ISSUES IN MEDICINE

Expanding access to ART in South Africa: The role of nurse-initiated treatment

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The South African government's recent policy decision to expand access to HIV care rapidly and 'ensure that all the health institutions in the country are ready to receive and assist patients and not just a few accredited ARV centres'[1] represents a dramatic and welcome about-turn on years of hesitation and confusion in the country's response to the HIV epidemic. In the first 6 years of the antiretroviral therapy (ART) programme, approximately 900 000 people have been started on treatment. In the next 2 - 3 years, the government proposes to initiate treatment in another 1.2 million people.[2] The medical and moral imperative for providing this life-saving treatment to all who need it does not need to be defended, but the limited capacity of the public health sector to achieve this scale of increase raises serious questions about the practicality of this objective. Along with raising the CD4 thresholds for access to treatment and scrapping the antiretroviral site accreditation process, nurse initiation and management of patients on ART (NIM-ART) is under discussion at the national level as a key strategy for expanding access. There are simply not enough doctors in the public sector to introduce and follow up this number of patients. The major load from this increase will therefore have to be shifted to nurses, themselves under severe pressure and in short supply.

Broadening the ART delivery platform to include nurses has been debated at the national level for several years. However, the discussion has focused on understanding the legal and regulatory frameworks that govern nurse prescribing, and little attention has been paid to how to implement NIM-ART. The legal difficulties are, in fact, minimal – the Minister of Health can simply authorise nurse prescription of ART in line with the Medicines Control Act. Rather, the key questions that should concern policymakers and practitioners are whether NIM-ART will provide the solution to expanding access to antiretrovirals, and how effective and sustainable it will be. Further, what systems and resources will be required to make it work, and what impact will this major push have on the health system and the broader health needs of the country?

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Current evidence around nurse-initiated ART

Although task-shifting is widely promoted as the solution to expanding ART access,[3-6] the evidence for non-physician-provided ART in Africa is limited. Few studies have compared the performance of non-physicians with doctors,[7-12] and only three have been randomised.[7-9] Although incompletely described, the interventions studied invariably do not reflect what might be feasible within the constraints typical of public sector care, with all having benefited from intensive training and support from predominantly overseas-funded non-governmental organisations. Further, in these studies non-physician care is restricted to the monitoring of patients already on treatment, with initiation usually being performed by study physicians. Under these conditions, all studies reported equivalent ART treatment outcomes, including viral load suppression, mortality and retention in care.

Field reports from programmes that have used non-physicians to deliver ART, including from rural settings in South Africa, are more plentiful and report similarly positive (although less reliable) results in terms of both ART outcomes and improved access.[13-20] Again, however, these programmes benefitted from either substantial NGO support or visionary and committed leadership, or both. Such resources are not available to the rapid national scale-up required to meet the ambitious targets set by government.

Developing evidence around complex health interventions – such as a particular model for the delivery of ART treatment – is difficult in the best of circumstances, but critical. Consider the directly observed treatment (DOT) approach for TB: implemented globally before robust evidence was available, a systematic review of 11 randomised controlled trials now shows it to be no more effective than self-supervised treatment in improving TB treatment outcomes.[21]

Evidence is limited that NIM-ART can expand access safely and efficiently at scale. We know that nurses *can* initiate and manage patients on ART successfully – on this count ART is no different from other clinical tasks nurses routinely undertake. However, we don't know enough about *how* to implement NIM-ART programmes effectively, including the key barriers and enablers at patient, provider and organisational levels.

Lessons from the STRETCH trial in the Free State

An ongoing trial being conducted in the Free State – the Streamlining Tasks and Roles to Expand Treatment and Care

for HIV (STRETCH) trial – attempts to address some of these gaps in the evidence.[22] STRETCH is evaluating the effect of NIM-ART on ART access (by comparing mortality among patients eligible for treatment), and on quality of ART care (by comparing viral load suppression rates in those receiving ART). It is a pragmatic trial that is being implemented within all the usual constraints of the public health system, including the much-publicised difficulties with maintaining ART supplies during late 2008 and 2009.[23]

A key component of STRETCH is the use of ART initiation guidelines tailored specifically to nurses. These guidelines are based on the successful PALSA PLUS guidelines that have been shown to improve the quality of respiratory and HIV care provided by nurses.[24-26] They provide clear clinical criteria for referral of complex cases to a doctor. The trial intervention is composed of three phases – training on the guidelines, nurse re-prescription, and finally, nurse initiation.

Quantitative outcomes for STRETCH will be available during the second half of 2010. But provisional findings from a qualitative process evaluation that has been running parallel to the trial raise a number of important points that should inform rapid national roll-out of NIM-ART.

The good news is that our research confirms that NIM-ART is highly acceptable among nurses, patients and doctors, and that managers and nurses expressed confidence in their ability to apply the guidelines and deliver ART successfully. This confidence developed slowly, however, through a phased and well-supported approach that guided nurses through training, re-prescription and initiation. Key to building and sustaining that confidence were two things: firstly, ongoing clinical support from a range of sources including doctors, district ARV co-ordinators, STRETCH trainers, and experienced fellow nurses, and, secondly, clear criteria for the referral of more complex cases. Such referral criteria are used routinely in the nurse management of other diseases, such as tuberculosis and hypertension.[27,28]

However, the qualitative research has also revealed that increasing access through nurse initiation results in significant knock-on effects in terms of training and support needs, workload and capacity constraints, logistical and infrastructural challenges, and shifts in the working and referral relationships between health staff. Importantly, these effects were not only felt among nurses and doctors but also among pharmacists, lay counsellors, data capturers and health managers. Decentralising ART to all facilities in the country will entail a significant re-organisation of workloads and relationships between different levels of care. These findings add to those from our northern neighbours and suggest that NIM-ART, as a complex health system intervention, involves far more extensive challenges than simply training up nurses, managing workloads and paying for the higher drug bill.[5,29]

In summary, the emerging evidence from the STRETCH trial suggests that NIM-ART is feasible and acceptable in the public sector, but these findings are based on an intervention model that: (*i*) uses an incremental approach to implementation, including an initial phase of external training and support; and (*ii*) is based on clinical guidelines tailored to nurses at different levels of care.

Translating evidence into policy and practice

What do these findings mean for the anticipated roll-out of NIM-ART in April 2010? Proponents of a rapid, national roll-out of NIM-ART argue that the needs of the country demand a drastic response, that a rare political space for decisive action in the health system has finally opened up, and that phasing in NIM-ART or offering nurses clear criteria for referral of complex cases will only serve to create bottlenecks and reduce access. This is a compelling argument, both from a moral point of view and in terms of the universal tendency of state bureaucracies to avoid change, promote inefficiencies and maintain entrenched habits and hierarchies.

The available evidence, however, points to NIM-ART being a potentially effective, sustainable and acceptable approach, but one that also entails significant stresses and realignments in the health system. The STRETCH qualitative research findings, along with the wider international literature on scaling up,[30] point to the potential dangers of a too-rapid roll-out that does not build incrementally the capacity, confidence, co-ordination and support needed to implement NIM-ART at scale. There is a risk that nurses will be left to shoulder the ongoing burden of rapid expansion without adequate training or support, and within a health system already under considerable strain.[31]

Several years of studying and supporting task shifting and guideline-driven care in primary care nursing have provided evidence for the ways to manage these significant changes in the health system and avoid the most obvious pitfalls. Along with basic training and support and an appropriately phased implementation, guidelines that are designed for and specific to nurses and that clarify referral options are an important component in the development of long-term clinical confidence and competence in NIM-ART. Our work suggests that nurses in the Free State accepted the significant increases in workload with NIM-ART because they felt adequately prepared and supported, and because they felt empowered by the opportunity to save patients who would have died without treatment access.[25,32]

Come April, the combination of decisive leadership, political will and an expanded delivery platform has the potential to accelerate ART access in our country like never before. But the complexity and risks this may present to the backbone of our public health sector, nurse-led primary care, must be recognised and addressed and all tested strategies employed to ensure that the system is strengthened and not undermined.

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