

HATiP

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Laboratory requirements for scaling up HIV treatment

Access to laboratory services varies

During the very first session of the 12th Conference of Retroviruses and Opportunistic Infections, a controversy surfaced over whether access to viral load testing is necessary for the rollout of antiretroviral care in resource-limited settings.

Dr. Des Martin, of the Southern African HIV Clinicians Society, addressed the subject during a review on the laboratory requirements for scaling up HIV treatment. He believes that viral load testing is necessary in order "to rollout antiretroviral therapy (ART) properly."

Currently, access to laboratory monitoring varies widely by setting - some areas have access to comprehensive viral load, CD4 and toxicity monitoring, while in others, the only available monitoring is of clinical symptoms.

Tiered laboratory capability in developing countries

Primary health care (level 1)

- Rapid HIV antibody testing
- Haemoglobin (if using AZT)
- Pregnancy
- Referral for sputum TB (if no microscope)

District hospitals (level 2)

- All primary level facilities

Plus

- Second serological method for HIV diagnosis
- FBC and differential
- ALT
- CD4 cell count

Regional referral centres (level 3)

- All secondary level

Plus

- Full chemistry
- Viral load

Technology intensive and expensive laboratory services usually are performed at centralized regional referral centres, which can make testing more affordable with economies of scale. But using centralized lab testing requires reliable and affordable ways to transport the laboratory samples - which are not always available.

Viral loads

Dr. Martin stressed that increasing access to viral load tests is especially crucial: "Once treatment has commenced", he said, "it is imperative to know what the virus is doing, particularly when drug options are limited."

As support, he noted that clinical studies have demonstrated that measuring viral load one month after starting HAART can strongly predict which individuals will have a viral load below 50 copies/ml after 6 months of treatment. He also presented some preliminary data from a South African cohort of 45 patients who have reached the 24 week time point on ART - 36/45 (80%) have viral load below 400 copies/ml, of whom 30/36 (83%) are below 50 copies/ml. Of the 36 patients with a good response, 31/36 (86%) had viral loads below 1000 copies/ml at 4 weeks.

Testing the envelope

Dr. Martin then described his efforts with colleague Dr. Jonathan Sim, to explore whether comprehensive monitoring for HIV could be made available locally at the primary care level - and what the cost would be.

"We have always straddled a barbed wire fence driven by need and held back by cost. Frustrated by the failure of suppliers to commit and develop low margin, high volume market opportunities," Dr. Martin said. "We are pushed and pulled between the capacity of peripheralising versus the efficiencies of centralising"

Other researchers who have tried to bring diagnostic monitoring to the primary care level have focused on using cheaper methodologies and simplified technologies.

However, Drs. Martin and Sim decided to take a different approach by setting up three remote labs using "best of breed" (and often expensive) technologies that are scalable, offer a high throughput and are simple in lab design.

The labs offer the full spectrum of laboratory tests required for HIV management. For viral load tests they use and to monitor CD4 cell counts, they are using standard). The labs are outfitted with the DNA HIV viral load test, FACS Count flow cytometry (for CD4 cell counts), chemistry and haematology analysers. A lab technician is needed to run the labs with some itinerant support from a mobile team that moves from site to site. Also, as the number of specimens increases another technician might be needed.

One of these labs is in a shipping container and is currently located in Gugulethu, a township outside of Cape Town. It has a back-up generator because of frequent power outages at the site. Nevertheless they are able to offer complete CD4/viral load monitoring for patients from the community.

At a rural site a couple of hours east of Johannesburg, an autonomous treatment centre/lab has been established in a brick and mortar building. This lab serves four outside clinics, one of which is a mobile clinic that goes out to workers on farms.

As of January 31, 2005, these lab sites have screened 986 patients. The majority of these 670 (68%) have started ART treatment. Of these, 15 (2.2%) have quit treatment, 42 (6.3%) died on treatment and 613 (91.5%) continue on therapy. 603 are still on their first regimen, while 10 were confirmed failures and have switched to their second regimen.

Costs

Dr. Martin concedes that during the introductory phase, the costs are quite high, but as more people are being treated, costs fall.

The shipping container represents "the extreme of the envelope" (about \$30,000 - before the costs of the chemicals needed to run the tests). Outfitting an existing facility is cheaper.

However, once the lab is running 84 specimens a day, the total cost for the entire menu of tests is around \$40. According to Dr. Martin's calculations, such a lab services around 8000 HIV positive

patients. "Beyond that" said Dr. Martin, "you need a more formalised laboratory."

Dr. Martin closed his talk by saying that these 'small operating laboratories represent a proof of concept.that peripheralisation, capacity development and community ownership may be another approach to meet the laboratory requirements for scaling up HIV treatment in resource-poor settings."

"The costs are high but we must put pressure on the powers that be to force economies of scale and get prices down to where they should be. Africa deserves this."

Discussion

Dr. Eric Goemere of MSF-Khayelitsha, who co-chaired the symposia told the audience "we knew when we programmed [Dr. Martin's] talk that it would be a bit controversial. Should we look at simplified technologies or go for this best of breed – what is the best approach?"

Others, including Professor Charles Gilks, one of the architects of the WHO 3x5 Initiative, took issue with the notion that viral load is necessary for patient management in resource limited settings.

"The WHO's treatment scale up plans do not use and support viral loads," said Dr. Gilks, "for a very simple reason. Our guidelines are based on simple formularies around first line and then second line treatment. Within that package, that public health approach, there are four clinical decisions that need to be made for someone who is HIV-infected: When to start treatment; when to substitute a drug for toxicity - either in first or second-line treatment; when to switch from first to second line treatment; and, then, when to stop and move to palliative and end of life care. Now within those four simple clinical management decisions, you have to ask what is the role of viral loads. Viral loads may help to predict when people are failing [but] in the majority of people, 3 monthly viral loads is really not going to help for when to switch.

"The experiences of MSF in South Africa is that when a patient is looking very fit, clinicians are very reluctant to switch from first to second line treatment- the only major option that patient has - just

with a single viral load. For the majority of people in these programmes, viral loads are a luxury not a necessity. We do not believe that countries that are not providing viral loads routinely are offering substandard care. Countries that have scaled up, on a population level, can deliver highly effective treatment without viral load methodologies."

But, Dr. Martin's associate Dr. Sim responded "I think there's no doubt that a lot of people would make use of monitoring if they could." He felt the emphasis should be on trying to drive the costs of diagnosis down. "We think the model that needs to be tested is to take technology out there. Whether that's right or wrong, I don't know, but it can be tested. The issue is, why should we give Africa a second rate solution? It's a pity that the virology of HIV is dismissed when treatment is introduced.

Concluding the symposium, Dr. Eric Goemere noted he came to the meeting to plead that the scientific community adapt its research to answer such operational questions on the delivery of health care, "we desperately need, if not viral load, then tests to know when to switch regimens - and we still have no affordable, patient friendly second line therapy."

Reference

Martin DJ and Sim J. *Laboratory Requirements for Scaling Up HIV Treatment*. 12th Conference on Retroviruses and Opportunistic Infections, Boston, Boston, abstract 3, 2005.

about HATIP

A regular electronic newsletter for health care workers and community-based organisations on HIV treatment in resource-limited settings.

The newsletter is edited by Theo Smart (Cape Town) and Keith Alcorn, NAM's Senior Editor (London).

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