

Laboratory Monitoring of HIV in the Context of Anti-retroviral Treatment Implementation in Resource-Limited Settings

Elizabeth M. Dax for the staff of the National Serology Reference Laboratory, Australia
41 Victoria Parade, Fitzroy 3065, AUSTRALIA

Nearly 95% of HIV infections have occurred in people living in resource-limited settings. Since 2002, there has been a huge injection of funds into getting antiretroviral therapy to people in resource-limited situations. This means a new era involving larger numbers of people on anti-retroviral treatments than ever before. To whom should therapy be given? How can the therapy get to those who need it; especially those in remote areas? How should its efficacy be assessed? How can the antiretroviral programmes' outcomes be gauged? How can opportunistic infections be diagnosed? Are diagnostic facilities and methods for CNS infections readily available? Part of the solution is in having effective laboratory systems.

HIV testing and monitoring in developed countries is carried out in sophisticated laboratories employing commercially prepared test kits that are highly regulated by national systems, using highly developed testing strategies, expensive equipment and well researched testing methods, under strict quality management and with participation in quality assurance schemes. The rates of false results are extremely low. The variation in performances between laboratories is low. However, these relative luxuries are not necessarily available in countries where regulation is absent. Purchase of kits may be by non-technical people with no understanding of quality assurance and often through deals in which there is personal gain for the purchaser but none for the laboratories and therefore the patients.

More recently, laboratories and funders have been paying greater attention to bringing reliable testing and monitoring to resource limited areas. Testing strategies for diagnosis of infection employ simple rapid tests (even for screening blood donations). Thus, they have attained high levels of reliability. However, there may still be difficulties in the specificities of the combinations of the HIV tests used. Diagnosis of HIV infection may be better achieved but other laboratory tests may not. Many places do not have access to adequate microbiology laboratories or equipment such as that for conducting immunoassays or even adequate microscopes. There are more economic monitoring tools becoming available such as for viral load estimations using an assay that quantifies reverse transcriptase levels. Funders have started to recognize the importance of developing laboratory infrastructure for countries rather than setting up their own laboratories essentially for research purposes. Facilities and equipment for diagnosis of opportunistic infections often are not optimal but are receiving more attention as therapeutic programs are established. There are also new approaches to quality assurance that will provoke better training and performances from the laboratories as they develop.

The NRL has developed a quality assurance method for monitoring the ability of test operators to interpret tests' results. Tests have been shown to operate with high sensitivities and specificities. Other schemes for microbiology also employ photographed results for quality assurance purposes.

Newer methods for monitoring viral load include:

- Quantification of reverse transcriptase
- PCR with fewer cycles
- Quantification of protease
- PCR with smaller target sequences
- Quantification of DNA levels

Most laboratories in resource-limited settings participate in quality assurance programmes for

- HIV Testing
- TB microscopy
- Cryptococcus EIA
- Ink stain microscopy
- All of the above
- None of the above