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NUMAT
NORTHERN UGANDA MALARIA AIDS TUBERCULOSIS PROGRAMME

NUMAT TECHNICAL BRIEFS

Essential Laboratory Test Reaches Rural Communities to Help Health Centers Treat HIV Infection More Effectively

NORTHERN UGANDA MALARIA, AIDS & TUBERCULOSIS PROGRAMME (NUMAT)

INTRODUCTION

There has been a significant effort to scale up access to antiretroviral therapy (ART) in Uganda, alongside prevention, care, and social support services. ART was formally introduced into the public health system in Uganda in 2003 and has since been progressively scaled up to reach even rural health care settings. By November 2011, approximately 700,000 people are estimated to be clinically eligible for ART, of which almost 43% (300,000) are accessing treatment.

The Ministry of Health's national guidelines on ART recommend initiation for clients who are symptomatic and/or have evidence of significant immunosuppression, either through use of laboratory tests or clinical assessment. The guidelines recommend the use of CD4 cell count as the preferred basis for initiating ART, except at facilities where such services are not available. In these cases, WHO clinical staging is recommended instead, which is the use of medical assessment of signs and symptoms to guide health providers in making clinical decisions. Apart from guiding decisions as to whether and when to initiate ART, the CD4 cell count is also essential for monitoring the results of the therapy. All clients are expected to receive a baseline CD4 count; once therapy is initiated, the test is supposed to be repeated twice per year to monitor the effectiveness of treatment and detect any possible drug resistance as early as possible. The same frequency applies to clients still in HIV chronic care.

Due to human resource constraints and the highly technical requirements associated with CD4 cell count determination, this test has only been rolled out to regional referral facilities in Uganda. With CD4 testing only available at the regional level, most people who need it do not have access and therefore have difficulty determining their CD4 cell count. This challenge has been felt most keenly in Northern Uganda because of the protracted civil strife and the collapse of the health care system.

NUMAT, funded by USAID and implemented by JSI, was designed to respond to the unique situation in the northern region and support the expansion and utilization of HIV & AIDS, TB, and malaria services—especially for the returning population after the dissolution of internally displaced persons camps.

BACKGROUND

At the onset of the project in early 2007, a rapid assessment of the existing capacity of HIV-related laboratory monitoring determined that six CD4 count machines were operating more or less regularly in Northern Uganda, four of which were placed in the two largest towns. As a result, only patients attending the referral health facilities could access CD4. While there was a steady increase in the number of health facilities providing ART services in Northern Uganda, there was no concomitant increase in the number of sites providing CD4 monitoring. Therefore, clients needing this service were expected to travel to these referral facilities for the test or be initiated on ART using the less precise clinical staging process.

The consequence of a limited number of sites offering CD4 testing was that patients opted to use only those sites, often foregoing more convenient clinics. ART clinics located in rural settings were underutilized, resulting in frequent congestion in the six regional sites offering CD4 monitoring. Clients travelled long distances to access what they believed was more appropriate care. Pediatric ART and prevention of mother-to-child transmission of HIV (PMTCT) were limited to the few centers that could carry out a CD4 test before initiating appropriate care. The widespread adoption of the national treatment guidelines for TB/HIV co-infection was also hampered by the limited availability of CD4 testing. Rural health workers were dissatisfied with their work since they were unable to provide appropriate treatment, care, and support for people living with HIV in accordance with the training that they had newly received.

PROJECT INTERVENTION

To increase access to ART (and other HIV services) by the rural population in the region, NUMAT supported the expansion of treatment services to 35 lower-level health facilities and a few hospitals. This was achieved by adopting an outreach delivery model that allowed clients in the peripheral facilities without CD4 laboratory equipment to have routine access to CD4 testing.

This outreach approach is a public-private partnership, where NUMAT provides funding and technical support, the health facilities provide ART and other services, and a subcontracted private laboratory (Cnapsis, Inc.) provides CD4 testing. Health workers at the selected facilities mobilize eligible clients to report for sample collection, which are collected every two weeks by Cnapsis using their laboratory staff, and then taken to the designated laboratory for testing. Twenty percent of the CD4 tests are also given a complete blood count (CBC). This enables the calculation of CD4 percentages for children as well as the evaluation of additional parameters, like total lymphocyte and hemoglobin levels. Test results were then disseminated back to the respective health facilities during the following visit and also to NUMAT headquarters.

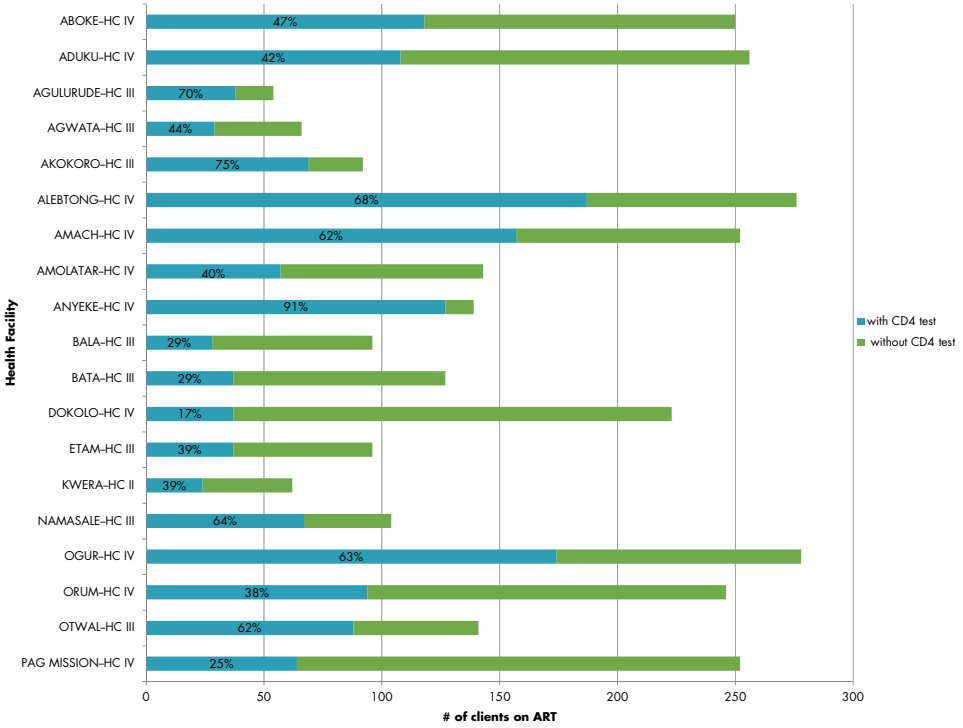
CD4 tests were made available to the designated rural health facilities prior to the provision of ARV supplies. This enabled clinicians to identify patients in need of ART among the patient populations and order supplies accordingly. Additionally, a quota system was employed to allocate the number of tests to different facilities based initially on their level of testing and subsequently on their ART recruitment and retention rates.

Clinicians working at the ART sites were aware of the number of tests allocated to their facility every month and the timetable of the outreach visits by Cnapsis. Patients could then be mobilized and asked to report to the facility on the day set for sample collection.

Initially, CD4 tests were intended specifically for patients not yet enrolled into ARV treatment. However, tests were also provided to patients previously initiated on ART to determine a baseline for monitoring. In the following years, the intervention has focused also on repeating CD4 tests for ART-enrolled patients to assess treatment effectiveness, and on newly-identified HIV-positive pregnant women, to facilitate selection of the most suitable ARV prophylaxis regimen for PMTCT.

- At the end of 2008, due to increased demand, the NUMAT CD4 outreach project increased by 125%, with 990 tests offered every month to clients assessing care at the supported sites. Increasing this number of tests was necessary as the number of sites benefiting from the intervention increased, the recruitment of new patients continued, and the need for follow-up of CD4 tests for ART monitoring increased.
- By the end of 2009, there were renewed requests from the sites for the provision of additional CD4 tests. An evaluation of the impact of the CD4 project showed that only 38% of new recruitments onto ART had done so on the basis of the CD4 tests offered (Figure 1). Without alternative avenues for making CD4 testing more available, the implication was that the large majority of all recruited patients were still initiated on the basis of clinical assessment.

Figure 1: Disparity between CD4 tests performed and newly-recruited ART clients at various health facilities



RESULTS

- The initiative—which started with only eight facilities providing ART services at the end of 2007 and then expanded to 28 facilities by 2009—currently targets 35 ART facilities and seven non-ART facilities. These facilities provide PMTCT services, with the latter included to increase service uptake by HIV-positive pregnant women, as one of the crucial patients' categories the project intended to reach (Box 1). Of the 35 facilities participating in the program, three are district hospitals, 16 are health centers grade IV, and another 16 are health centers grade III.
- By December 2011, almost 70,000 CD4 tests have been provided to all supported facilities.
- At the inception of the project, the number of tests provided monthly to all facilities participating in the intervention was 440, with individual quotas ranging between 10 and 25, depending on the level of the facility and its client load.

Eventually, the monthly allocation of CD4 count tests was raised to 1,734, a 75% increase from the previous allocation to address the fact that more facilities were providing ARVs and more patients (54%) were enrolled into ART after assessing their CD4 count. At the same time, the number of CBC tests increased from the initial 198 tests per month in 2008 to 345 tests per month in 2010, to more than 450 a month in 2011. This has assisted the supported facilities to serve more children and access relevant clinical information on potential adverse effects of the commonly used ARV drug regimens.

In addition, the pattern of patients' categories benefiting from the CD4 test intervention gradually changed. At the beginning, the majority were patients yet to be enrolled into ART, whose eligibility was to be assessed. By late 2011, the share of tests done as a follow-up has reached half of total tests, and the proportion of tests targeting pregnant women for immunological assessment increased from 1% in 2008 to 5% in 2011 (Figure 2).

Box 1: Patient Categories

Category 1: The CD4 test is needed by those people preparing for ART. This category includes HIV-positive children, adults, and TB patients.

Category 2: The CD4 test is for patients already on ART, but who are not responding to care and need a CD4 test to help in planning clinical care.

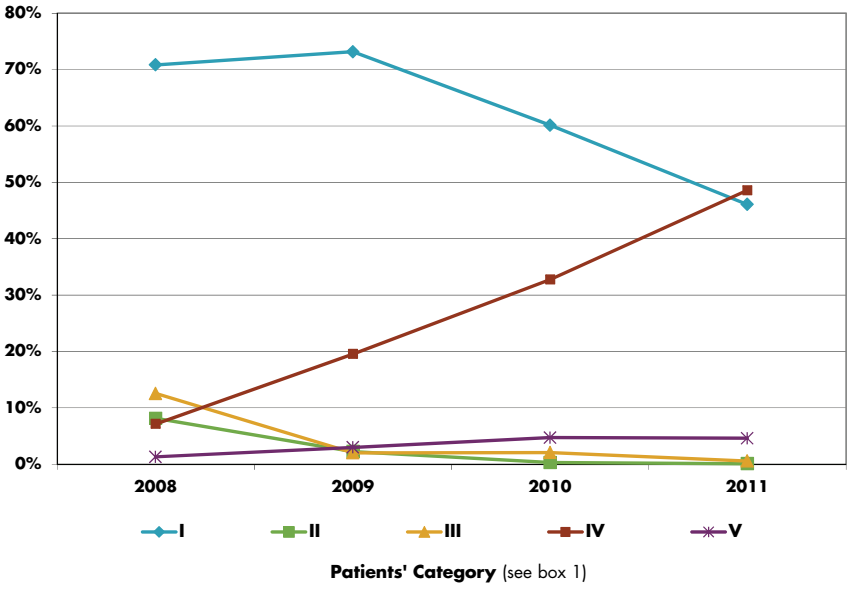
Category 3: The CD4 test is for patients already on ART, who have never taken a CD4 test before, and whose initiation was based on clinical staging.

Category 4: The CD4 test is for patients on ART who had a test done more than six months before and need a follow-up test.

Category 5: The CD4 test is for HIV-positive pregnant women, who need an assessment for PMTCT interventions.

As previously stated, the number of tests carried out every month has gradually increased, ultimately contributing to an increase in the number of patients initiated into ART following the national guidelines' recommendation.

Figure 2: 2008-2010 trend in provision of CD4 count tests by patient category



However, this was not the only achievement. There were other benefits realized as a result of this outreach model:

- The outreach model—compared with the alternative of purchasing CD4 machines and deploying them to designated facilities—had shifted the responsibility of maintaining continuous laboratory functionality and procuring reagents and consumables to an outside testing company. This has proven to be very efficient and successful in ensuring that tests are collected and analyzed and results taken back within the stipulated time.
- Similarly, creating and communicating the outreach schedules, coordinating with volunteer people living with HIV & AIDS (PLHIVs) at the facilities for the mobilization of their fellow PLHIVs, collecting samples, and verifying that all patients' details are properly recorded by health workers was also delegated to Cnapsis. This has greatly reduced management and coordination responsibilities on the part of NUMAT.
- There were fewer issues regarding quality assurance than in laboratory services at government facilities. The main reason was that the same people were involved in handling samples from collection to testing, and reporting across all supported facilities. A standardized method for collection of samples was adopted to minimize invalid samples. The contracted laboratory was responsible for overall quality assurance, and requested to maintain high quality standards.
- Patients' data - including age, sex, category and detailed test results - were more accurate than the average health data collected by facilities because of the regular monitoring applied by Cnapsis.
- Cnapsis was very flexible in their response to emerging demands by NUMAT, like expanding to new sites and increasing the quota of tests allocated monthly to facilities.

LESSONS LEARNED

- Involvement of PLHIVs is vital for a successful outcome. Involving beneficiaries of health services in their monitoring and overall management is easier said than done. In NUMAT's case, the existing PLHIV support network and the availability of linkages between the facility and the community made the intervention more likely to succeed. PLHIVs were very active in mobilizing fellow clients, sent reminders for people booked for testing, and helped minimize the gap between the limited number of tests allocated and the high demand.
- The focus of the service gets adapted as the context changes. Initially, the number of tests available was kept low because of the small number of ART-providing facilities involved. But later this number was increased and reviewed constantly in order to meet rising demands and take into consideration the different pattern of beneficiaries across facilities and the changes in HIV treatment policy guidelines. At the beginning a large majority of PLHIVs receiving CD4 test were adults; subsequently, the share of tests meant for pregnant mothers and children increased due to changing priorities. CD4 cut offs used in the current national HIV treatment guidelines to determine ART eligibility are not congruent anymore with use of clinical assessment as compared to CD4 cut offs used in previous treatment guidelines. This enhanced the demand for CD4 lymphocyte testing for clinical decision-making.
- Increased costs can be outweighed by increased and more equitable coverage. Increasing the number of tests provided throughout the program area impacted total costs. However, this was combined with high efficiency in testing samples and delivery of their results as stipulated, with virtually no interruption in service provision. In addition, the outreach system adopted for CD4 testing allowed many more people to access it, with particular emphasis on the most disadvantaged ones such as those living in remote areas, the poor, and the sick.

- Availability of CD4 lymphocyte testing improved quality of HIV care at lower level health facilities. Although health workers at participating lower level health facilities were not involved in collecting samples, they played a crucial role in identifying and selecting patients for CD4 testing. Individual facility allocation of tests was also based on the perceived need for the service. The availability of CD4 testing improved health worker decision-making and built confidence of communities and clients accessing HIV treatment and care at lower level health facilities. Clients advised on the basis of a CD4 test to continue on cotrimoxazole prophylaxis were more accepting of this decision. Many new clients at these facilities were "transfers" from congested higher level units. This contributed to the decongestion of high volume referral centers.

CONCLUSIONS

The impact of the CD4 outreach model implemented by NUMAT has been substantial in both expanding the CD4 test availability across peripheral health facilities, and assisting health workers to make better clinical decisions as far as ART initiation was concerned.

The number of facilities benefiting from the intervention steadily grew with inclusion of ART sites serving people in remote and hard-to-reach areas. The increase in the number of tests provided every month to the supported facilities also helped to meet the rising demand for this service.

More ART clients were enrolled after baseline CD4 tests were performed and more clients were monitored for ART effectiveness through a repeated CD4 count test. ART services were made more accessible to HIV-positive children and pregnant women; clinicians could access additional blood parameters in their follow-up of ART-recruited patients. Overall, optimal laboratory quality standards were achieved and maintained by the contracted laboratory and a high level of efficiency was put in place to ensure that there would be no service interruption at any point in time, and that test results would be communicated back timely.

This innovative model used to address the insufficient CD4 laboratory capacity in rural areas could be replicated by similar projects that implement HIV-related interventions. It was well received by health workers who actively participated in its execution and contributed to its successful results. Its design may help in tackling the complex challenge of providing ART services in an equitable way, by expanding the CD4 component beyond referral facilities and more towards the often-neglected rural populations.

The outreach CD4 testing model was found more economically viable and equitable in providing HIV laboratory monitoring for remote populations of Northern Uganda as compared to the chronically, sub-optimally performing static laboratories. However, sustainability concerns can be addressed by recognizing the greater cost benefit that may be derived by harnessing the strengths of both the outreach and static CD4 testing models. This can be done by increasing the number of static laboratories at district or health sub-district level and linking them to remote sites through a courier system, like in the NUMAT outreach model.

As the NUMAT project comes to a close, opportunities in this regard have been recognized. The Uganda Ministry of Health and other partners have procured and distributed CD4 machines to some lower level health facilities in Northern Uganda. Machines that use Cyflow technology are designated for high volume sites, while those using point of care technology are sent to small volume health facilities. In tandem with this effort, the National Medical Stores now stocks and pledges to provide an uninterrupted supply of CD4 reagents for these machines. In addition, the Ministry of Health is developing a network of regional hubs for testing of early infant diagnosis laboratory samples collected from remote sites and then taken to the central laboratory. Given the developments above, there is opportunity to use these hubs to collect blood samples from remote HIV clinics and ferry them to the regional hubs where they are tested with results returned to the respective sites within an appropriate turnaround time.

NUMAT is a six-year, USAID-funded project designed to expand access to and utilization of HIV, tuberculosis, and malaria prevention, treatment, and care, and support activities in conflict-affected districts of Northern Uganda.

Over the course of the project, NUMAT has expanded the geographic coverage and populations served through strengthening local government responses, expanding the role of communities in planning implementation and monitoring activities, and building upon existing networks.

Northern Uganda Malaria, AIDS, & Tuberculosis Programme
Lwani House
Plot 2, Elisabeth Road
Laroo Division
Gulu, Uganda
Tel: 256.372.260.051
www.numat.jsi.com

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JSI Research & Training Institute, Inc.

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