evidence of selection bias in the delivery room data. Women who do not complete pregnancy are excluded, and women who present late in labor are also sometimes excluded. Additionally, because HIV-uninfected women who had antenatal care at out-of-network clinics deliver at network hospitals, delivery room prevalence may underestimate true prevalence.

Thailand has used programmatic data for HIV surveillance since 1995 although the effect of changing from a surveillance system based on unlinked anonymous testing to one based on voluntary antenatal testing is unknown. Given the high coverage of the Thai program, with 97% of women consenting to testing, more than 95% of births occurring in hospitals, and more than 80% of births occurring in public hospitals, the generalizability of the Thai experience for other countries may be limited. ANC-based HIV sentinel surveillance and ANC testing data from the Perinatal HIV Intervention Monitoring Program have markedly similar results, mostly because they are surveying the same population. In the longer term, if the proportion of women consenting to HIV testing declines, more biases may be introduced into the Perinatal HIV Intervention Monitoring System.

Table 21. HIV prevalence among pregnant women by surveillance system, Thailand, 1999-2003.

		Perinatal HIV Intervention Program	
Year	**HIV sentinel surveillance**	**ANCs**	**Delivery rooms**
1999	2.0%	NA	NA
2000	1.6%	NA	NA
2001	1.5%	1.4%	1.2%
2002	1.4%	1.3%	1.1%
2003	1.2%	NA	NA

NA, data not available

In conclusion, the Perinatal HIV Intervention Monitoring System has provided good data for more than two years and so far has met the criteria of stability, validity and timeliness. The Ministry of Public Health plans to evaluate both systems intensively this year and decide on continuation of the sentinel serosurveillance system.

Dr. Kereng Masupu of the BOTUSA Project in Gabarone, Botswana, discussed the Botswanan experience with PMTCT data.[54] HIV prevalence among pregnant women in Botswana is high, estimated at 35.4% in 2001. Annual HIV sentinel surveillance has been conducted among pregnant women since 1992, and ANC attendance is high, with more than 95% of pregnant women seeking antenatal care. In 1999, Botswana started Africa's first national PMTCT program.

Botswana's National AIDS Coordinating Agency has compared data from the national PMTCT program to those from ongoing ANC-based sentinel serosurveillance. PMTCT data are collected in logbooks maintained at facilities and aggregate reports are sent monthly to the national level. HIV testing is carried out off-site at the district laboratory. After testing, the form with the test result is returned to the ANC and a copy of the form is submitted to the central level and entered into a database. The HIV sentinel surveys are conducted over a 12-week period in all 22 health districts using unlinked anonymous testing of blood taken for routine syphilis screening.

PMTCT HIV testing forms were submitted from only 13 of the 22 health districts, and three of these submitted fewer than 50 forms and were omitted from analysis. The remaining 10 districts submitted 4,136 HIV request forms, representing 47% of the 15-to-49-year-old female population in Botswana. This compares to a total of 22,917 new ANC patients seen in these 10 districts in 2002. The much lower number of available PMTCT test records was due to missed counseling, test refusal, missed testing and missed data entry of the test results. Overall, mean age was 25.7 years, and the HIV prevalence was 35.8%. In comparison, in the ANC-based HIV sentinel surveillance system 2,889 women were tested in 2002. They had a mean age of 25.8 years and an overall prevalence of 37.3% (p=0.38). There were also no differences between the two systems in terms of prevalence by age group or province.

In conclusion, the results suggest that HIV prevalence estimates obtained through the PMTCT program could substitute for sentinel surveillance. However, in order for programmatic data to replace the sentinel survey, the acceptance of HIV testing among pregnant women needs to increase. Botswana has now recruited lay counselors for the PMTCT program, and preliminary figures for 2003 indicate that 60% of women are accepting HIV testing. Furthermore, an opt-out approach for testing was implemented in January 2004. Validation of programmatic data will continue over the next few years to monitor the progress of the PMTCT program and to determine when data from the program can replace ANC-based HIV sentinel surveillance.

Dr. Nicole Seguy of CDC presented an assessment of the utility of PMTCT data in Kenya for HIV surveillance.[55] Kenya has a generalized HIV epidemic with the national prevalence among women attending ANCs estimated at 9.4% in 2003. For the past three years there has been a rapid expansion of services for the PMTCT from fewer than 10 sites in 2001 to 130 by 2003. This study described the availability and quality of programmatic data, compared estimates derived from them with those from HIV sentinel surveillance and identified determinants for differences between estimates derived from the two sources.

In Kenya, annual HIV sentinel surveillance is conducted in 42 ANCs in urban, rural and "mixed" areas, using consecutive sampling and unlinked anonymous testing. Variables collected include age, marital status, education, urban versus rural residence, number of live births, number of abortions and syphilis test results. Over 10,000 women participated in 2003. PMTCT services are conducted in 130 clinics in Kenya, mostly focused on the urban population. HIV testing is based on the principle of VCT. Program indicators potentially useful for HIV surveillance include counseling and testing uptake and the ANC HIV prevalence.

Of 13 sites selected for this comparison (clinics with both ANC-based HIV sentinel surveillance and PMTCT programs present), data were available for only one site at the time of this conference. Individual PMTCT program line-listed data were collected on site by digital camera, covering the same time period as that for sentinel surveillance in 2003. PMTCT data were recorded in two or three different logbooks at the different clinics. There was limited access to the logbooks as they were permanently in use and could not be taken from the clinic. Format varied from clinic to clinic, as did the number and order of variables.

At one health center in the Coast Province, 283 women were included in ANC surveillance and 266 were tested through the PMTCT program from May 15 to August 19, 2003. There were no statistically significant differences observed in HIV prevalence among the two groups overall (9.5% from sentinel surveillance versus 7.4%, p=0.47), among women 25 years old and older (15.2% versus 10.0%, p=0.37) or among women younger than 25 years (6.0% versus 6.1%, p=0.81). Acceptance of HIV testing was higher among women less than 20 years old (68% versus 46%, p=0.002) and primagravida women (58% versus 39%, p=0.015). Younger age persisted as a risk factor for HIV infection after adjustment (adjusted odds ratio 2.3, 95% CI 1.1-5.2).

In conclusion, HIV testing uptake varied considerably among ANCs in Kenya, and analysis is ongoing for the remaining clinics. In the one clinic examined, intensively low HIV testing uptake resulted in participation bias, especially among women 20 years older and older, resulting in programmatic data underestimating HIV prevalence among older women. Although these differences were not statistically significant, the differences may be seen as real as the unlinked anonymous testing group included all PMTCT clients plus those clients that refused testing (the observation period was limited to the unlinked anonymous testing period).

One of the most frequent reasons for test refusal was that the woman had to ask her husband about testing. Also ANC clients knowing their HIV status from prior testing (e.g., during a prior pregnancy) may have refused testing on the grounds that they already knew their status.

Table 22. Work Group 3 discussion questions.

1. What criteria should guide when VCT and PMTCT data can be used for surveillance?
2. How do we validate VCT and PMCT data for use in surveillance?
3. What variables need to be collected and standardized when using VCT and PMTCT data?
4. What are the data management, implementation and analysis capacity needs when using VCT and PMTCT data for surveillance?

Work Group 3 focused on the issues discussed in Session 4.* They were asked to discuss a series of questions dealing with using VCT data and PMTCT data for HIV surveillance (Table 22). The group focused initially on the basic question of the role and relationships among surveillance, monitoring and evaluation and services data. Many countries capture VCT data, but unknowns include comparability of data elements, completeness of data and accessibility of data sets. Key issues and questions regarding the use of VCT data for surveillance purposes include:

- The primary use of VCT data is for monitoring and evaluation
- Participation bias in VCT clients is the primary factor limiting the use of these data for surveillance. They are of doubtful use for estimating HIV population prevalence, but may have some utility for measuring HIV prevalence trends over time assuming participation bias remains constant.
- As VCT also provides data on men, this may be an additional data source to estimate the HIV prevalence sex ratio
- There is a need to evaluate subpopulations and to select sites and methods to reduce this bias. The reported inclusion and exclusion criteria from the Ugandan evaluation – first visit for HIV test, free-standing VCT sties only, excluded if coming for illness or widowed – are clever solutions that should be tested elsewhere.

These considerations led to an objective to evaluate the utility of VCT data for surveillance and standardize protocols for analysis (Table 23).

PMTCT programs are newer than VCT programs and based at health facilities. Unfortunately, most countries collect aggregate programmatic data except in research sites and possibly Botswana and Lusaka, Zambia. It should also be realized that sentinel surveillance sites and PMTCT sites differ and may not be completely super-imposable. Finally, these programs are subject to a wide variety of reporting requirements from the Global Fund, PEPFAR and other donors. There are two key issues and questions regarding the use of data from PMTCT programs for surveillance purposes. The first is can and should PMTCT service data replace or complement ANC-based sentinel surveillance? This includes ethical issues associated with unlinked anonymous testing, the role of unlinked anonymous testing in validating programmatic data, the selection of sentinel sites to provide PMTCT programs and the balance between using sentinel sites and collecting data nationally. The second question is what are the magnitude and nature of participation bias in HIV testing in PMTCT programs given that the levels of uptake of

* Mr. Woflgang Hladick, facilitator; Dr. Nicole Seguy, rapporteur; Dr. Lawrence Marum , presenter. Other work group members were Drs. Courval, Kaharuza, Khotenashvih, McFarland, Roels and Shields.

Table 23. Objectives and activities, Work Group on Use of VCT and PMTCT Data for Surveillance.

Objective 1. Evaluate the utility of VCT data for surveillance and standardize protocols for analysis

Activities:

- Catalogue and compile information on existing VCT data sets
- Establish a working group to reach consensus on selection criteria and an analysis plan
- Assess existing VCT data and compare with ANC-based sentinel surveillance data
- Disseminate Uganda paper and other individual country analysis reports
- Consider meta-analysis paper on VCT and ANC-based sentinel surveillance

Objective 2: Expand use of PMTCT service data to complement ANC-based sentinel surveillance

Activities:

- Recruit three additional countries for a study to assess utility of PMTCT program data for surveillance
- Develop or adapt a generic protocol for unlinked anonymous test-based sentinel surveillance and collection of line-listed PMTCT service data
- Collect line-listed PMTCT service data from sentinel surveillance sites in four countries
- Report retrospective data at International AIDS Conference in Bangkok
- Analyze the correlation between unlinked anonymous test and PMTCT data and hold consensus meeting on methods

counseling and testing prevalence rates in sentinel surveillance clinics do not equal those in VCT settings? There are also different types of testing going on in clinics, such as opt-in versus opt-out, and different service sites, such as ANCs and maternity wards, governmental and private, that may influence rates. Moreover, there are different background prevalences, differences in prior knowledge of HIV status and a variety of social and cultural factors and stigma about testing that may influence comparability of results from the two systems. These considerations led to an objective to expand use of PMTCT service data to complement ANC-based sentinel surveillance (Table 23).

Session 5. AIDS Reporting and Monitoring the Impact of ART in the Context of Care and Treatment

Dr. Theresa Diaz of CDC opened the session with an overview of HIV morbidity and mortality surveillance in resource-constrained settings.[56] In industrialized countries, HIV morbidity and mortality has been monitored primarily by AIDS case reporting and death certification with cause of death. These data have allowed monitoring of temporal, geographic and risk-group trends and the measurement of the impact of ARVs. In resource-constrained countries, however, the focus of HIV surveillance has been monitoring HIV prevalence, and, while AIDS reporting exists, it suffers from severe under-reporting (Table 24), which limits in usefulness especially in countries with generalized epidemics.

Table 24. Under-reporting of AIDS cases, Ethiopia, Mozambique and Nigeria, 2001.

	Ethiopia	Mozambique	Nigeria
Estimated AIDS deaths	160,000	60,000	170,000
Reported AIDS cases	5,872 (3.7%)	7,000 (11.7%)	3,661 (2.2%)

To monitor the impact of ART, we need to know:

- Coverage, as measured by the number of HIV-infected persons receiving HIV care divided by the number of HIV-infected persons who are symptomatic
- Impact on morbidity, as measured by a decrease in persons developing symptomatic HIV infection
- Impact on mortality, as measured by increased survival and a decrease in the number of persons dying of HIV

However, we are currently unable to monitor morbidity trends in many resource-constrained countries. There are at least four possible approaches to improving morbidity surveillance – supplementing tuberculosis surveillance, cohort analyses of persons in treatment, improving universal AIDS reporting especially in countries with low-level or concentrated epidemics with already somewhat reasonable AIDS surveillance programs and possibly implementing sentinel AIDS surveillance in generalized epidemics – whose strengths and weaknesses are outlined in Table 25.

Mortality surveillance comprises counts of the number and causes of death, and most commonly these data are collected through vital registration systems. Alternate approaches, however, have been developed to collect these same data. Vital registration in many resource-constrained countries has very limited geographical coverage, the coverage rates themselves are low, there are delays in registration and there is inadequate analysis and dissemination. In fact, only nine countries in the WHO African Region have functioning vital registration systems,[*] and the coverage of these systems, with the exceptions of the Seychelles and South Africa, is low.

One alternate approach is collecting data on deaths in households in the past year during the national census. The census has the advantage of having national coverage with the potential for sub-national analyses. However, there is typically incomplete reporting, and the interval between censuses is too long. Another approach involves the DHS and similar surveys. In fact, most of what we know about mortality in Africa is based on these surveys, and they have been an essential source of information on infant and child mortality. Methodologically, adult mortality would be derived from reported deaths among a respondent's siblings. There are issues, however, of ample size and missing information. A third method is the Demographic Surveillance Sites (DSS), which provide complete enumeration of vital events and migration in a defined population. DSS field sites, called INDEPTH sites, are currently in place in 13 countries in Africa. These are easier to implement than national vital registration, have the potential to produce quality data and, if samples are constructed correctly, can be used to produce national estimates.

[*] Burkina Faso, Ghana, Kenya, Mauritania, Mozambique, the Seychelles, South Africa, Zambia and Zimbabwe

Table 25. Possible strategies for morbidity surveillance.

Strategy	Strengths	Weaknesses
Cohort analysis using ART program data	• Data available from routine program monitoring • Extensive information	• Only persons in care • Extensive resources if no medical information system or individual records • Must follow-up lost patients
Universal AIDS reporting	• Includes those not on ART • Measures burden of disease • Able to follow trends	• Under-reporting • Reporting delays • Additional resources
Sentinel AIDS reporting	• More complete information	• Bias depends on sites chosen • Additional resources
Tuberculosis surveillance with HIV status	• Already existing system • Trends can be monitored	• May not have HIV status • Requires modification of current protocols • Short follow-up

Another approach has been special vital registration with verbal autopsies. These are an add-on to DSS with interviews of relatives of the deceased to obtain information on possible causes of death. These interviews are referred to as "verbal autopsies". The advantages are that many people die at home, and these interviews can be used to reconstruct information on functional status and health care utilization prior to death. These data can be used to analyze not only the total numbers of deaths, but also the proportion of deaths due to HIV and AIDS.

Some other approaches include review of cemetery logbooks and HIV testing of cadavers, although this has yet to be validated. Modeling can also be useful. It is dependent on seroprevalence surveillance and data on survival from special studies. If consistent methods are applied, countries can be compared. However, there are concerns about the appropriate approach and parameters, and models are only as good as the data used to create them. Thus, with regard to mortality surveillance, the basic conclusion is that the quality and availability of data are problematic in many resource-constrained countries.

In conclusion, there were four recommendations:

- Create and analyze cohorts of HIV-infected persons in care, which will also entail creation of medical information systems to gather the data and creation of methods to seek out persons actively who have been lost to follow up
- Modify tuberculosis surveillance to include information on persons with HIV infection
- Improve vital registration in selected countries
- Implement special vital registration systems with verbal autopsies taking advantage of pre-existing DSS

Professor James Whitworth of the London School of Hygiene and Tropical Medicine next spoke on AIDS case definitions and clinical staging systems.[57] Case definitions and clinical staging systems are important because they are prognostic indicators, they measure the burden of disease, they can be used to monitor the impact of interventions and they allow comparisons between studies. They are particularly relevant in developing countries where there is very little vital registration, there is rarely information on causes of death, there is substantial under-reporting of HIV and AIDS morbidity and immunological and virological markers are often unavailable. Finally, they are very relevant to ART and can be used to identify individuals who might benefit from ARVs and to monitor the impact of treatment.

AIDS case definitions are numerous. CDC has changed the U.S. case definition three times, the European case definition is the same as the current CDC definition but without the CD4 criterion and there are other case definitions in use in Africa (Bangui, 1985, and Abidjan) and Latin America (the Pan American Health Organization's revised Caracas definition and the Brazilian case definition). This creates a number of problems. It is confusing and leads to an incomplete picture of the burden of disease, and none are consistent with the WHO clinical staging system. Moreover AIDS is not a single disease entity but a surveillance definition of advanced HIV disease, and its incomplete reporting suggests its inherent impracticality.

The WHO clinical staging system, on the other hand, has greater utility, especially in developing countries where diagnostic facilities are not always available, as clinical stages correspond better to actual clinical conditions. The system is based on the assumptions that HIV slowly destroys the immune systems, that infected individuals progressively become more clinically ill, that advanced HIV infection is characterized by a few diseases and that death is the ultimate outcome. The relationship between clinical stage and hazard of death is shown in Figure 22.

Figure 22. Survival following HIV infection by WHO clinical stage.

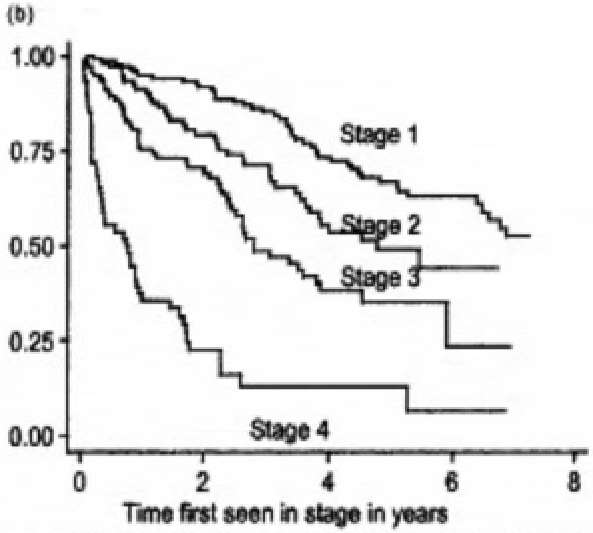


Fig. 1. KaplanÐMeier (KM) survival curves from (b) first seen in a WHO clinical stage.

Clinical staging is useful for prognosis. The median survival from WHO stage 4 to death is nine months; and the median CD4 cell counts entering the stages are 516 cells/ml for stage 2, 428 cells/ml for stage 3 and 126 cells/ml for stage 4. Overall, the clinical staging system is comparable to CD4 counts for prognosis. Individual characteristics are also important for prognosis. In stage 3, survival less than one year is associated with a weight loss of more than 10% of body weight, chronic diarrhea or oral candidiasis. On the other hand, survival for more than three years is associated with severe bacterial infections and pulmonary tuberculosis. In stage 4, survival less than six months is associated with cryptococcosis, esophageal candidiasis, Kaposi's sarcoma and wasting syndrome, while survival for more than 20 months is associated with chronic *Herpes simplex* infection and cryptosporidial diarrhea.

But are these prognostic markers generalizable? It is important to take into account background levels of morbidity and mortality. High background levels of morbidity lead to apparent rapid clinical progression, whereas high background levels of mortality mean that fewer persons with HIV infection die with AIDS, although 80-90% do. The proportion of patients dying within 45 years of their 15th birthday ($_{15}Q_{45}$) was higher in Africa in the pre-HIV era, ranging from 0.26 to 0.67, than in the developing world, where it ranged from 0.10 to 0.13. Thus, in Africa the high but variable background mortality suggests that the prognostic value of clinical conditions will vary at different sites.

To better identify people clinically who might benefit from ARVs, a better AIDS case definition in needed. It should be standardized and consistent, it should be revised to be more appropriate and more easily used for surveillance and it ought to be compatible with the WHO clinical staging system, at least for stage 4. The WHO clinical staging system is already a useful prognostic tool, but it may possibly benefit from revision and repositioning some conditions.

Can the WHO clinical staging criteria be used to monitor the impact of ART? The staging system currently is hierarchical, so progress is only in one direction with deterioration toward death. If this restriction could be lifted, clinical improvement could be documented, but the question remains whether the prognosis of stage 3 infection is the same whether a patient is treatment-naïve or treatment-experienced. An alternative is to clarify the stage by whether a patient has been treated or not, which would allow the staging system to be bi-directional. This, however, remains problematic because the prognosis of stage 3 may or may not be the same if a treated patient is on an initial course of first-line therapy or undergoing salvage therapy.

In conclusion, the AIDS clinical case definitions are currently unhelpful, generally underused and badly in need of revision or abandonment. The WHO clinical staging criteria are more useful but could be improved by possibly adjusting the position of some clinical criteria or by revising the system to allow disease burden to be monitored. Any revisions will need consensus and will need to be based on available data from multiple sources. Moreover, the revisions will need input from clinicians using ART in developing countries, and the revisions will need to be evaluated at sentinel sites.

A comment from the audience after Professor Whitworth's presentation pointed out that Brazil has revised its case definition to match its criteria for initiation of ART. A question was also asked if WHO had any concrete plans to address the AIDS case definition

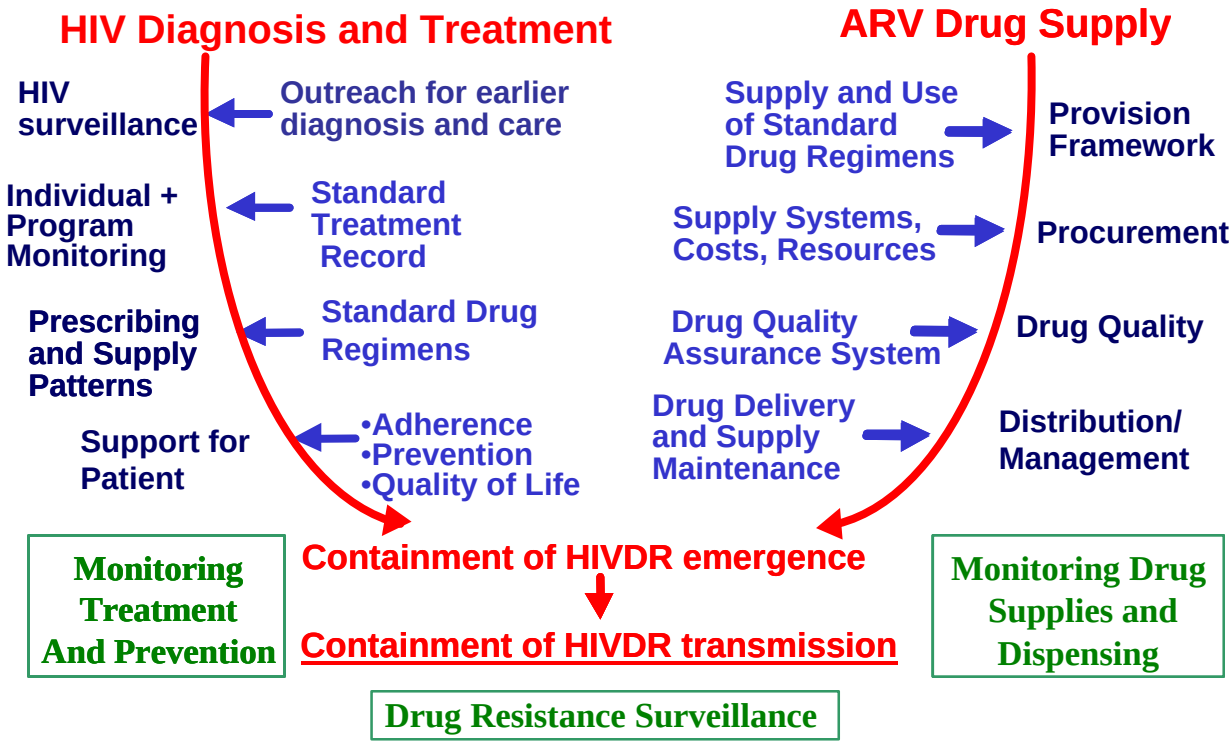
Dr. Donald Sutherland of WHO described surveillance for ARV resistance.[58] WHO's 3x5 Initiative envisions having 3 million persons on ART by the end of 2005. However, there are possible unwarranted consequences of rapid scale up of ART, including insufficient attention being paid to prevention efforts resulting in the resumption of high-risk behaviors and HIV drug resistance. WHO has developed and implemented surveillance and monitoring methods to support the containment of HIV drug resistance as ART is rolled out worldwide. This group, called HIVResnet, is composed of a technical committee and subcommittees on epidemiology, laboratory, data management, technology transfer and data use co-chaired by one developing-country and one industrialized-country expert.

Some degree of HIV resistance is inevitable with lifelong treatment, no cure and a high rate of mutation. The goal is, therefore, containment of HIV drug resistance, that is, reducing the rate and emergence of resistance and limiting its public health consequences, rather than its total prevention. Principles of containment include appropriate drug prescribing and usage, fostering adherence, reducing HIV transmission and taking appropriate actions based on monitoring and surveillance. This is shown schematically in Figure 23.

Program elements to support containment of HIV drug resistance include standard ARV treatment regimens, QA for drugs, adequate and continuous drug supplies, standardized individual treatment records, support for and monitoring of adherence, monitoring of key indicators of resistance containment, prevention program to reduce HIV transmission from persons receiving ART, HIV drug resistance surveillance, provision of information for action and clear guidance on "trigger levels" for public health action. Monitoring for resistance should begin simultaneously with treatment. These indicators will make up an early-warning system that can identify conditions that could foster the emergence of HIV drug resistance. Many of these indicators will be gathered for other purposes, and others will need to be unique to resistance surveillance. Aggregate HIV drug-resistance indictors should include the percentage of treatment failures in the first year, the percentage of regimen switches in the first year and the percentage with low adherence to prescribed therapy. Many people meeting these criteria will not have drug-resistant HIV, but programs with high levels of these three indicators are less likely to be able to contain drug-resistant HIV. Trigger levels will need to be decided in advance.

HIV drug resistance surveillance will have different objectives in drug-naïve persons and persons on treatment. Among drug-naïve patients, the objectives are to estimate the prevalence of HIV drug resistance, especially among those recently infected with HIV and those newly diagnosed and being evaluated for treatment, to evaluate trends in HIV drug resistance and to evaluate risk factors for HIV drug resistance. Among treated patients, the objective is to estimate the prevalence of resistance emerging in response to current ARV treatment regimens, drug usage, adherence and treatment practices. Surveillance for HIV resistance should not begin until there is some indication that transmitted resistance is sufficiently widespread to be measured. Resistance threshold surveys, a methodology based on Lot Quality Assurance, will be used to evaluate whether HIV drug resistance remains less than 5% in sites where the transmission of drug-resistant HIV is likely to be seen first. Initial identification of drug resistance will involve sentinel surveillance of HIV diagnostic sera or dried blood spots. Monitoring of resistance could be done either at the time therapeutic regimens are switched in individual patients or in cross-sectional surveys of either routinely drawn laboratory specimens or as special studies for all persons in the first year of ART who need to switch regimens. The optimal sampling methodology is still under discussion.

Figure 23. Containment of HIV drug resistance emergence and transmission: program elements.



Our knowledge of the transmission of HIV drug-resistant strains is very limited. There are no population-based estimates of HIV drug resistance in persons with newly diagnosed or recently transmitted HIV infection anywhere in the world. In the United States, 90% of prevalence studies of HIV drug resistance have been done among MSM, and 88% have been done among whites, although MSM comprise only 45% of new U.S. HIV diagnoses and whites only about 25%. In multicity studies, different cities contribute different proportions in different years.

Among treated persons, HIV drug resistance monitoring would be used to evaluate the utility of current ARV regimens and specific drugs; to guide recommendations for clinical HIV drug-resistance testing where available; to use with other indicators to evaluate overall HIV diagnosis, HIV care, ARV treatment, adherence support and prevention program effectiveness; and to evaluate actions taken to contain HIV drug resistance. WHO has several milestones planned for HIV drug resistance in 2004. First, HIV drug resistance containment is an integral part of the 3x5 strategy. WHO plans on developing surveillance guidelines and monitoring guidelines, on piloting a surveillance methodology for HIV drug resistance in Mexico, on conducting initial HIV drug-resistance threshold surveys in 20 countries, on instituting drug resistance monitoring in treated patients in five countries, on planning an international genotyping laboratory QA program and on conducting a variety of operational research projects. These projects will evaluate potential indicators for HIV drug-resistance containment, will examine optimal strategies for population-based monitoring in treated individuals, will evaluate use of dried blood spots for drug-

resistance surveillance, will examine point mutation assays to guide the choice of first and second regimens in countries with high levels of resistance and no access to clinical drug-resistance testing and will integrate HIV drug-resistance surveillance into HIV-1 subtype surveillance.

Three recommendations were made:

1. All countries carry out a population-based threshold HIV drug-resistance surveillance study in untreated HIV-infected persons, ideally those who have been recently infected, following WHO guidelines
2. All countries consider HIV drug-resistance monitoring studies in HIV-infected persons on treatment to assess the emergence of resistance
3. WHO develop a protocol for performing HIV drug-resistance monitoring in treated persons as soon as possible

Work group 5 focused on the issues discussed in Session 5.* They were asked to discuss a series of questions dealing with HIV/AIDS surveillance and monitoring the impact of ART (Table 26).

The group listed six objectives (Table 27). These included ways to improve the current surveillance system, by expanding the existing tuberculosis surveillance to include data on HIV infection and by capturing better data from AIDS case reporting system. The Group also outlined some new activities, focusing on capturing data from individual patient records at point of entry into HIV care and, because patients will be lost to follow up, determining outcomes in a sample of these patients. Another new recommended activity was cohort studies that would follow patients from HIV diagnosis to death with intensive follow up for biological parameters, treatment, behavior (adherence, sexual risk behavior), health services utilization and outcomes. With regard to improving mortality surveillance, a series of activities was outlined to improve both overall mortality data and HIV-specific mortality data in high-burden countries. Finally, the Group endorsed the notion of integrated data analysis and data synthesis to measure the impact of ART.

Table 26. Work group 5 discussion questions.

1. What existing surveillance systems can be used to measure the impact of ARVs? What is the current state of these systems? Do they need improvement, and, if yes, what parts need to be improved? What are the next steps to improve these systems? What collateral effects of ARV in the non-treated population (e.g., child mortality, TB, deaths among young adults) should also be monitored?
2. What systems need to be developed that do not yet exist? With regard to cohort studies, how many cohorts are needed and in what countries? At what stage of infection should participants enter cohorts?
3. In what countries does it make sense to invest in improving the vital registration system?
4. Are verbal autopsies and cadaver studies worthwhile ways to measure cause-specific mortality? What questions would verbal autopsy require (e.g., behavioral questions, exclusion of traumatic causes of death, etc.)

* Dr. George Loth, facilitator and lead author; Dr. Rebecca Mammo, rapporteur; Professor George Rutherford , presenter. Other work group members were Drs. Alebchew, Buckner, Diaz, Nash, Nnorom, Sutherland and Veloso and Ms. Broyles.

Table 27. Objectives and activities, Work Group on AIDS Reporting and Monitoring the Impact of ART in the Context of Care and Treatment.

Objective 1: Expand existing tuberculosis surveillance system to include data on HIV infection

Activities:

- Examine existing data on incidence of tuberculosis to determine indirect effect of ARV
- Modify tuberculosis case report forms (electronic, paper) to include item on HIV infection and follow proportion of patients with new tuberculosis with HIV co-infection
- Supplement funding for vertical tuberculosis programs to pay for universal HIV VCT
- Pilot studies to obtain outcome data on representative cohort of HIV-tuberculosis co-infected patients. Can compare Botswanan and South African pilots (PROTEST) with non-integrated program, e.g., Malawi.

Objective 2: Capture better data from AIDS case reporting system

Activities:

- Develop new guidelines on AIDS surveillance in low-level and concentrated epidemics
- Develop and disseminate consensus on new case definition
- In countries with generalized epidemics, consider sentinel surveillance. Evaluate current Nigerian sentinel surveillance demonstration project.

Objective 3: Capture data from individual patient records at point of entry into HIV care and determine outcome in a sample of patients lost to follow up

Activties:

- Reach consensus on which elements of individual patient record to capture
- Design protocol to determine outcome for samples of patients lost to follow up

Objective 4: Promote cohort studies of patients from HIV diagnosis to death with intensive follow up for biological parameters, treatment, behavior (adherence, etc.), health services utilization, outcomes

Actitivies:

- Articulate benefits of 4-6 intensive cohort studies designed primarily for programmatic and research purposes for surveillance data elements, including opportunistic infections and survival

Objective 5: Improve overall and HIV-specific national-level mortality data in high-burden countries

Activities:

- Develop annual HIV mortality estimate for each high-burden country by:
  a. Where vital registration system is adequate, validate and use overall and HIV-specific mortality data
  b. Where vital registration system is sufficiently advanced to merit investment, seek opportunities to improve national-level vital statistics data
- Where existing sub-national demographic sentinel surveillance sites exist (e.g., DSS INDEPTH), validate verbal autopsy data for HIV/AIDS; if validated consider expanding to other countries
- Examine census and other population-based surveys (e.g., DHS) for overall HIV-specific mortality where available
- Promote examination of other ways to measure mortality
  a. Modeling HIV-related and excess mortality
  b. Examine literature on other ways to measure mortality (e.g., cemetery records, burial societies, funeral homes, burial certificates, coroner records, etc.
  c. Include mortality data on US Bureau of Census CD-ROM

Objective 6. Synthesize data on impact of ART

Session 6. Experiences in HIV Surveillance Data Use

Ms. Elizabeth Pisani of Family Health International discussed using surveillance data for program-level planning in Indonesia.[59] In Indonesia, USAID, the World Bank and AusAID had begun funding HIV prevention programs in 1996; FHI implemented the USAID HIV/AIDS Prevention Project from 1996 to 2000, and the USAID-sponsored Asa Project starting in 2001. All the programs had a similar focus on information, education and counseling especially among female CSWs. They were geographically limited and centered on non-governmental organizations. They were designed at a time of very low HIV prevalence with little available behavioral data, but over time they invested in surveillance, especially behavioral surveillance. The results of the behavioral surveillance indicated that the prevention programs were not producing the desired outcomes. Specifically, condom use in Jakarta remained low at 10.3% to 11.7% among CSW and 4.1% among their clients, while HIV prevalence among sex workers in Jakarta quadrupled to 6.7% among massage parlor-based sex workers and 2.7% among brothel-based sex workers by 2003.

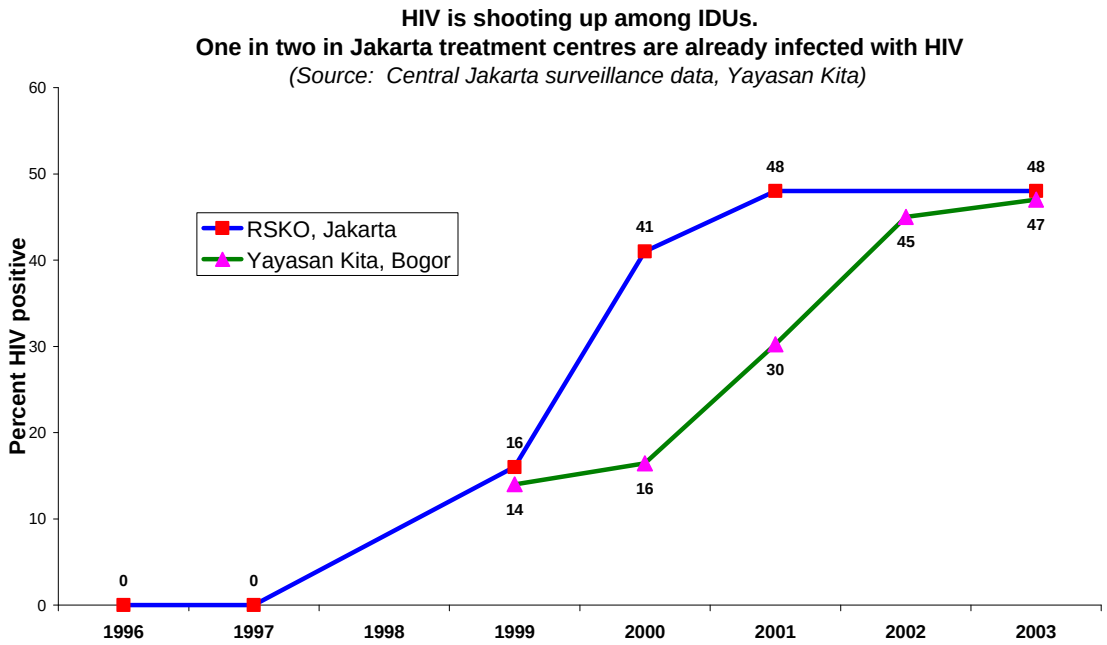
These observations led to a series of questions that prompted a thorough review of all available surveillance data:

- Why was condom use not rising in response to health promotion efforts? Was the wrong thing being done? Were the wrong people being reached?
- Since condom use had always been low, why was HIV in CSWs just beginning to rise in 2002? Was something being missed?

Populations routinely included in HIV surveillance included female CSWs, transvestite CSWs, IDUs and prisoners. Populations routinely included in behavioral surveillance included these with the exception of prisoners plus male sex workers, clients of sex workers, MSM and youth. The Asian Epidemic Model was then used to explore the epidemic in subpopulations and to examine the interaction of risk between them. Program monitoring data were also included. From triangulating these various sources of data it was apparent that knowledge and availability did not seem to be obstacles to condom use in commercial sex transactions and that the major reason that condoms were not being used is that the clients did not want them. In surveys in three provinces, it was apparent that lack of condom use did not reflect absence of risk. In these surveys, fewer than 50% of men were abstinent or only had sex with their wives, a small percentage used condoms for all extramarital sex and almost 50% had risky sexual behaviors. Moreover, the proportion of sex workers reached by non-governmental organization programs was very low, ranging from 3% to 11%. Estimates of the proportion of clients reached by these programs was even lower, ranging from less than 1% to 3%. Given the low coverage, if condoms were used by 100% of persons reached by the program, there would only be a small impact on HIV incidence. Interestingly, those who said they were reached by interventions had safer behavior than those who were not, but government interventions and mass media were as effective as non-governmental organization programs.

From HIV data it was apparent that there had been rapid rises in prevalence in three populations, *waria* or transvestite CSWs, prisoners and IDUs. By 2002 the prevalence in *waria* was estimated to be 21.7% and in prisoners 24.5%. Heterosexual men appeared to be integral to the increased incidence among female CSWs because these men obtain sex from both female and transvestite sex workers. Prisoners were responsible for transmission inside and outside of prison upon release. However, the largest increase was among IDUs (Figure 24), in whom prevalence rose from 0% in 1997 to 47% and 48% in two separate surveys in 2003.

Figure 24. Prevalence of HIV infection among IDUs, Indonesia, 1996 to 2003



Simple spreadsheet models suggested that the risk of incident HIV infection was approaching 100% in one year in IDUs and 40% in prisoners in Indonesia. About 55% of IDUs were found to be sexually active in behavioral surveys, few used condoms regularly and 53% of those who were sexually active had more than one sexual partner. Twenty percent of men in this risk group were having sex with CSWs. Modeling three separate prevention strategies, by 2010 in Jakarta 16,000 HIV infections could be averted by not sharing needles, 18,000 by not initiating drug use and 26,000 if IDUs stopped having unprotected sex. Using the Asian Epidemic Model with data through 2003, by 2010 about one-third of infections would have occurred in IDUs and the other two-thirds in other risk groups, with a large contribution from sexual partners of injectors. If the epidemic among IDUs had been prevented, the model showed virtually no HIV epidemic in Jakarta by 2010 (Figure 25).

These data have led to complete rethinking of program priorities. IDUs and prisoners have emerged as major priority populations, and there is a recognition that early action on the epidemic in IDUs is critical. In addition, programs for IDUs must stress safe sex, and programs for high-risk sex must focus more on clients of CSW. Coverage is key. Without coverage there can be no impact, and the government is a key partner for achieving coverage. This rethinking has led to a realignment of prevention funding between 2001 and 2003 from 71% to 23% for female CSW, from 11% to 53% for high-risk men and from nothing for IDUs or for prisoner advocacy to 17% and 10%.

Dr. Lu Fan of the Chinese Centers for Disease Control discussed the impact of improved estimates on surveillance activities in China.[60] China's surveillance program includes case reporting, sentinel surveillance, behavioral surveillance and epidemiological survey data. The 2001 national HIV estimates in China were based on surveillance data, the components model and the Delphi method. The output was the cumulative number of HIV infections. Using these methods, there were an estimated 850,000 cumulative cases of HIV infection. In 2003, the estimates were based on seroprevalence surveillance data and the Workbook method. The output was the number of persons living with HIV infections and AIDS (Figure 26).

Figure 25. Cumulative HIV infection among IDUs and others, Jakarta, 1995-2010.

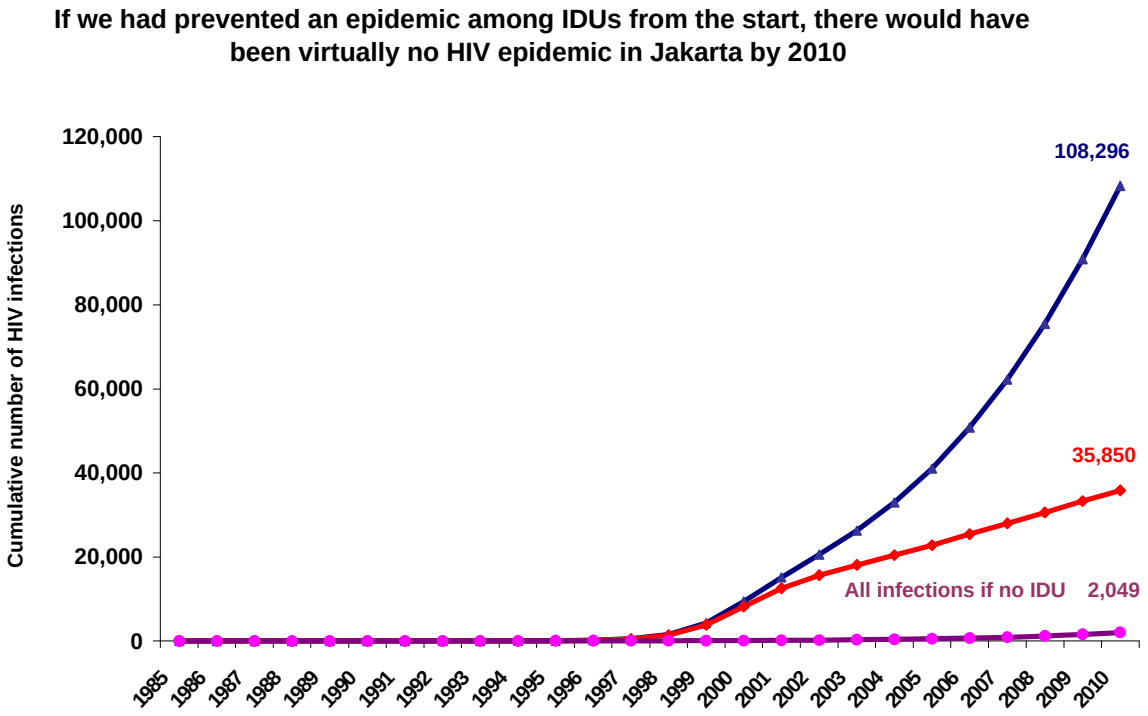


Figure 26. Workbooks estimates of the number of persons living with HIV and AIDS, China, 2003.

2002	Population Sizes Estimates		Prevalence Estimates (%)		Estimates of People living with HIV/AIDS				Average PLWHA
贵州	*Low*	*High*	*Low*	*High*	*(Low Population x Low Prevalence)*	*(Low Population x High Prevalence)*	*(High Population x Low Prevalence)*	*(High Population x High Prevalence)*	
Region Adult population (15-49)	18,367,294								
% Urban population	23.87%								
1. Populations at higher risk (PHR)									
DU	200,000	400,000	2.00%	15.00%	4,000	30,000	8,000	60,000	**25,500**
MSM	43,843	87,685	0.50%	2.00%	219	877	438	1,754	**822**
Sex workers	160,000	200,000	0.33%	2.00%	528	3,200	660	4,000	**2,097**
Male STD	45,918	183,673	0.01%	0.40%	5	184	18	735	**235**
FPD	80,000	100,000	0.20%	5.00%	160	4,000	200	5,000	**2,340**
Rural MSM	69915	139830	0.005	0.01	350	699	699	1,398	**787**
MTCT					**0**	**0**	**0**	**0**	**52**
blood/blood products					**0**	**0**	**0**	**0**	**0**
Sub-Total PHR	**599,676**	**1,111,189**			**5,261**	**38,960**	**10,016**	**72,887**	**31,833**
2. Populations at lower risk (PLR) that are not already included in PHR					Select one:	X	PLR AHC data		
a. Partners of high risk populations			**Selected Partners of high risk populations!**						
Partners of IDU	17,000	34,000	5.00%	15.00%	850	2,550	1,700	5,100	**2,550**
Female partners of MSM					0	0	0	0	**0**
Partners of FPD with HIV	199	597	10.00%	27.00%	20	54	60	161	**74**
Optional LR1					0	0	0	0	**0**
Clients without STD	183,673	734,692	0.00%	0.04%	2	73	7	294	**94**
Optional LR3					0	0	0	0	**0**
Sub-total Partners of high risk	**200,872**	**769,288**			**872**	**2,677**	**1,767**	**5,555**	**2,718**
b. ANC data applied to low risk women									
Urban female low risk pop									
Rural female low risk pop									
Sub-total of low risk women									
Sub-Total PLR					**872**	**2,677**	**1,767**	**5,555**	**2,718**
No Risk Population									
TOTALS	**800,548**	**1,880,477**			**6,133**	**41,637**	**11,783**	**78,442**	**34,550**

As a result of these estimates, the government paid more attention to HIV/AIDS surveillance. The new estimates led to a better understanding of the distribution of transmission groups. HIV and AIDS case reporting data had shown that 62% of infections were among IDUs, 19% were among persons with no known risk factors, 9% were among female partners of IDUs, 8% were sexually transmitted, 2% were transmitted through blood or blood products and less than 1% was the result of mother-to-child transmission. In contrast, data from the 2003 national estimates indicated that 44% of cases were among IDUs, 31% were sexually transmitted, 24% were among female partners of IDUs and less than 1% were transmitted through blood or blood products or as the results of mother-to-child transmission. Data gaps that were clarified included prevalence data, data on high-risk groups and their partners, geographic data and the population size of high-risk groups.

The specific action plan that was formulated as a result of these data included enhancing sentinel surveillance, conducting research on population size estimates, conducting HIV serological surveys in the community, initiating mortality monitoring and developing HIV estimates by province

Dr. Mohamed Shaukat of the Indian National AIDS Control Organisation spoke on India's experience with using HIV surveillance data.[61] There are now 3.8 to 4.6 million persons estimated to be infected with HIV in India. Twenty-eight percent of Indians live in the six states with generalized epidemics. One characteristic of the Indian HIV epidemic is that it is actually several diverse epidemics; nearly 85% of HIV infection has been acquired heterosexually, but in the state of Manipur in northeastern India 73% of HIV infections are due to injection drug use. Eighty-two percent of cases are in the 15-to-44-year-old age group. Surveillance in 455 sentinel surveillance sites, of which two-thirds are ANCs and one-third STI clinics, is an integral component of the National AIDS Control Program, and 3% to 5% of its annual budget is spent on surveillance. Surveillance data are used to work out HIV estimates in the country, to help generate public response and to help target prevention activities and plan resources.

More recently the National AIDS Control Program has shifted its emphasis to now include strong political advocacy, decentralization and state ownership of programs, involvement of the non-health sector, focus on vulnerable groups, promoting behavioral change, enlisting participation of non-governmental organizations and communities, focusing on care and support of persons living with HIV and AIDS and mainstreaming HIV and AIDS care in the health system. The data that have driven this program realignment have come from several sources. These include surveillance for HIV through sentinel surveillance, 450 VCT centers and 850 blood banks; AIDS case reports; a national behavioral sentinel surveillance survey in the general and high-risk populations in 2001; and secondary markers from STI clinics and blood banks (hepatitis B and C). There is also a computerized information system that provides state-level data. Using a decentralized approach has worked well.

There were four ways that surveillance data led to changes in program activities in India. One example was the Sonagatchi Sex Worker Intervention Project, which found that there was a temporal association between increased condom use in female sex workers and decreases in HIV and syphilis. This led to a new emphasis on targeted interventions for sex workers, and there are now 734 such programs nationwide. A second area in which surveillance data were used to drive policy was PMTCT. A third area involved data from STI clinics, which led to a new focus on the role of STIs in HIV transmission in low-prevalence states. The behavioral surveillance system indicated that for a large portion of the country, less than 50% of respondents knew that HIV can be prevented by having one uninfected monogamous partner and by always using condoms. Overall, 6.6% reported non-regular sex partners, and 49% reported using a condom with the last non-regular sex partner. Surveillance data demonstrated that in the northern

states, HIV prevalence was low although foci of high prevalence areas and the presence of risk behaviors which indicate the potential for HIV transmission. Finally, examination of AIDS case reporting data showed that 65% of all opportunistic infections reported was tuberculosis.

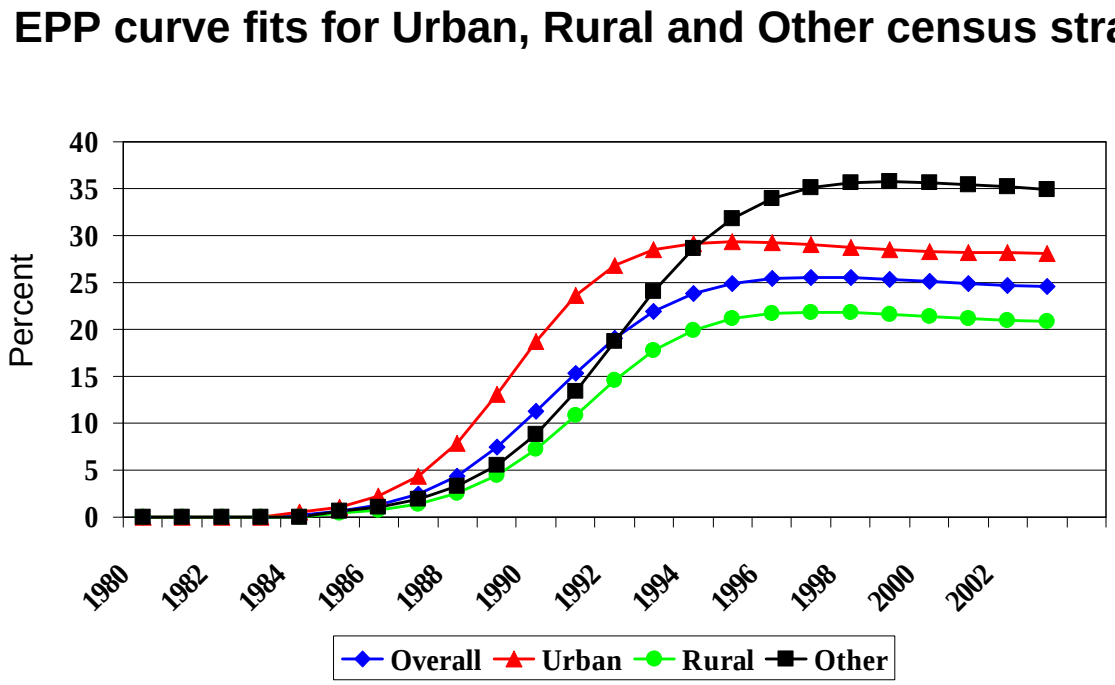
The data resulted in improved targeted action by program managers that included expanding coverage of prevention programs, such as PMTCT and VCT. They also contributed to many programs that are in various stages of planning and action. These include a community survey of STI prevalence, specific HIV prevalence studies in high-prevalence states, a second wave of behavioral surveillance in the general and high-risk populations, continued mapping of high-risk groups, expansion of sentinel surveillance to include more of the targeted intervention based high-risk group sites, validation of the assumptions used in HIV prevalence estimations and expanded efforts to work with states to improve their capacity to use data in program planning and the documentation and dissemination of data.

Dr. Owen Mugurungi from the Zimbabwean Ministry of Health and Child Welfare spoke on how lower prevalence estimates in 2003 were communicated in Zimbabwe.[62] Data have been used since 1997 to generate biennial HIV and AIDS estimates. In 2002 the adult prevalence rate of HIV was estimated to be 33.7%. UNAIDS and WHO conducted a training workshop in Harare in April 2003 to train southern African countries to use EPP, which was subsequently used to produce the 2003 estimates. Sources of data for the 2003 estimates included the 2002 census report, which allowed classification of populations and sites as urban, rural and "other"; UN population estimates in Spectrum, which had a lower population estimate for Zimbabwe than that used in previous estimates; the 2002 ANC prevalence surveys, which were lower at 27% than they had been in 2000 (33.4%) and 2001 (31%); and other population-based surveys such as the Young Adult HIV prevalence and behavior survey of 2001 and the Manicaland HIV and STI prevalence project conducted from 1998 to 2000.

Using EPP, the prevalence of HIV infection in adults 15 to 49 years old was estimated to be 24.6% with a range from 20% to 28% with 166,000 new infections in adults and 40,000 in children, 138,000 new adult AIDS cases, 38,000 new pediatric AIDS cases and 171,000 AIDS deaths. This method was also used to estimate adult prevalences from 1980 to 2003, resulting in lower estimates. For example, estimates for prevalence among 15-to-49-year-old adults were lowered from 33.7% to 24.9%, corresponding to a decrease in the number of infected persons by 500,000. The reasons for this were that updated and adjusted ANC data were entered into EPP. Data used for the previous estimates contained duplicate sites and implausible results for some sites during certain years. The current estimates were based on new and more accurate ANC data and excluded implausible data points. Dividing rural areas into true rural areas and "other" areas, which included large-scale commercial farms, administrative centers, growth points, other urban areas such as mines, state land such as national parks and army camps, as opposed to lumping them all into the rural category resulted in a less inflated estimate of rural prevalence (Figure 27). Also contributing to the lower prevalence estimates were the updated United Nations prevalence estimates in Spectrum, which reflected declines in the Zimbabwean population since the last estimates.

Communicating the change in estimates was important. The Minister of Health and Child Welfare launched the estimates. The initial debate focused on whether this was a real decline in adult HIV prevalence from 33.7% to 24.6%, and some tried to use the comparison of the new estimate with the previously published estimates to justify this interpretation. However, using the current estimates methods, the prevalence rate for Zimbabwe was 24.9% in 2001 and 24.9% in 2003, thus showing a leveling off but no decline in HIV prevalence.

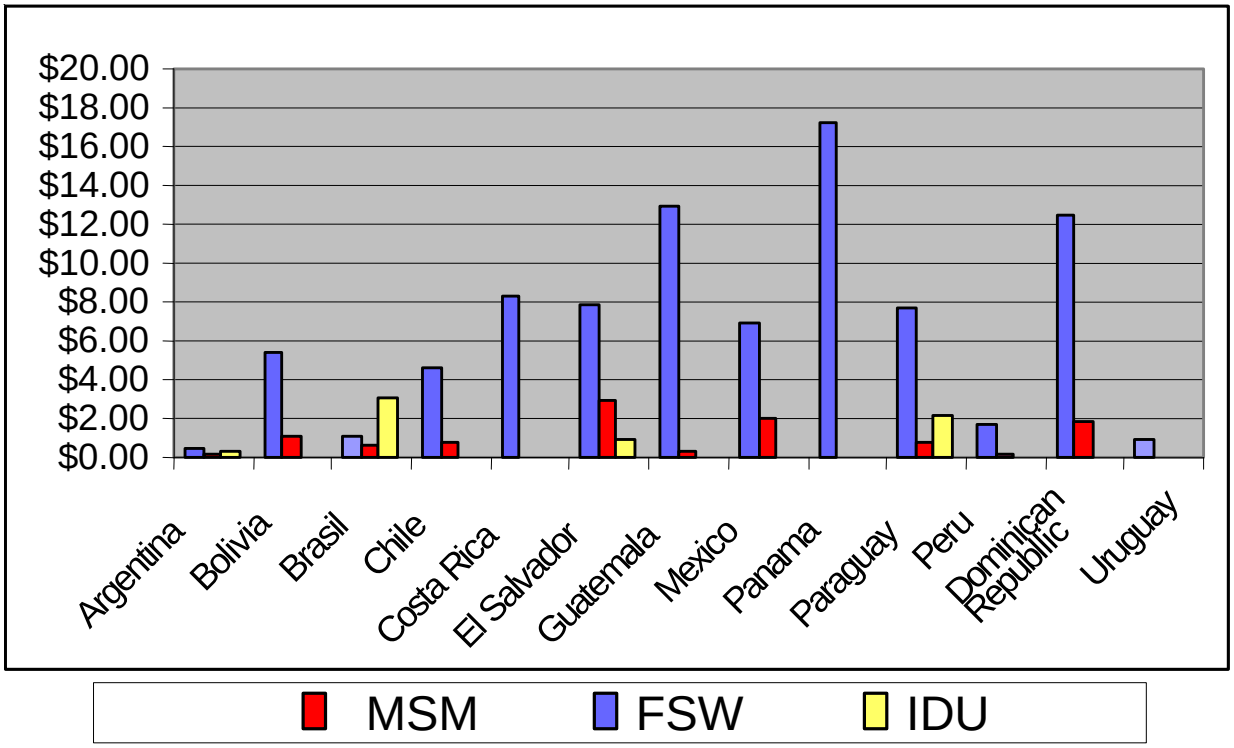
Figure 27. HIV estimates for urban, rural and other areas, Zimbabwe, 1990-2003.



Dr. Rúben Mayorga of the Asociación para la Salúd Integral y Ciudandania de América Latina (ASICAL) presented his group's experiences with using surveillance data to advocate for improved resource allocation to at-risk and vulnerable populations in Latin America and the Caribbean.[63] In Central America, HIV prevalence is higher in MSM men than female CSW. However, if prevention spending per case of HIV infection is examined, substantially more is spent on female CSW than on MSM (Figure 28). This mismatch in where prevention funds are spent and where infection is occurring is also seen if the data are analyzed by percentage of prevention funds or by AIDS cases.

In Guatemala, Spectrum was used to estimate the numbers of persons living with HIV and AIDS by transmission sub-group. MSM accounted for 32% of all persons with HIV and AIDS, whereas female CSWs accounted for only 1.9%. ASICAL conducted a political mapping exercise and devised policy strategies for increasing prevention funding for MSM in Guatemala. This strategy included incorporating a specific strategic plan for MSM into the National Strategic Plan, making visible the implications of the HIV/AIDS in MSM with stakeholders and decision makers, providing advocacy tools for men who have sex with me, involving new stakeholders in strategic alliances, strengthening financial and technical capacity of non-governmental organizations for actions and promoting empowerment and equal rights for MSM. Data were used for several of these strategic elements, such as advocacy with stakeholders, decision makers and bilateral and multilateral agencies; strengthening technical capacity for non-governmental organizations; and creating strategic alliances with human rights organizations. Estimates from Spectrum were specifically used for prioritizing Guatemala's Global Fund proposal.

Figure 28. Per capita spending for prevention in specific populations, Latin American, 2000.



Source: JA Izazola, SIDALAC

In conclusion, prior to ASICAL's efforts data had not been used for coherent policy formulation in Latin America and the Caribbean resulting in a disparity between the ways HIV affects at-risk and vulnerable groups and the resources assigned for prevention. To improve this situation, Dr. Mayorga advocated for more specific markers that can be used for advocacy and a combination of approaches including epidemiological data and human rights arguments. While some data exist and have been used for adequate public policy formulation around HIV/AIDS in Latin America and the Caribbean, better sampling methodologies, such as respondent-driven sampling, are needed in order to have more consistent and representative data. Finally, if these epidemics are to remain small and concentrated, data will need to be used more effectively to make intervention decisions.

Dr. Cyril Pervilhac of UNAIDS spoke for Dr. John Stover of the Futures Group, who was unable to attend, on the experiences from Africa on using surveillance data for policy and program decisions.[64] There are five best practices for dissemination and use of surveillance data:

1. Disseminating surveillance reports annually
2. Providing national estimates to planners and advocates and using the release of these data as an advocacy opportunity, as was done, for example, in Mozambique
3. Distributing a press release and conducting a press conference on the annual estimates to decrease problems with misinterpretation, as was done, for example, in Malawi
4. Providing documents for advocacy such as booklets and brochures; this has been done successfully in Kenya, Mozambique, Ethiopia, Zambia, Zimbabwe and Ghana
5. Use population-based surveys to validate national estimates, as was done in Zambia

The most common problems he reported were errors in multiplication, assuming that the estimated numbers of cases of HIV infection were the same as the number of cases of AIDS, that no increase in prevalence meant that the epidemic was over and that a decrease in the estimates equated with prevention success rather than methodologic changes.

Dr. Timothy Brown of the University of Hawai'i concluded the session with a discussion of integrating data analysis and advocacy.[65] Although there are a lot of HIV sentinel surveillance trend data available from many countries and behavioral surveillance trends in a few countries, we have had only limited success in linking biological and behavioral data. This in turn raises three questions:

- Can we ever truly understand HIV epidemics?
- Is all this data collection worth it?
- Are our prevention efforts having any effect?

The links between biomarkers and behavior are present at the level of the individual, and prospective cohort studies show strong links between behavior and biological outcomes. However, to see these links at the population level we need to include temporal dynamics, that is, it is *past* trends in behaviors, HIV and STIs that determine *current* prevalence levels. This leads to a need for models as well as for data. The main reason that these links are not being seen is that while a lot of data are being collected, no one is charged with putting together the "big picture". That is, existing information on past and present responses, on the epidemiology of HIV and STI and behavioral data, are not being analyzed in an integrated fashion with appropriate attention to the influence of the past on the present, and we are not incorporating the effects of responses into our analyses.

New modeling tools, including simple incidence spread sheets[66], EPP and, at a more advanced level, the Asian Epidemic Model, can contribute to reconstructing and understanding epidemics and knowing where to target prevention resources for maximum benefit. The Asian Epidemic Model replicates HIV dynamics in Asian settings. It examines five transmission routes – sex work; needle sharing; pre-, extra- and intra-marital sex; mother-to-child transmission; and MSM – and uses sizes of key populations over time and behaviors over time as its principal inputs. It uses these data to calculate epidemiological trends over time. This model provides an excellent fit for observed data in the different groups and can show both changes in each group's contribution to the current epidemic over time (Figure 29) and the effect of interventions, such as Thailand's 100% condom program (Figure 30). Similar modeling exercises using both the Asian Epidemic Model and EPP are underway in Cambodia, Jakarta, Indonesia and Vietnam. Where data are insufficient and data gaps exist, informed assumption can fill many of them.

Integration of analysis and advocacy is a process at the local level for systematically gathering and analyzing data, synthesizing those data, building relevant models with the latest tools, extracting informed policy and programmatic recommendations and effectively advocating to put them into action. Eight steps for integrated analysis were outlined:

1. Collect and synthesize biological, behavioral, programmatic and policy, resource allocation and coverage information
2. Extract key trends in HIV, behavior and responses over time
3. Highlight and plan to fill data gaps

Figure 29. Proportion of HIV infections by transmission categories, Thailand, 1988-2005.

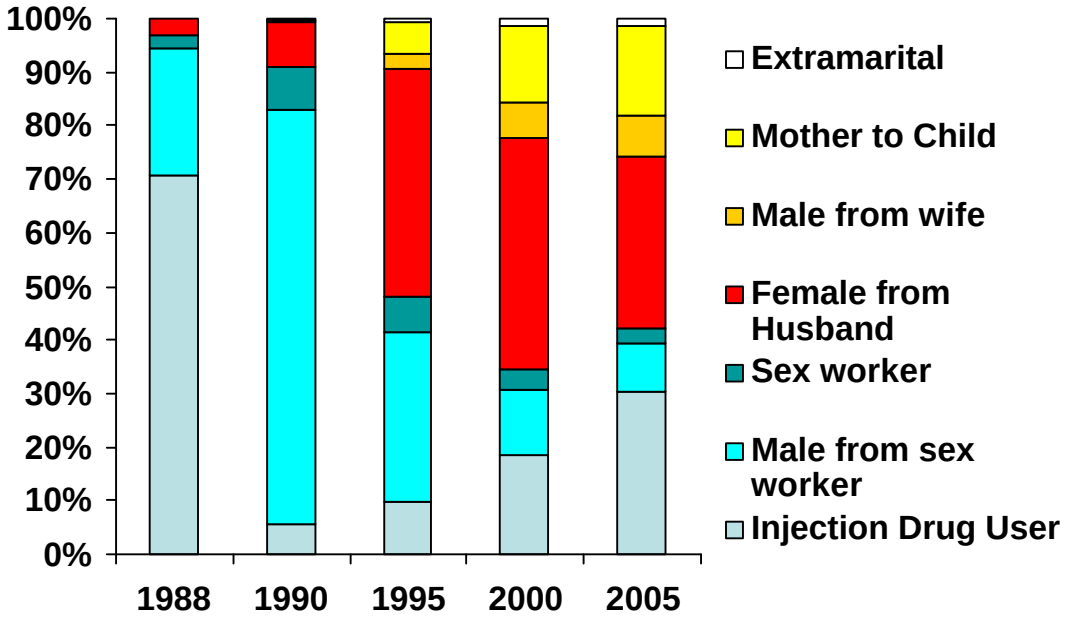
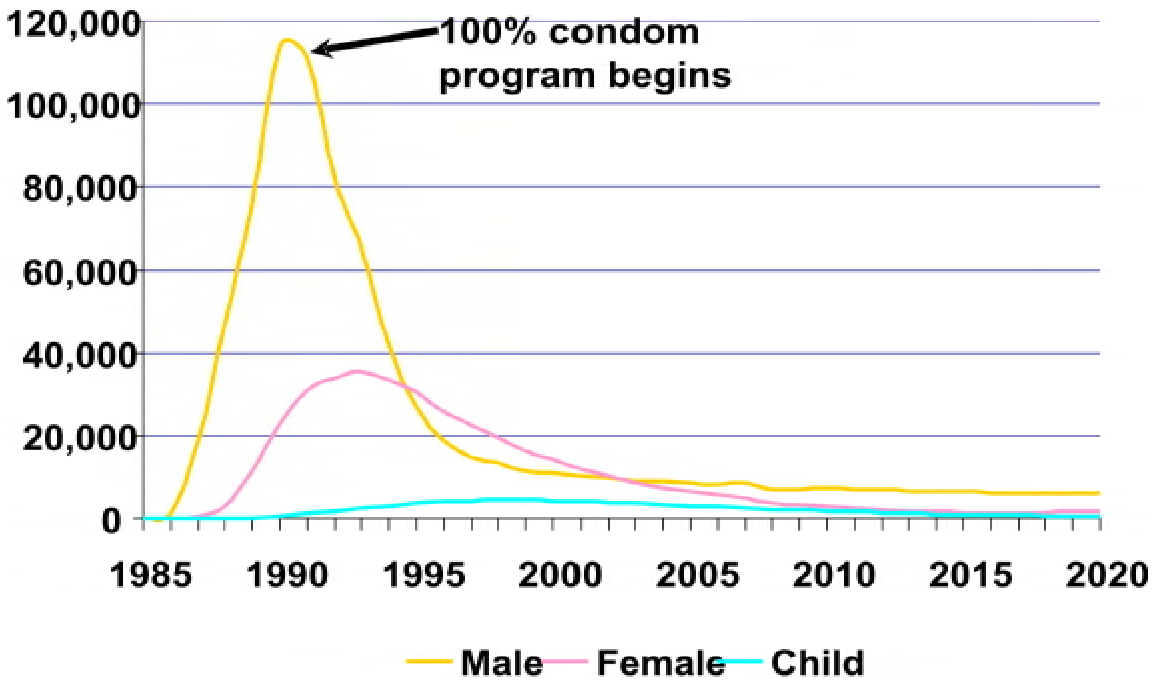


Figure 30. HIV incidence by sex and age, Thailand, 1985-2020.



4. Use latest tools to build models and projections, including prevalence spreadsheets, EPP, the Asian Epidemic Model and Spectrum
5. Analyze past and current responses for relevance and effectiveness
6. Use models to evaluate and estimate costs for alternative strategies
7. Strengthen advocacy efforts to promote change
8. Proactively advocate and support use of strategy analyses to make the most effective program choices and to mobilize adequate resources

Barriers to understanding national epidemics and evaluating and targeting resources include limited support for analysis from donors, too much emphasis on quick and dirty approaches, such as short consensus meetings and "hit and run" epidemiology and lack of capacity to analyze and synthesize data. There are no stable positions for pulling all the data together, and there is grossly inadequate technical support for doing so. Models provide the glue for linking epidemiologic, behavioral and response data, but capacity building for integrated analysis is needed at the national level and, to provide adequate regional and global technical support, at the international level.

Discussion

Dr. Brown was asked what sort of capacity he envisioned as being needed for the data synthesis function he described. He replied that ideally there would be a synthesis specialist in every country and a network of three or four people who could provide technical assistance in each country. As for their level of training, he envisioned some having one to two years of university-level training or internships and others trained through shorter regional workshops. He characterized the 13 regional estimation workshops that were held during the past year as incredibly productive. A participant pointed out that data synthesis needs to be linked to monitoring and evaluation as well as to projections and estimates. A member of the audience asked the meaning of the component model described in Dr. Mugurungi's talk and the goodness of its fit in Zimbabwe. The component model involves computing subgroups by province and then summing to create overall estimates; it has been used both in China and Zimbabwe. Another question involved what components of the model caused the estimates in Zimbabwe to be changed. Dr. Mugurungi responded that the more recent model excluded implausible results and that that change was the basis for the different estimates.

Another participant felt the Indonesian experience was an excellent case study that should be disseminated. This participant added that capacity would be difficult to build given the misalignment of the incentive system; he felt that changes in structural incentives would be required for positions devoted to data synthesis to get off the ground. A final comment dealt with the mismatch between prevalence and resources that Dr. Mayorga described in Central America and how the inclusion of data regarding response and expenditures are important in data synthesis. Integration of monitoring and evaluation data into the synthesis process is important but the data needs, such as program coverage, need to be defined clearly.

Work group 6 focused on the issues discussed in Session 6.[*] Participants were asked to discuss a series of questions dealing with best uses of surveillance data (Table 28).

[*] Drs. Cyril Pervilhac, co-facilitator and presenter, Dr. Peter Ghys, co-facilitator, Mr. Ezra Jones, rapporteur. Other work group members were Drs. Cuchi, Damoh, Dondero, Ismail, Keenlyside, Lu, Mayorga, Morgan, Neal, Schwarcz; Mr. Aberle-Grasse and Mss. Kufa and Pisani.

Table 28. Work group 6 discussion questions.

1. Is there enough technical guidance? Review available and in-the-pipeline guidelines, and decide what more (if any) is needed.
2. How can analytical tools (including EPP, Spectrum, others) be improved and/or extended? What research is needed to inform these further developments?
3. Do we need different tools and guidance and capacity building for different data uses (advocacy, program planning, monitoring and evaluation)?
4. Are data leading to better policies? What structural changes need to be made to ensure that they are? How should this information be systematically applied? Is it more a question of capacity and organization than of tools?
5. How can analysis of surveillance data be linked to monitoring and evaluation?
6. Are there guidelines, standards, or formats for the minimum number and types of reports that should be produced? At what level (district, province, national)should these reports be produced and disseminated? Should protocols for these activities be developed?
7. How should surveillance data be used for advocacy, treatment impact, prevention programs and coverage?
8. What are the needs, goals, and resources for capacity building? What structural changes need to be changed to facilitate capacity building?

The group first reviewed the uses of surveillance data, which included:

- Formulation of public policy
- National estimates
- Advocacy
- Guidance for programs on prevention and care
- Empowerment of marginalized groups
- Identification of research questions
- Use of data as part of a broader monitoring and evaluation system

They are used at the international, national and local levels. The group then identified some issues related to use of surveillance data. They felt that several things were lacking, such as an organized structure at the country level to make use of the data, a national plan for data use, an integrated database, a dissemination strategy, analysis capacity, multiple data sources, the right type of data for the local epidemic and a basic understanding of the limitations and expectations of surveillance data. To improve and extend analytical tools several things would need to happen. First there would need to be longer-term training, networking and meetings to generate the needed individual and organizational capacity for effective synthesis and use of surveillance data. There would need to be substantial capacity for data analysis and interpretation, and there would need to be incentives and motivators for people collecting the data. The group described four main objectives and a number of activities (Table 29).

Table 29. Objectives and activities, Work Group on Uses of Surveillance Data.

Objective 1: To identify and support appropriate organization structure and staff to improve analysis of surveillance data

Activities:

- Develop recommendations for appropriate organizational structure
- Place trained individuals in 10 key countries to support integrated data analysis and work with previously identified local counterparts
- Develop mechanisms to address staff retention in country

Objective 2: To increase capacity to analyze, interpret and disseminate surveillance data

Activties:

- Identify appropriate training needs (conduct training needs assessment)
- Identify appropriate training programs
- Conduct training
- Develop a training course, such as a six-week field epidemiology training program
- Build sustainability within the system at national, regional and local levels (with adequate staff and quality training)
- Institute public health programs with emphasis in epidemiology in existing training institutions
- Develop regional networks for information exchange

Objective 3: To assure and enhance analysis and publication of data from surveillance sources

Activities:

- Develop and maintain an inventory of tools and guidelines for analysis, estimations and reports
- Assist in production of timely report of surveillance data
- Assist in extracting surveillance data specific for M&E indicators

Objective 4: To improve national capacity to communicate surveillance data to maximize information used by different audiences

Activities:

- Identify organizational structures responsible for communication
- Develop strategies for marketing surveillance data
- Disseminate local and national surveillance reports/data to district and community levels
- Assist local stakeholders in using surveillance data for HIV/AIDS prevention activities
- Develop mechanisms for data to be used for monitoring and evaluation

SUMMARY OF KEY ISSUES FROM THE CONFERENCE

Dr. Timothy Brown of the University of Hawai'i summarized the key issues from the conference.[67]
The context of the conference was an era of expanding resources and an era of increased demands on surveillance systems. These demands include better estimates and projections, better assessment of countries' needs, better evaluations of the impact of programs and better responses. Specifically, the system needs to be modified to address the impact of widespread ART.

In reviewing the conference, he compared the consensus reached in Addis Ababa with the consensus on treatment reached at the Durban international AIDS conference. This consensus includes offering populations under surveillance the prevention and care programs and services that are their right, collecting the data needed to guide and direct programs intelligently, analyzing the data that we do collect and forming links to prevention and care programs. Moreover, budgetary constraints that interfere with these obligations are unacceptable and unethical. Expanded budgets will be needed if this job is to be done correctly, but the budget will pay off in improved prevention and care. Capacity for improved and integrated surveillance, however, is the real rate-limiting step, including capacity at national, international and regional levels, capacity to provide prevention and care services and capacity in data collection, data use, data analysis and data advocacy. Finally, he observed that surveillance has had a huge impact on how the HIV epidemic has been managed. It has kept the epidemic in the spotlight and led to the mobilization of massive resources. However, to do the job better than we have done in the past will require demands for resources and the resolution that every piece of data collected will contribute to reducing new infections and helping people with HIV obtain the support and services they need.

Dr. Brown's presentation was followed by a series of concluding remarks by representatives of the organizations that sponsored the conference. Dr. Novak said that the present surveillance system is incomplete and needs to be improved, but that resources are finite and the challenge is to make surveillance adequate for the job. He stressed that a series of interim medium-term steps were needed to work up to standards and that guidance was needed on the most appropriate interim steps to be able to measure Millennium Development Goals, the UNGASS, 3x5 and PEPFAR goals.

Dr. Stefan Wiktor of CDC GAP reflected that the goals of the conference had been broad – to update, to provide future directions for research and guidelines and to produce a series of peer-reviewed journal articles on the state-of-the-art in HIV surveillance. The issues that he saw emerging from the conference were the use of programmatic data and the narrowing gulf between surveillance and programmatic data, new approaches to surveillance and major initiatives on measuring the impact of multilateral and bilateral initiatives.

Dr. Ghys summarized that the purpose of surveillance is to target programs and to monitor progress. The old surveillance strategies are still valid but can be improved, but the new reality is how surveillance will effect prevention programs. A better job needs to be done analyzing and using surveillance data and linking them with monitoring and evaluation and with health economics and financial flow information. With surveillance comes a responsibility for dissemination and communication, and policy advocacy is one of the best uses of surveillance data. UNAIDS will continue to work with partners to develop its surveillance tools further, it will conduct training and it will continue its Working Group on Global Surveillance for HIV and STIs to provide guidance.

Dr. Sutherland reiterated the context of the 3x5 initiative, moving the number of persons on ARVs from 400,000 to 3 million by 2005, which is approximately half of what is really needed. He saw their being agreement among WHO, USAID and the United States government on connecting surveillance with the monitoring process, and he closed his remarks by commenting on the impressive capacity at the national level.

H.E. Dr. Kebede Tadesse, the Minister of Health of Ethiopia, closed the conference with a call for "evidence-based resource allocation".

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New strategies for HIV/AIDS Surveillance in Resource Constrained Countries

Addis Ababa, Ethiopia
UN Conference Center
January 26th- 29th, 2004

BACKGROUND:

HIV and AIDS surveillance in developing countries has traditionally involved anonymous serosurveillance of antenatal clinic attendees (ANC), HIV or AIDS case reporting or HIV serosurveillance of high risk populations. Second generation surveillance not only encourages the continuation of these surveillance strategies but expansion of these activities, dependent on the type (low, concentrated, generalized) and stage of the HIV epidemic in a particular country, in order to obtain a more complete picture of the epidemic. Newer HIV surveillance strategies have been recently developed that can improve the representativeness and quality of information collected. For example, general population based surveys in countries with a high prevalence of HIV can provide a more accurate determination of the true HIV prevalence and distribution of infection throughout a country. Increased experience in monitoring risk behaviors and changes in these behaviors over time has improved the quality of data gathered through behavioral surveillance. New laboratory methods to measure incident infection can be used on cross sectional samples to assess which persons are newly infected. Also, other new laboratory methods, such as rapid HIV testing, can be used to decrease reliance on the cold chain and thus assist countries in expanding ANC surveillance to rural areas.

Additionally, methods to prevent and treat HIV and AIDS have improved over time. Better sampling methods to access hard to reach populations for prevention activities can result in improved representativeness of these groups and are thus also useful for HIV surveillance. HIV testing and prevention of mother to child transmission programs are other possible data sources that can be used for HIV surveillance. Increased availability of antiretroviral (ARV) therapies necessitates changes in surveillance such as increased AIDS reporting, the need to monitor ARV resistance, and to track mortality.

Considering these new advances in HIV surveillance, monitoring, prevention, and treatment, a conference to update public health HIV/AIDS surveillance workers on the newest strategies for surveillance, develop a consensus on the best new methods, and determine what further research is needed to improve HIV surveillance activities is urgently needed. We propose to have such an international conference as a collaborative effort of four agencies who work extensively on HIV surveillance: the Global AIDS Program (GAP) at the Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), the Joint United Nations Programme on HIV/AIDS (UNAIDS), and the United States Agency for International Development (USAID).

PURPOSE:

To bring together public health HIV/AIDS surveillance staff from throughout the world to:

- Provide updates on emerging strategies for HIV and AIDS surveillance in update sessions
- Present and discuss the issues for six consensus/future research topics for new strategies in HIV/AIDS surveillance
- Develop ideas presented at the plenary sessions to determine what further research, resources and technical assistance are needed to improve HIV and AIDS surveillance activities during expert workgroups to be held after the conference
- Write a summary document and journal supplement to update persons on emerging best practices by which to conduct surveillance for HIV and AIDS in resource constrained settings

LOCATION AND DATE:

Addis Ababa, Ethiopia
UN Conference Center
January 26-29th, 2004

ONLINE REGISTRATION:

http://www.ethioconference.com/surveillance

PARTICIPANTS:

We will encourage the participation of all persons responsible for HIV/AIDS surveillance at the national and regional levels in all countries in the world. Additionally, persons who work for international organizations that do surveillance will be encouraged to attend.

OVERALL COORDINATION:

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AGENDA

DAY 1: Monday, January 26
Moderator: John Novak, USAID

8:30AM – 9:20AM	**OPENING CEREMONY** Master of Ceremonies: Tadesse Wuhib, Chief of Party CDC-GAP Ethiopia
8:30-8:40	• Introduction of Dignitaries -Tadesse Wuhib, CDC-GAP
8:40-8:50	• Welcome address- H.E. Ato Arkebe Equbay, Mayor of Addis Ababa
8:50-9:00 9:00-9:10 9:10-9:20	• Remarks-Aurelia E. Brazeal, Ambassador, US Embassy Bjorn Ljungquist, UN Theme Group Chair H.E. Dr. Kebede Tadesse, Minister of Health of Federal Democratic Republic of Ethiopia
9:20AM- 10:00AM	**OPENING SESSION**
9:20-9:25 9:25-9:30 9:35-9:40 9:40-9:45	• Remarks: Mike St. Louis, CDC Ties Boerma , WHO Peter Ghys, UNAIDS John Novak, USAID
9:45-10:00	• Overview of Conference –Theresa Diaz, CDC
10:00 AM- 10:30AM	**Break**
10:30AM – 12:00PM	**Update I: Overview of history, current status and new approaches for HIV/AIDS surveillance in resource constrained countries** Session leader: Don Sutherland, WHO
10:30-11:00	• Generalized epidemics-*Kevin DeCock , CDC*
11:00-11:20	• Low-level/Concentrated epidemics- *Tim Brown, East-West Center*
11:20-11:30	• Overview of the HIV/AIDS epidemic in Ethiopia—*Aseged Woldu, Ethiopia MOH*
11:30-12:00	• Discussion

12:00PM – 1:30PM	**Lunch**
UPDATES	
1:30PM – 2:30PM	**Update II: Ethical Issues in Surveillance** Session Leader: Mike St. Louis, CDC Emerging Framework for Surveillance in the Expanded Global Response to HIV/AIDS, and associated emerging and re-emerging ethical issues.
1:30-1:40	• Ethics of Surveillance- *Mike St. Louis, CDC*
1:40-1:55	• Toward a New Ethics for Surveillance? - *Ron Bayer, Columbia University*
1:55-2:10	• Ethical concerns in conducting surveillance: the Ethiopian situation-*Shabbir Ismail, CDC-Ethiopia*
2:10-2:30	• Discussion
2:30PM-3:00PM	**BREAK**
CONSENSUS/FUTURE RESEARCH SESSIONS	
3:00PM-5:00PM	**Session I: Measuring Recent HIV Infection** Session Leader: Steve McDougal, CDC Description of the newest epidemiologic methods and laboratory technologies and public health applications of methodologies to measure recent infection in the US and internationally
3:00-3:20	• Principles and validation of assays for estimating HIV incidence from cross-sectional population samples- *J. Steven McDougal, CDC*
3:20-3:40	• Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS) for estimating incidence- *Bernard M. Branson,CDC*
3:40-4:00	• BED-Capture EIA: Subtype-independent assay for HIV-1 incidence estimation -*Bharat S. Parekh, CDC*

4:00-4:20	• HIV RNA screening for real-time monitoring of HIV incidence- *Christopher D. Pilcher, UNC-MEASURE*
4:20-4:40	• Potential uses of measuring recent infections in Africa- *Guy Gershy-Damet, WHO-AFRO*
4:40-5:00	• Discussion
6:30PM – 9:00PM	**Reception (Crown Hotel)**

Day 2: Tuesday January 27 ***Moderator: Theresa Diaz, CDC***	
UPDATES	
8:30AM –10:00AM	**Update III: Quality assurance with HIV testing technologies** Session Leader: Robert Martin, CDC Description of quality assurance systems and HIV testing technologies for surveillance.
8:30-8:45	• An overview of testing in the field, what are key components, planning, evaluation, QA, and other technologies that may have surveillance applications in the future- *Robert Martin, CDC*
8:45-9:05	• Rapid test technologies – *Mark Rayfield, CDC*
9:05-9:20	• Laboratory quality assurance issues in Thailand- *Teeraratkul Achara, Thailand*
9:20-9:35	• Système de contrôle de qualité dans la serosurveillance du VIH: Experience du Rwanda-*Eugenie Kayirangwa,TRAC/MOH and Pierre Rugimbanya, National Reference Laboratory*
9:35-10:00	• Discussion
10:00AM – 11:00 AM	**Update IV: Informatics** Session Leaders: Meade Morgan, Kimberly Marsh, CDC Session will provide background on current informatics activities as they relate to HIV Sentinel Surveillance. In addition, an overview of the CDC module for Electronic Data Processing, Analysis and Reporting for HIV Sentinel Surveys using Epi Info will be presented.

	Discussion on how to scale up and support the course in different venues will be welcome.
10:00-10:30	• Update on informatics activities-*Meade Morgan and Kimberly Marsh, CDC*
10:30-10:40	• Review of pilot training of Electronic Data Processing, Analysis and Reporting for HIV Surveillance course in Ethiopia-*Shabbir Ismail, CDC-Ethiopia*
10:40-11:00	• Discussion
11:00AM – 11:30AM	**Break**
CONSENSUS/FUTURE RESEARCH SESSIONS	
11:30AM – 1:00PM	**Session II: General population based surveys** Session Leader: Txema Calleja, WHO Description of the different sampling issues, non-response issues, ethical issues, and HIV testing and linking of questionnaire data to HIV test results used in large population based surveys.
11:30-11:50	• Non-response issues in population based surveys – *Ann Way , Macro Int. USA*
11:50-12:10	• Field issues of population based surveys in Zambia - *Lovemore Kaetano, Tropical Diseases Research Centre, Ndola, Zambia*
12:10-12:30	• Field issues of population based surveys in Kenya- *James Muttunga (Kenya Medical Research Institute) and Larry Marum (CDC-Kenya)*
12:30-12:50	• The National Household-based General Population Survey of Risk Behavior and Sexually Transmitted Disease (STD) Prevalence in Peru-*Cesar Carcamo, Peru*
12:50-1:10	• Discussion
1:10PM – 2:30PM	**Lunch**
2:30PM – 3:30PM	**Session III: Linking Behavioral and HIV Surveillance** Session Leader: Ties Boerma, WHO Goal of the session is to assess the benefits and costs of linking

	behavioural and biological (HIV) trends. This will include issues related to: measurement (can we accurately measure trends in behaviour, and how accurate are trends in antenatal women for population trends, operational costs (how feasible is it to link antenatal clinic based surveillance to behavioural monitoring,), empirical data (what are the results of linking biology and behaviour in the same research population or in specific risk populations, what are the results of linking trends at subnational or national levels).
2:30-2:45	• Measurement of sexual behaviour and HIV trends: methodological issues and practical experiences – *Basia Zaba, London School of Hygiene and Tropical Medicine*
2:45-3:00	• Trends in HIV prevalence, incidence and sexual behaviour in a community cohort study in rural Tanzania – *Mark Urassa, National Institute for Medical Research, Mwanza, Tanzania*
3:00- 3:15	• Operational issues related to linking of behavioural and HIV surveillance – *Txema Calleja, WHO Geneva*
3:15-3:30	• Assessment of results of behavioural and biological surveillance in Tanzania, Nigeria, Burkina Faso from the second generation surveillance project – *Emma Slaymaker, London School of Hygiene and Tropical Medicine*
3:30PM – 4:00PM	**Break**
	Session III: Continued
4:00-4:15	• General population trends in sexual behaviour and HIV: the ABC study - *Priscilla Akwara, MEASURE Evaluation, ORC Marco, Calverton, Maryland*
4:15-4:30	• Behavioural and biological trends in the general and risk populations in Cambodia - *Heng Sopheab, National Center for HIV/AIDS, Dermatology and STDs, Cambodia*
4:30-5:00	• Discussion

DAY 3: Wednesday, January 28 ***Moderator: Ties Boerma, WHO***	
UPDATES	
8:30AM – 9:30AM 8:30-8:35 8:35-9:10 9:10-9:30	**Update V: State-of-the-art sampling for hidden populations: Time-Location and Respondent Driven Sampling** Session Leader: Keith Sabin, CDC Description of available methods used, pluses and minuses, description of respondent driven sampling and time location sampling and examples of use of some of these sampling methodology. • Introduction- *Keith Sabin, CDC* • State-of-the-art sampling for hidden populations: Time-Location and Respondent Driven Sampling-Tobi Saidel, *Bob Magnani, Family Health International* • Discussion
9:30 AM- 10:30AM 9:30-9:35 9:35-9:50 9:50-10:00 10:00-10:15 10:15-10:35	**Session IV: Use of VCT and PMTCT Data for Surveillance** Session Leader: Wolfgang Hladik, CDC This session focuses on the potential utility of VCT and PMTCT program data for surveillance and the biases these may introduce. Presentations include work and experiences from Uganda, Thailand, Botswana, and Kenya. . • Introduction- *Wolfgang Hladik, CDC* • Using VCT data for surveillance. An example from Uganda- *Frank Kaharuza, CDC-Uganda* • Discussion • A comparison of antenatal HIV prevalence determined from annual sentinel surveillance and a perinatal HIV implementation monitoring system (PHIMS)-*Plipat Tanarak, Ministry of Public Health, Thailand* • Discussion

10:30AM –11:00AM	**Break**
CONSENSUS/FUTURE RESEARCH SESSIONS	
11:00AM-12:00 PM	**Session IV: Continued**
11:00-11:15	• An Alternative to Annual HIV Sentinel Surveys Among Pregnant Women: Botswana's Experience with Prevention Of Mother-To-Child Transmission (PMTCT) Program Data- *K. Masupu, National AIDS Coordinating Agency, Botswana*
11:15-11:25	• Discussion
11:25-11:40	• Assessing the utility of PMTCT data for HIV surveillance in Kenya-*Nicole Seguy, CDC*
11:40-12:00	• Discussion
12:00PM-1:30PM	**Lunch**
1:30 PM- 3:30PM	**Session V: AIDS Reporting and Monitoring the Impact of ARV Therapy in the Context of Care and Treatment** Session Leader: George Loth, WHO Description of current strategies for HIV/AIDS/mortality reporting, how these reporting systems can be used to monitor the impact of ARV treatment, and suggested recommendations for improvements of these systems.
1:30-1:45	• An overview of HIV Mortality and Morbidity Surveillance- *Theresa Diaz, CDC*
1:45-2:00	• How to improve AIDS case definition and clinical staging – *James Whitworth, LSHTM*
2:00-2:15	• Measuring impact of ARV using mortality data in resource poor countries- *Lyndwe Makub, South Africa MOH*
2:15-2:30	• Monitoring of ARV, Brazil experience- *Valdilea Veloso, FIOCRUZ/MOH, Brazil*
2:30-2:45	• ARV resistance surveillance - *Dianne Bennett, CDC*

2:45-3:15	• Discussion
3:15PM- 3:45PM	**Break**
3:45PM- 5:00PM	**Update VI: Estimation and Projections Tools** Session Leader: Peter Ghys, UNAIDS
3:45-3:55	• EPP: recent developments and future changes- *Tim Brown, East-West Center*
3:55-4:05	• Workbook and Spectrum: recent developments and proposed future changes- *Karen Stanecki, UNAIDS*
4:05-4:15	• Ranges of uncertainty in estimates- *Neff Walker, UNICEF*
4:15-4:30	• Comparing sentinel surveillance based estimates to survey based estimates-*Peter Ghys (UNAIDS) or Ties Boerma (WHO)*
4:30-5:00	• Discussion

Day 4: Thursday, January 29
Moderator: Peter Ghys, UNAIDS

8:30AM-10:30AM	**Session VI: Experiences in HIV surveillance data use** Session Leaders: Peter Ghys, UNAIDS/ Cyril Pervilhac, WHO Description of the uses of surveillance data and strategies to communicate findings from surveillance data.
8:30-8:40	• The wrong thing at the wrong time? Using surveillance data to re-evaluate HIV programming at a local level- *Elizabeth Pisani, Family Health International-Indonesia*
8:40-8:50	• Impact of improved estimates process on surveillance activities in China- *Lu Fan, CDC/NCAIDS, China*
8:50-9:00	• Linking behavioural and biological surveillance for improved use of data in India- *Mohammad Shaukat, NACO-India*

9:00-9:10 9:10-9:20 9:20-9:30 9:30-9:40 9:40-10:00	• Communicating an artefact: lower HIV prevalence in Zimbabwe in 2003-*Owen Mugurungi, Ministry of Health (Zimbabwe)* • Contrasting surveillance data with data on resource flows in the Latin and Central America region: *Ruben Mayorga, OASIS (Organizacion de Apoyo a Una Sexualidad Integral Frente al SIDA), Guatemala* • The use of surveillance data for policy and program decision-making: experiences from Africa: *John Stover, The Futures Group International (US)* • Integrated Analysis of HIV/AIDS epidemics-*Tim Brown, East-West Center/Thai Red Cross Collaboration(Thailand)* • Discussion
10:00AM-10:30AM	**Break**
10:30AM-11:00AM 10:30-10:45 10:45-10:50 10:50-10:55 10:55-11:00 11:00-11:05 11:05-11:15	**Closing Session** • Summary of key issues from conference—*Tim Brown, East-West Center* • John Novak ,USAID • Stefan Wiktor , CDC • Peter Ghys, UNAIDS • Donald Sutherland, WHO • H.E. Dr. Kebede Tadesse, Minister of Health of Federal Democratic Republic of Ethiopia
11:15PM-12:30PM	**Lunch**