



# **Overview of Laboratory Support for the Global AIDS Program (GAP)**

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Good morning. Thank you for the opportunity to give you an update on the Global AIDS Program. What I'd like to do is briefly cover the most recent global epidemiologic information from UNAIDS and then tell you how GAP is responding to the world's AIDS crisis.

I'll give you a little GAP history and discuss our program activities, ending with our monitoring and evaluation framework and accomplishments over the first two years of the program.

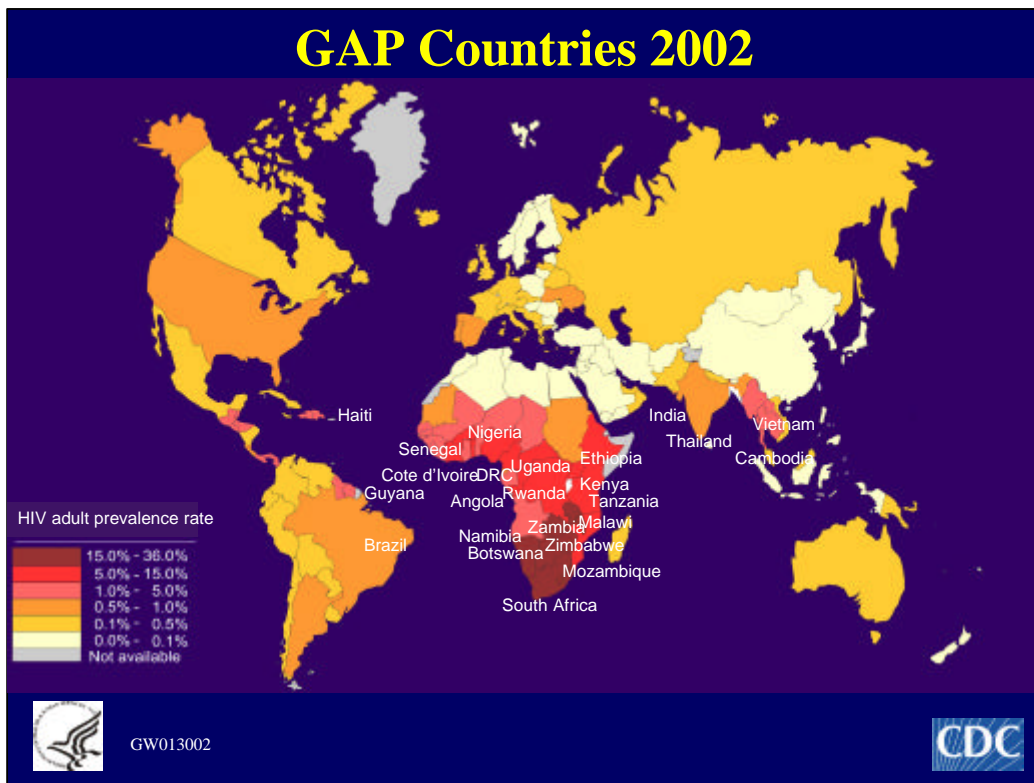
# GAP Partner Countries 2002

- **24 countries total**
  - 17 in sub-Saharan Africa
  - 3 in Asia (Cambodia, Thailand and Vietnam)
  - 3 in Caribbean and Latin America
  - India
- **Currently, 45 CDC staff assigned to 17 countries; remainder by the summer of 2002.**



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GAP is currently working in 24 countries, and soon to add China, as I mentioned earlier. Of the current 24, we have staff in place in 17, and hope to have the remaining countries staffed within the first quarter of the new calendar year.

## HIV/AIDS Burden in GAP Countries, 2000

- Total estimated HIV-infected worldwide = **40 million+**
- Total HIV burden in GAP countries = **29 million+**
- **72%** of all HIV-infected persons live in countries with, or soon to have, a CDC Global AIDS Program.



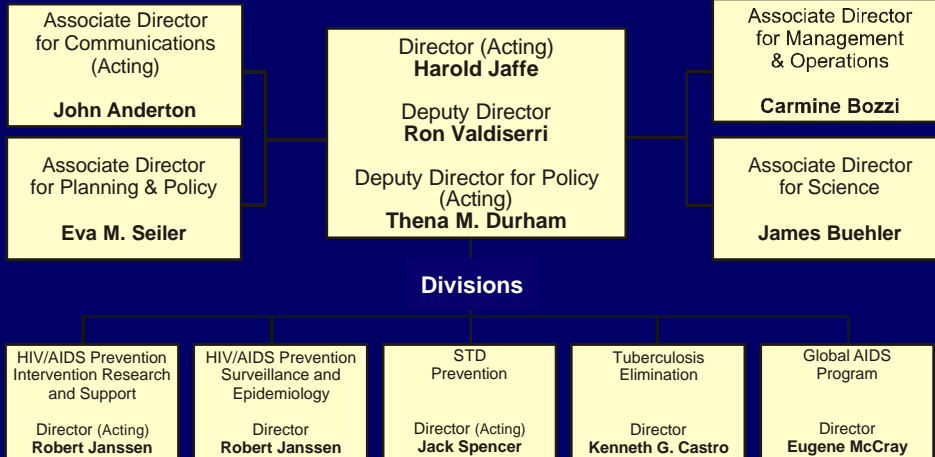
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Source: UNAIDS, 2000



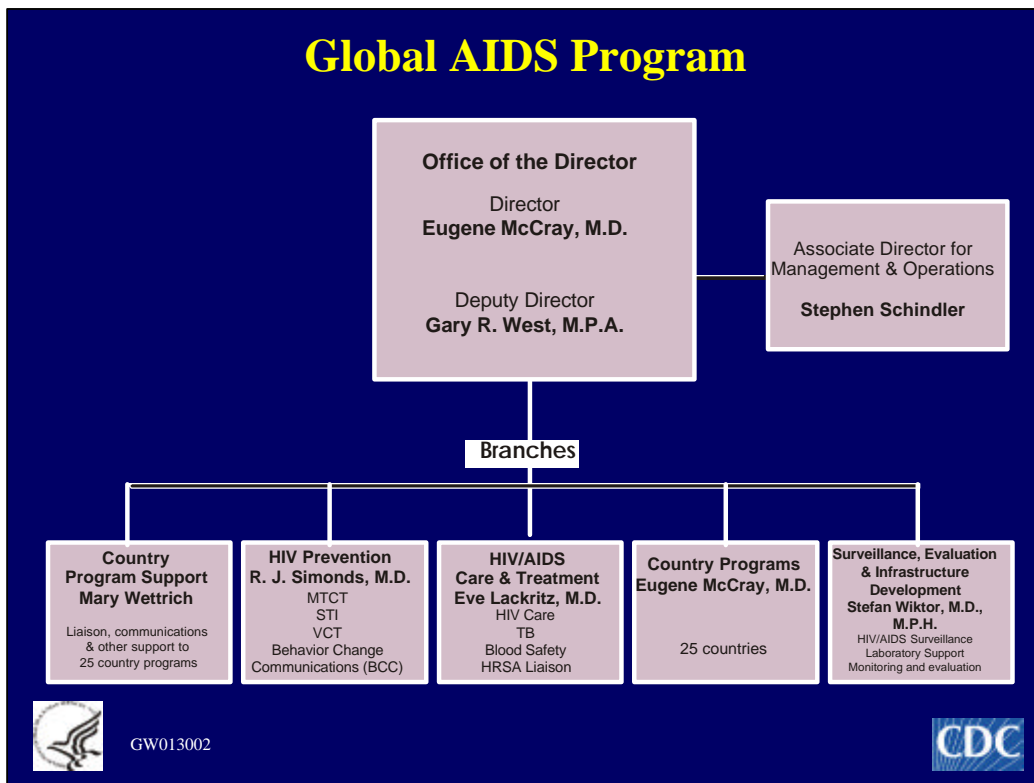
UNAIDS recently released new estimates of worldwide HIV infection, revising the estimate of those infected upwards to 40 million. At this point, they have not released country-specific numbers, so we cannot estimate accurately the burden in GAP countries, however, a simple ratio would indicate that it will be approximately 29 million. This estimate does not include China.

# U.S. National Center for HIV, STD and TB Prevention



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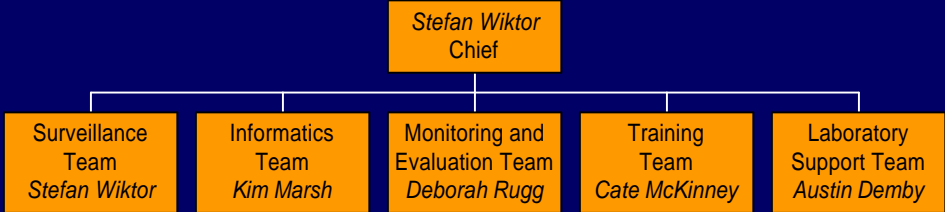




GAP's staffing is a work in progress. Currently, we have

	<u>Hired</u>	<u>Allocated Positions</u>
HQ	42	52
Field	48	71
Total	90	123

# Surveillance, Evaluation and Infrastructure Development Branch



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# Goal of CDC Response

*Assist in reducing HIV transmission and improving HIV/AIDS care and support in partnership with countries with heavy disease burden.*

## Seven Strategic Objectives

1. Assist in decreasing sexually transmitted HIV infections.
2. Assist in developing the capacity of partners in host countries for HIV prevention and care efforts.
3. Assist in expanding and strengthening HIV/STI/TB surveillance programs.



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This goal and its objectives are familiar to you because of your involvement with the CDC HIV Prevention Strategic Plan. Although GAP is not the only element of CDC working internationally, GAP does have the lead responsibility for the international goal of the strategic plan. To accomplish these objectives, CDC will work with host countries and other key partners to assess the needs of the country and design a customized program of assistance that fits within the national strategic plan. In general, the CDC contribution will be focused on scaling up two or three major program areas.



## Seven Strategic Objectives, CDC Response, *cont.*

4. Assist in improving basic scientific knowledge of HIV and the safety and efficacy of newly developed biomedical interventions.
5. Assist in decreasing HIV infections transmitted from mother to child.
6. Assist in increasing access to improved HIV care and support, including prevention and treatment of opportunistic infections.
7. Assist in decreasing parenterally transmitted HIV infections.



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## Major GAP Activities

- **HIV Prevention Programs**

Including behavior change, voluntary counseling and testing, prevent/treat other sexually transmitted infections, prevent mother-to-child transmission, blood safety.

- **HIV/AIDS Treatment and Care Programs**

Including diagnosis, prophylaxis and treatment of opportunistic infections and tuberculosis; operational research related to developing program models, standards and guidelines.

- **Program Infrastructure**

Including surveillance, operational research, informatics, training, laboratory support and monitoring and evaluation.



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## **Most Frequently Expressed Needs During Country Assessment Visits**

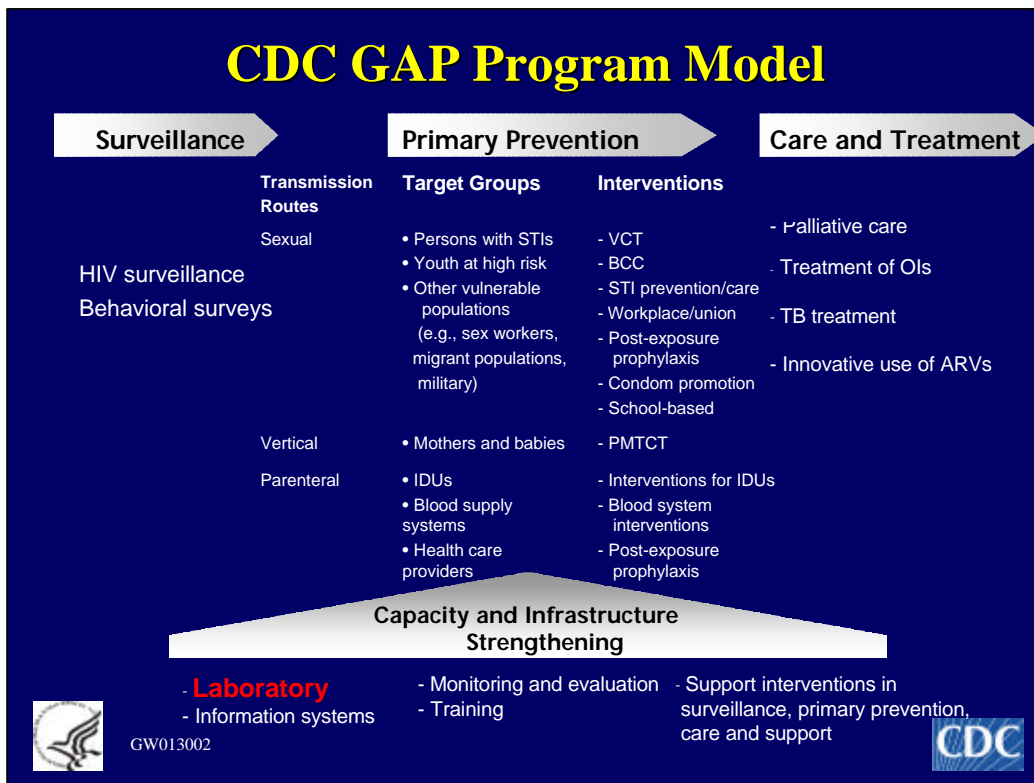
- Surveillance
- Voluntary counseling and testing
- Strengthening laboratory capacity
- Improving care of persons living with HIV
- Prevention of mother-to-child transmission
- Training



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# CDC GAP Program Model



Capacity-building and infrastructure-strengthening are essential to accomplishing all other GAP programmatic elements. These two components under gird all other activities.

## Focus of GAP Lab Support

Balance between:

- Supporting quality technical laboratory services at national level –HIV/STI/TB/OI
- Supporting the creation/strengthening of PH **Laboratory Systems** to support quality testing



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# GAP APPROACH TO LAB SUPPORT

- Laboratory technical strategy based on good science and best practices
- Biological markers a priority to monitor program successes or failures
- Strong partnership with host nation and regional organizations
- Prevention focus with rapid demonstration of success while building long term infrastructure



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## Laboratory Technical Support

- Conduct laboratory capability and needs assessment
- Strengthen National Reference laboratories:
  - Quality Reference work – national level
  - National standards, guidelines and protocols
  - Perform QA/QC and national oversight
- Support District level laboratory capacity/capability
- Training (technical and management)



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- Support National Reference Laboratories to retain technical staff and to assure minimum standards.
- Since no basic research is anticipated, advocate a change in role to:
  - Reference work for HIV/TB/STI drug resistance
  - Test kit evaluation and validation
  - Supervisory national QA role to assure quality of testing
  - Supervisory national QC and proficiency testing
- Rapid HIV tests to support GAA program areas.
- Assure minimum standards for TB diagnosis and monitoring - basic smear microscopy and periodic culture to monitor resistance
- Rapid tests for STI
- Possible cooperative agreement with APHL to foster linking laboratories in Africa with sister laboratories in the United States

## Support for HIV Activities

- Based on in-country capacity and coverage

### Primary focus

- EIA based serological assays
- Evaluate rapid tests with appropriate algorithms  
(VCT, blood safety, surveillance)
- Dried blood spots for quality assurance

### Secondary focus

- Incidence assays
- Disease monitoring
  - viral load, CD4/CD8 cell counts
- ARV Resistance monitoring



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# Support for TB Activities

## Primary focus

- Smear microscopy at all levels
  - diagnosis and monitoring

## Secondary focus

- National surveillance for drug resistance



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# Support for STI Activities

## Primary focus

- Evaluation of syndromic management
- Basic serology
- Basic microbiology

## Secondary focus

- Molecular methods for diagnosis
- Surveillance for STI drug resistance



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# Technical Laboratory Support Mechanisms

## Memorandum of understanding - CDC:

NCID – Division of AIDS, STD and  
TB laboratory Research

PHPPO – Division of Laboratory Systems

NCEH – New born screening

## Cooperative agreement - partner organization:

Association of Public Health Laboratories  
(APHL)



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# Key Questions

Programs depend on laboratory data for policy decisions  
and results can be life-changing for individuals

Are public/private laboratories organized in a rational manner?

Are the labs producing true and reliable results?

Are the results consistent and reproducible?

Is the quality of testing acceptable throughout system?

Are the laboratory staff adequately trained at all levels?

Are there mechanisms for identifying and correcting errors?



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# EXIT COMPETENCY

- Common understanding of quality laboratory systems
- Recognize the added value PT/EQA systems bring to the fight against HIV
- Clear guidelines on the utility of PT as part a QA program in GAP countries
- A plan of action for improvement or implementation in GAP programs
  - institutional and non-institutional
  - priority VCT/MTCT/Surveillance



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