

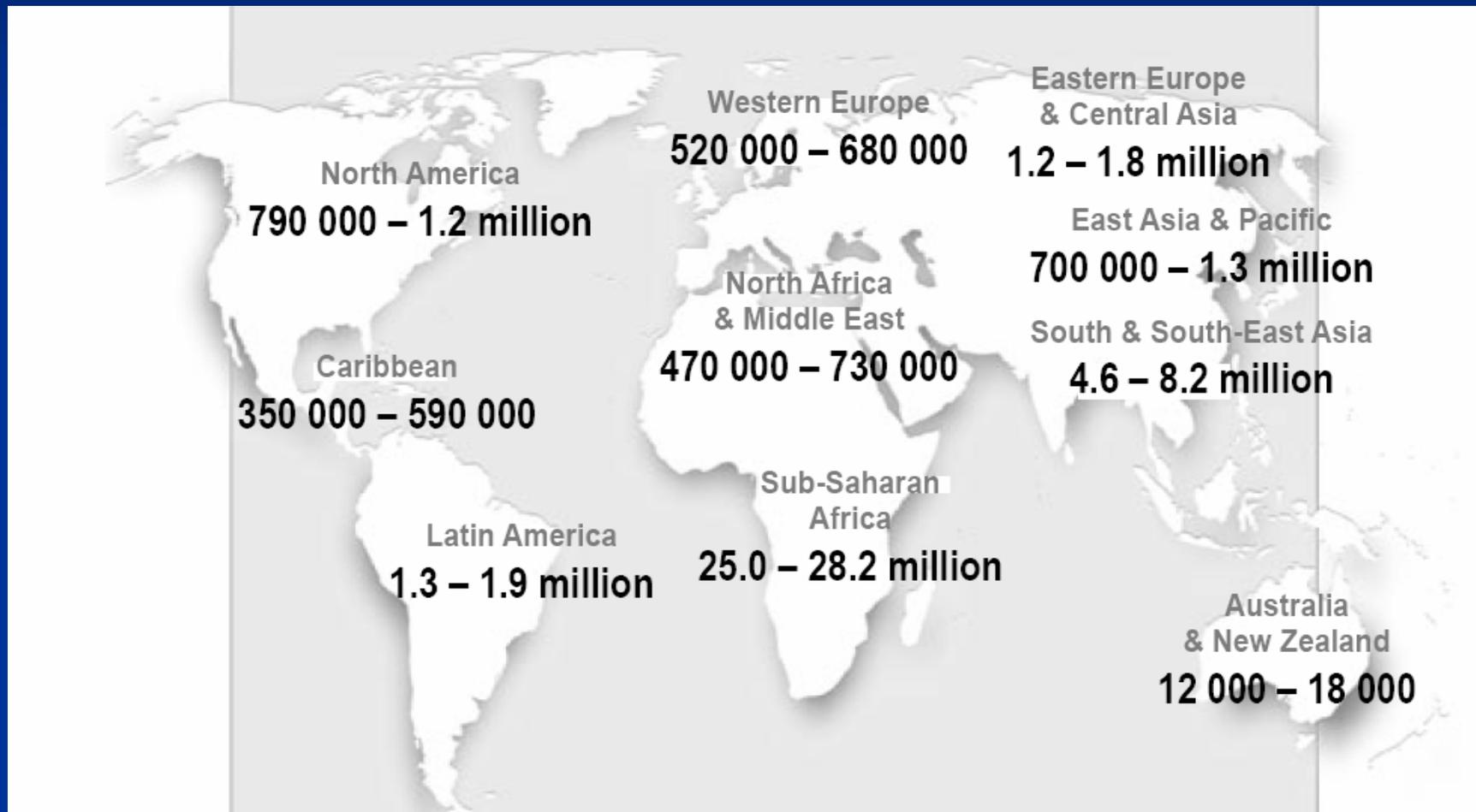


HIV Monitoring Technologies for Resource-Limited Settings

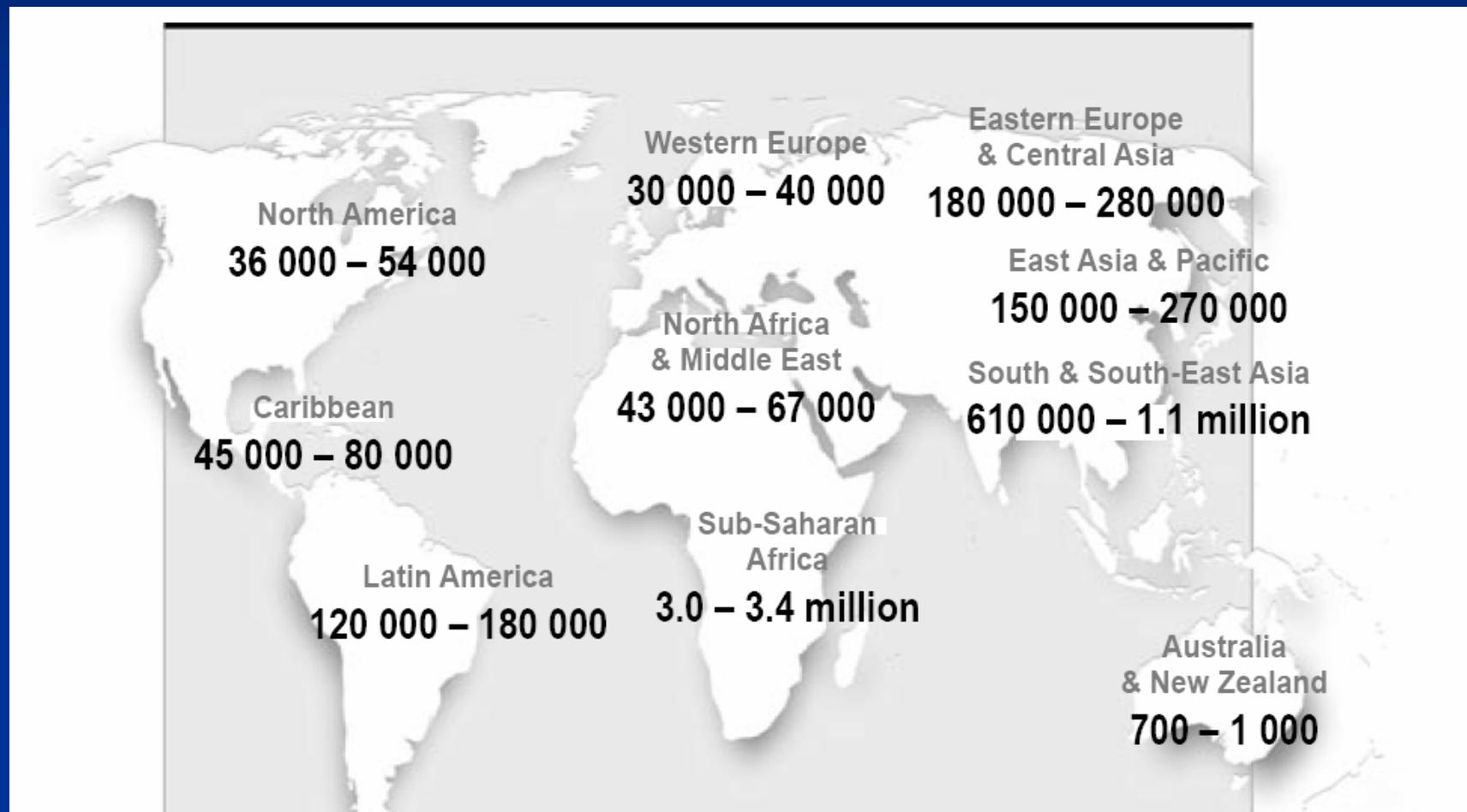
Integration of New Monitoring Technologies into ARV
Rollout Plans

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Adults & Children Estimated to be Living with HIV/AIDS, END 2003



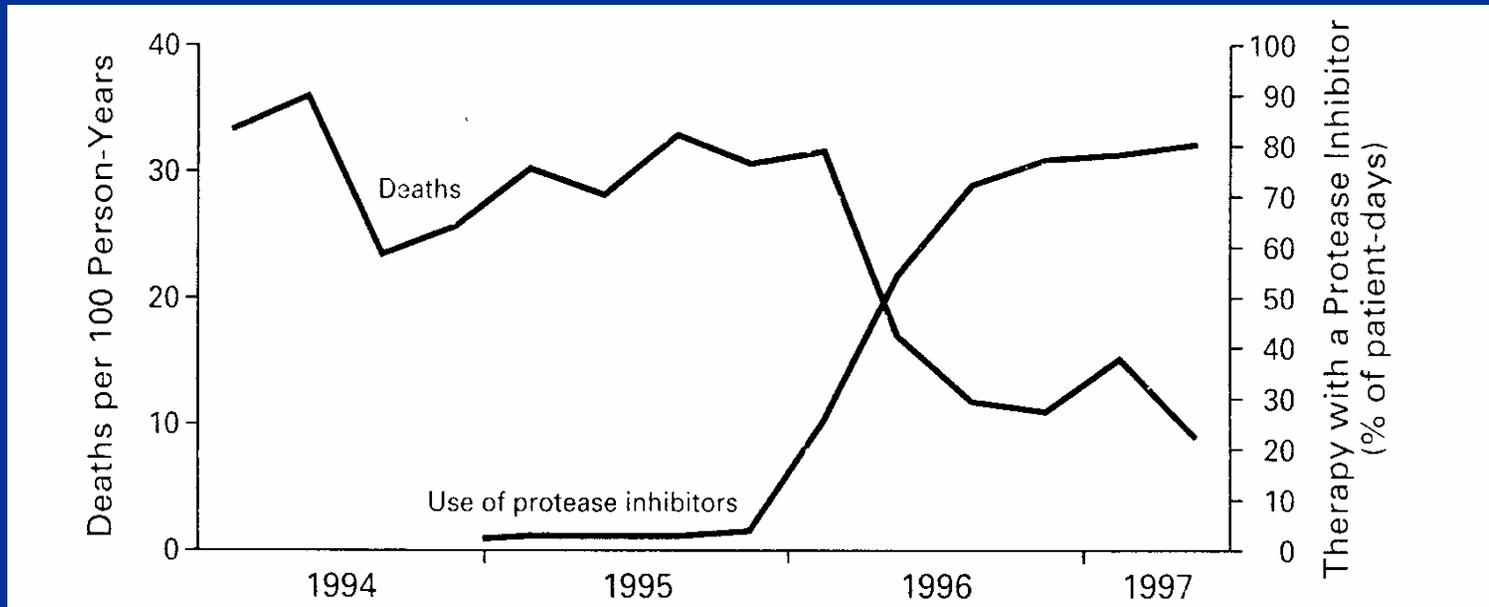
Estimated no. of Adults & Children newly infected with HIV during 2003



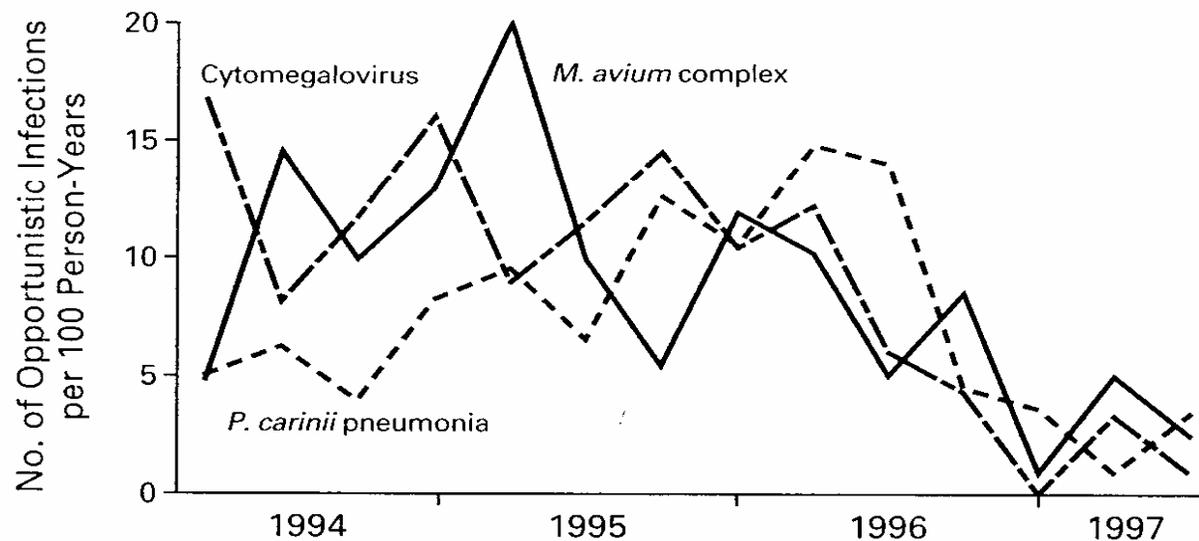
Antiretroviral Therapy

- The introduction of ART especially HAART changed the outlook of HIV infection in the developed world
 - Reduction in mortality
 - Reduction in morbidity
 - Improvement in quality of life

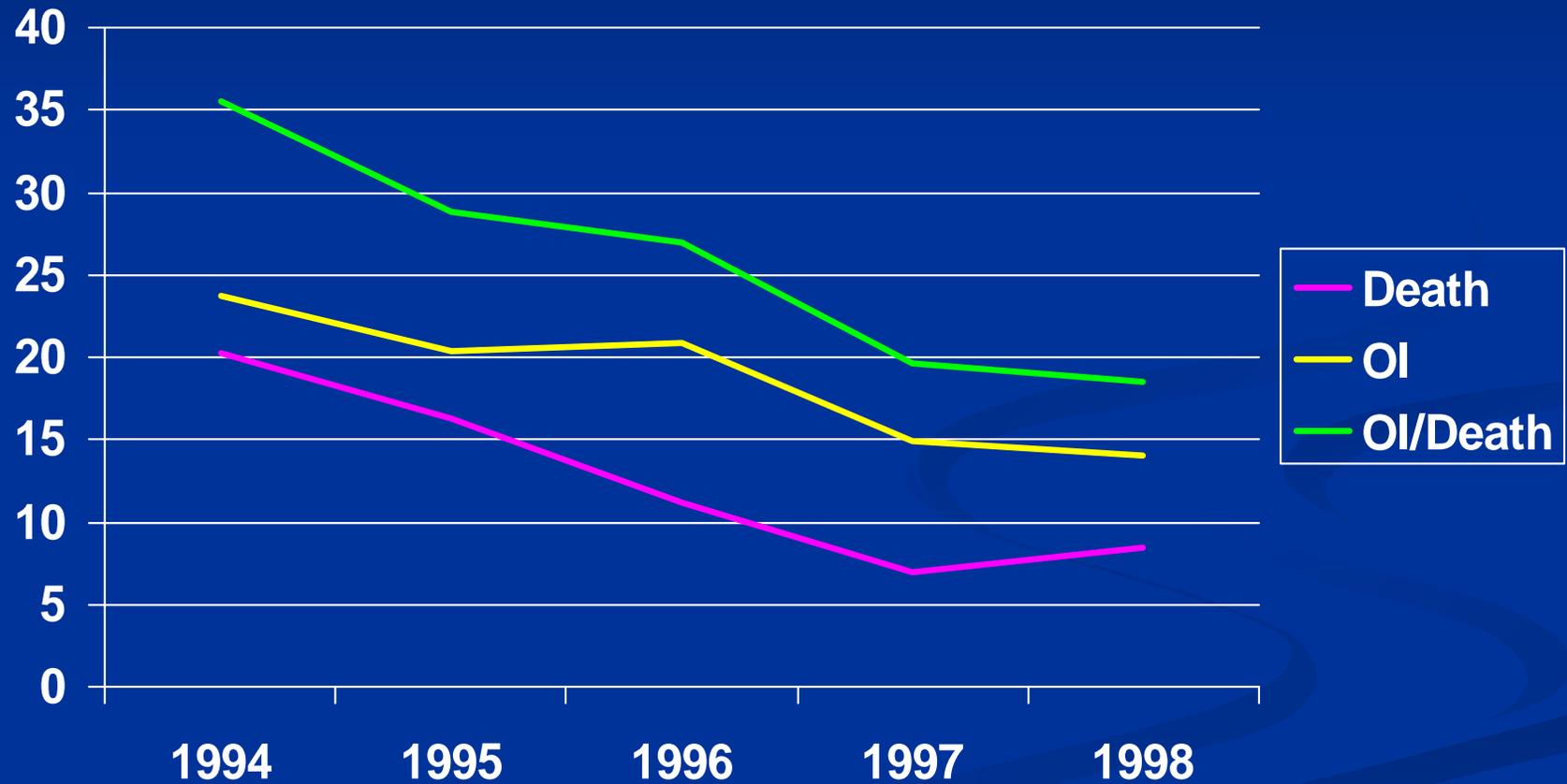
Mortality and frequency of use of combination antiretroviral therapy including a protease inhibitor among HIV-infected patients with fewer than 100 CD4+ cells/mm³, according to calendar quarter, from January 1994 through June 1997



Rates of cytomegalovirus infection, *Pneumocystis carinii* pneumonia, and *Mycobacterium avium* complex disease among HIV-infected patients with fewer than 100 CD4+ cells/mm³, according to calendar quarter, from January 1994 through June 1997.



Effects of Changes in Antiretroviral Therapy on Course of HIV Infection



ART in Resource-Limited Settings

- The world has increasingly realized that the benefits of ART must be extended to all mankind
- The need for ART in resource limited-settings is a moral imperative which cannot be ignored

ART in Resource-Limited Settings

- Worldwide 6 million people are estimated to be in immediate need of ART
- Less than 400,000 people outside the advanced countries of North America and Western Europe are estimated to be on ART
 - Most of these are in middle income countries like Brazil
 - Sub-Saharan Africa has a miniscule number of people on ART compared to the magnitude of the epidemic

The scale-up of ARV in resource-limited countries is therefore the only way to go.

ART in Resource-Limited Settings

- There has been a fusion of purpose among various actors in the HIV/AIDS arena which has brought ARV roll out into reality
 - The international community
 - Western governments and leaders
 - Multinational organizations
 - Charitable and humanitarian organizations
 - Resource-limited countries
 - Political commitment
 - Civil society
 - NGOs, etc

Initiatives assisting roll-out of ARVs

- UN Global Fund to fight AIDS, tuberculosis and malaria
- WHO 3-by-5 campaign
- President's Emergency Plan for AIDS Relief (PEPFAR)
- National governments
 - Brazil & Thailand initiatives
 - South African "Operations Plan for Comprehensive HIV/AIDS Care, Management & Treatment for South Africa"
- Humanitarian Organizations
 - Medicine San Frontier, etc

ARV Roll Out: Barriers

- Cost and Supply of ARVs
- Infrastructure to deliver ARVs
- Monitoring of ART

Monitoring of ART

■ Clinical

- Always required-body weight, organ specific evaluations and patient well-being
- ? Can it wholly or partially replace aspects of ART monitoring
 - Evidence that it can be used to some extent-Haiti-experience
 - On-going research such as the Development of Antiretroviral Therapy in Africa (DART Study)-Uganda and Zimbabwe

Monitoring of ART

- Laboratory
 - Toxicities-organ specific and general
 - CD4 T-Lymphocytes
 - HIV RNA viral load
- Challenges
 - Cost of technology-equipment, reagents, maintenance, staff salaries, QA/QC
 - Lack of expertise and training of lab personnel
 - Diverse levels of health providers delivering ART

Monitoring of ART: Toxicities

- Bone marrow, liver, renal, pancreatic, biochemistry, etc
 - Standard equipment available up to various levels of the health delivery infrastructure
 - Rationalization of the use of these tests
 - Eg choice of tests at start of ART
 - ? No routine tests or limited choice of routine tests
 - ? Symptom driven choice of routine test
 - A referral system for patients or specimens

Monitoring of ART CD4 T-Lymphocytes

- Standard technology (flow cytometry)-limited availability and penetration
 - Cost US\$25-US\$40/test
- Low-cost assays (manual CD4 assays-Dynal, Coulter, Capcellia)
 - What is their place in the ARV roll-out?
 - When to institute prophylaxis (in addition to clinical, WHO staging, etc)
 - When to start ART
 - Suspected ARV failure
 - Routine assays- ? Every 6 months or yearly

Monitoring of ART Plasma HIV RNA Viral Load

- Molecular assays-expensive and not widely available
 - US\$60-\$100/test
- Low-cost assays-ultrasensitive rt (Cavidi) and p24 assays
 - What is their place in the ARV roll-out?
 - When to start ART
 - Suspected ARV failure
 - Routine assays- ? Not recommended

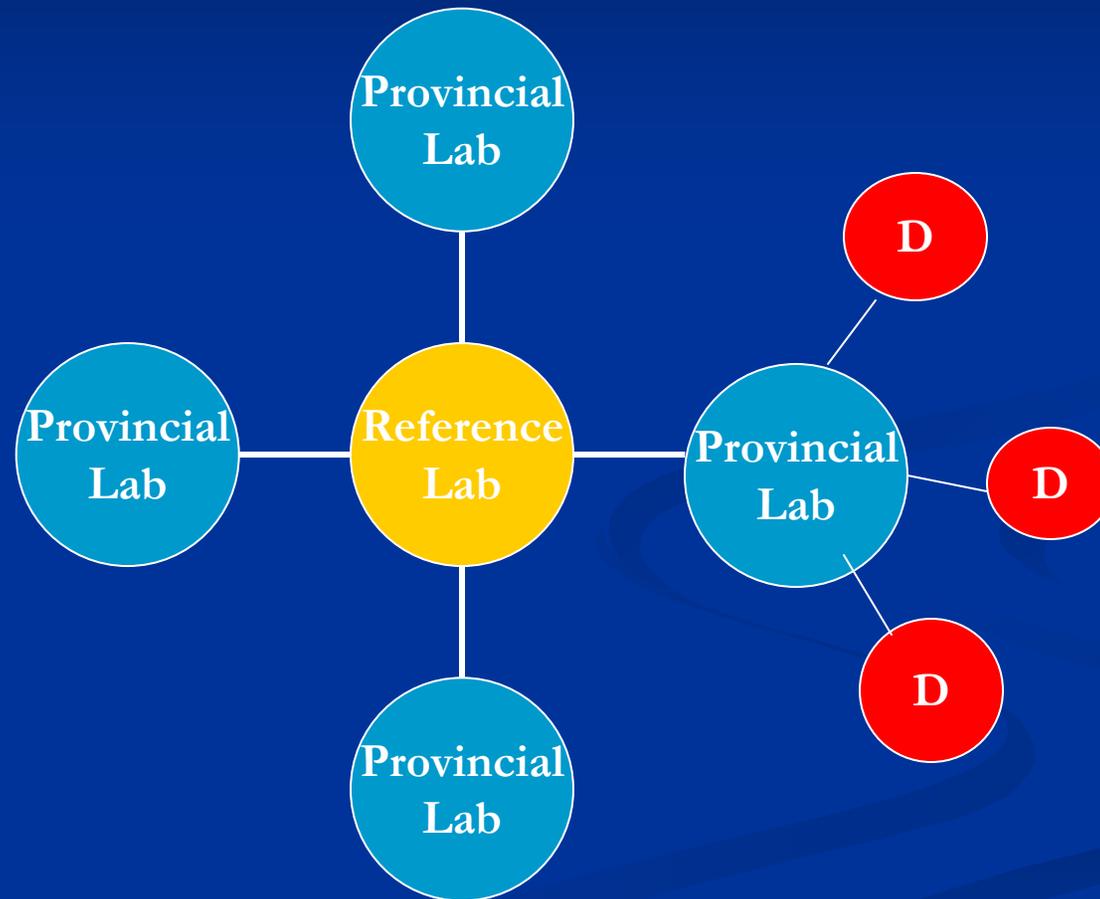
Monitoring of ART

Other

- P24 antigen-claims
 - Cheaper than HIV RNA tests
 - Requires less expensive equipment
 - That newer assays may give data in a variety of clinical settings comparable to HIV RNA
- β 2-Macroglobulin
- Etc...

Hierarchy of Laboratory Setup

Reference → Provincial → District



ART Monitoring in Resource Limited Settings Conclusion

- Large number of patients in each setting
- Variability in resources
- Cheaper tests need to be truly cheap
 - Cost-instrumentation, reagents, etc
 - Infrastructure required-technician training, QA/QC
- Tailor tests to level of health care
- National guidelines must address the issue of monitoring of ART explicitly

Thank You

