

## Improving access to antiretrovirals in rural South Africa – a call to action



South Africa (SA) already has the world's biggest antiretroviral (ARV) programme. With the introduction of extended criteria for initiating ARVs, the National Department of Health (NDoH) wishes to increase the number of people on ARVs by around

two million over the next 2 years. Adoption of a chronic disease management model, with extended task shifting, decentralisation and new approaches to distribution of ARVs, must be embraced if this is to be successfully achieved without huge increases in resources. In this editorial we discuss the need for change, and the current substantial blocks to progress (principally in prescribing and dispensing legislation) that contradict national treatment guidance and should be addressed as a matter of urgency. In addition, we draw attention to threatened regulatory changes that may further worsen the situation.

### HIV management as a chronic condition

The implementation of nurse prescribing of ARVs, through nurse-initiated management of antiretroviral treatment, has been a great success and has proved not to be inferior to doctor-monitored ART.<sup>[1,2]</sup> However, this very success is feeding the challenges. Patients in ever-growing numbers are required to attend nurse-managed clinics monthly, or at best 3-monthly, to obtain their medication –

whether or not they also need to attend for care. Consequently large workloads have caused a 'vicious tangle' of problems in clinics, including high staff stress, turnover, sickness and shortages, and therefore poor-quality care (including reduced attention to adherence and identification of treatment failure<sup>[3]</sup>). These affect the patient experience through long waiting times and lack of person-centred care, and are likely to contribute to the substantial losses to follow-up and undermine effective disease control.<sup>[4,5]</sup> Increasing patient numbers will put an additional burden on the infrastructure of health facilities, for example waiting areas and storage space for increasing stocks of ARVs.

Regular visits, which may be as frequent as monthly, with face-to-face counselling by a pharmacist, are no longer the gold standard in resource-rich settings, where demedicalisation of patients and efficient use of resources are also drivers for change. In such a setting, 6- or 12-monthly review by a clinician is the norm for stable patients, with resources concentrated on patients with higher clinical needs. This shift has been recognised in SA in part, with 3-monthly supplies being issued where stocks allow, but further flexibility is now essential.

There is a cry for changes, including in our national guidelines,<sup>[6]</sup> that will see the adoption of a chronic disease management model with demedicalisation of healthy patients and supported self-care.<sup>[7-10]</sup> Consequent improved efficiencies in respect of nurse time can enable

an increased clinical focus of attention on those whose need is highest.<sup>[11]</sup> Such models depend on stable patients being able to obtain a safe and regular supply of medication between clinical reviews. This in turn depends on: (i) having a trained clinician able to determine which patients are clinically stable, and 'enable' their future medication to be issued, at appropriate intervals, until the next clinical review; (ii) a pharmacist, pharmacist's assistant or other trained support person able to provide 'between-review' medication for individual patients at appropriate intervals; (iii) 'between-review' medication being available at appropriate (convenient and safe) locations; and (iv) clinical review intervals being determined according to clinical need and national guidelines, and not hampered by over-restrictive laws, interpretations of those laws or tertiary legislation (such as Good Practice standards).

All of this, of course, requires intelligent implementation, with the presence of some simple, essential checks and balances such as are standard for chronic disease management, e.g. the ability to identify, and act on, non-attendance.

### Barriers to progress in rural clinics

In rural SA, there are barriers to achieving these steps. About 40% of the SA population is rural, and this includes areas with the highest prevalence of HIV in the world. There are concerns about the ability of nurses to prescribe safely when clinics are 'overloaded with the healthy'<sup>[10]</sup> and nurses are dispensing medication individually to each patient. The potential for errors would be much reduced if this task were to be systematised, and nurses freed to prioritise their time and attention on the clinically needy, only seeing stable patients at routine review.

Rural nurses work in the absence of 'individual patient level' pharmacy and medical support, and are operating in terms of an exceptional permit (section 56(6) of the Nursing Act).<sup>[12]</sup> Under this Act, they are required to do all of their dispensing, and cannot use other clinic personnel (as listed in (ii) above) to dispense 'between-review' repeat medication. Hospital pharmacies are generally remote from their clinics, and providing detailed support for 'between-review' prescribing will necessitate substantial additional resources. Rural areas also lack access to private sector community pharmacies, which might otherwise be able to support such programmes.

If nurses are enabled to 'trigger' 'between-review' prescriptions of medication for patients in a rural setting, the use of centralised pharmacy support using postal or courier delivery will be hampered by the lack of formal postal or residential addresses in rural areas.

There has been a national shift, supported by an NDoH circular (July 2010, unpublished), for at least first-line ARV regimens to be available as 3-monthly supplies (as opposed to monthly), which, locked as it is to attendance, leads to some improvement. However, medicine stock-outs (threatened or actual) currently pitch nurses and patients backwards from 3-monthly into monthly clinic attendance, with all its negative impacts on quality of care and patient quality of life. In addition, there are concerning reports from some rural clinics that the shift to 3-monthly supplies has met with a negative reaction from clinic managers who are angry because there has been a consequent drop in the clinic attendance head count.

Legislation and guidance on the interval for clinical review are currently contradictory. Conservatively defined, adult, established-stable ARV patients only require annual clinical review, with blood tests, according to national guidelines<sup>[6]</sup> – as long as simple problem-screening questions are used when interim medication is collected.

However, currently section 22A(6)(f) of the Medicines and Related Substances Act<sup>[13]</sup> indicates that medication should not be repeated beyond 6 months from the original date of the prescription: in other words, a prescriber must sign a new prescription, and the implication is that the patient should be reviewed. There are reports that this requirement is widely circumvented in the private sector for some conditions (such as stable HIV and controlled hypertension) where the evidence, and clinical guidance, supports only annual clinical review.

An additional problem is posed by the status of nurses as authorised prescribers. There is an impasse between the national (and provincial) departments of health, which wish to see nurses recognised as authorised prescribers able to issue prescriptions that can then be dispensed by pharmacists or pharmacist's assistants, and the South African Pharmacy Council, which holds that they are not authorised prescribers.<sup>[14]</sup> The Pharmacy Council seems determined to set ever-higher standards for each element of the dispensing and medication supply process. In this regard they risk allowing the perfect to be the enemy of the good. Things may get worse. Draft amendments to the Rules relating to Good Pharmacy Practice would restrict the ability of pharmacies (both community and institutional) to operate mobile services and to deliver medicines once dispensed.<sup>[15]</sup> These draft rules, as well as rules that have been issued in final form,<sup>[16]</sup> have also introduced restrictions on the use of technological options such as remote automated dispensing units. These options may not be easily applicable in the public sector, yet should not be discounted as potential future solutions.

This impasse contributes to the impression that the needs of hundreds of thousands of patients a day in rural public sector health clinics, and their nurses, are invisible to some policymakers.

### Finding solutions

Chronic disease management systems will require careful piloting and evaluation, with support of the nurses, as well as system changes and safety nets. However, such approaches contain natural incentives for nurses (through the prospect of rationalised and rewarding workloads) and patients (through demedicalisation and reduced attendance) to achieve stable status by paying increased attention to adherence and to viral load results. It is therefore essential to overcome the barriers in their way. A prerequisite for implementation of chronic care models for effective decongestion of primary healthcare facilities is a stable, flexible and patient-centred supply of ARVs, with refills for at least 3 months and delivered close to patients' homes, supported by national legislation. Underpinning this is dependence on the willingness and flexibility of provincial and hospital pharmacy managers to provide for sufficient buffer stocks of ARVs.

A variety of chronic disease management models are being explored or used, both in SA and elsewhere, some endorsed by the WHO and included in national guidelines.<sup>[17]</sup> Adherence clubs can shift healthy patients out of the clinics, and enable them to collect 'between-review' medication that has been prepacked and labelled by pharmacy staff. Some hospital pharmacies are supporting community pick-up points (such as churches), supported by pharmacists' assistants. A chronic dispensing model has been implemented in National Health Insurance urban and semi-urban pilot areas and the Western Cape public sector, successfully delegating ordering, warehousing, prepacking and labelling of chronic medication to a public-private entity that delivers the medicine packs to the facility for fast-tracked collection by patients. A central chronic medicine dispensing and distribution programme,

providing distribution to designated pick-up points, has also been started in the public sector.

However, for their implementation in rural Department of Health clinics, every one of these solutions depends either on new legal flexibilities for nurse prescribing or the reintroduction of doctors and pharmacists into routine rural HIV care. Clearly the latter is not a viable option. The only existing alternative for those desperate for change is circumvention, reports of which are becoming more widespread.

## Call to action

Those keen to implement efficiency and quality in primary care will not be able to pilot and implement solutions to the above conundrums until SA rural nurses are unlocked from huge-scale dispensing of medication and freed to focus more closely on clinical need, whether for HIV or other chronic diseases.

- The Medicines Control Council (as custodians of the Medicines Act) and the SA Nursing Council (whose legislation permits public sector nurses to 'supply' medicines) should give a clear and positive direction.
- The South African Pharmacy Council is urged to support and enable the following essential measures:
  - Pragmatically interpret existing legislation so as to provide for the recognition of nurses as authorised prescribers (albeit through an exceptional mechanism, until specialist registers are created and populated).
  - Allow and encourage patient-centred and decentralised drug supplies with a minimum of 3 months' refill for stable patients.
  - Allow for mobile and decentralised treatment points to be managed with regular support, but without direct personal supervision by pharmacists.
- The NDoH is urged to put in place logistical and legislative measures to:
  - Ensure continuous availability of safe and appropriate ARVs for all eligible patients.
  - Optimise access to these appropriate medicines closer to patients' homes, through community and mobile dispensing and allowing multiple months' supplies.
  - Consider possible amendments to the Medicines Act to enable clinicians to tailor clinical follow-up, within appropriate medication issuing systems and according to individual clinical need, up to 12 months.
  - Ensure responsibility and accountability for a range of systems of medication issuing that can be clearly, if flexibly, defined.

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1. Nyasulu JC, Muchiri E, Mazwi SL, Ratshefola M. NIMART rollout to primary healthcare facilities increases access to ARVs in Johannesburg. *S Afr Med J* 2013;103(4):232-236. [http://dx.doi.org/10.7196/SAMJ.6380]
2. Sanne I, Orrell C, Fox MP et al. Nurse versus doctor management of HIV-infected patients receiving antiretroviral therapy (CIPRA-SA): Randomised non-inferiority trial. *Lancet* 2010;376:33-40. [http://dx.doi.org/10.1016/S0140-6736(10)60894-X]
3. Mutevedzi P, Lessells RJ, Heller T, Barnighausen T, Cooke G, Newell M-L. Scale-up of decentralized HIV treatment programme in rural KwaZulu-Natal, South Africa: Does rapid expansion affect patient outcomes? *Bull World Health Organ* 2010;88(8):593-600 [http://dx.doi.org/10.2471/BLT09.069419]
4. Rosen S, Fox MP, Gill CJ. Patient retention in antiretroviral therapy programs in sub-Saharan Africa: A systematic review. *PLoS Med* 2007;4:e298 [http://dx.doi.org/10.1371/journal.pmed.0040298]
5. Lessells RJ, Mutevedzi P, Cooke GS, Newell M-L. Retention in HIV care for individuals not yet eligible for antiretroviral therapy: Rural KwaZulu-Natal, South Africa. *J Acquir Immune Defic Syndr* 2011;56:e79-86. [http://dx.doi.org/10.1097/QAI.1090b1013e3182075ae3182072]
6. Department of Health, South Africa. National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults. Section 2.1-2.5, p. 20/ section 6.6.6, p. 70. 2014. [http://www.hst.org.za/sites/default/files/HIV\\_Guidelines\\_Jan%202015\\_YP\\_0.pdf](http://www.hst.org.za/sites/default/files/HIV_Guidelines_Jan%202015_YP_0.pdf) (accessed 24 June 2015).
7. Mutevedzi P, Lessells RJ, Newell M-L. Disengagement from care in a decentralized primary health care antiretroviral treatment programme: Cohort study in rural South Africa. *Trop Med Int Health* 2013;18(8):934-941. [http://dx.doi.org/10.1111/tmi.12135]
8. Deeks S, Lewin SR, Havlir DV. The end of AIDS: HIV infection as a chronic disease. *Lancet* 2013;382(9903):1525-1233. [http://dx.doi.org/10.1016/S0140-6736(13)61809-7]
9. Beaglehole R, Epping-Jordan J, Patel V, et al. Improving the prevention and management of chronic disease in low-income and middle-income countries: A priority for primary health care. *Lancet* 2008;372(9642):940-949. [http://dx.doi.org/10.1016/S0140-6736(08)61404-X]
10. Ellman T. Demedicalizing AIDS Prevention and Treatment in Africa. *N Engl J Med* 2015;372(4):303-305. [http://dx.doi.org/10.1056/NEJMp1414730]
11. Murray CJL. Maximizing antiretroviral therapy in developing countries: The dual challenge of efficiency and quality. *JAMA* 2015;313(4):359-360. [http://dx.doi.org/10.1001/jama.2014.16376]
12. Republic of South Africa. Nursing Act (Act 33 of 2005). <http://www.sanc.co.za/pdf/Nursing%20Act%202005.pdf> (accessed 24 June 2015).
13. Republic of South Africa. Medicines and Related Substances Act (Act 101 of 1965), as amended. [http://mcca.com/genericDocuments/Act\\_101\\_of\\_1965\\_published\\_2003.pdf](http://mcca.com/genericDocuments/Act_101_of_1965_published_2003.pdf) (accessed 24 June 2015).
14. Gray A. Prescribing and dispensing by nurses - neglected steps in the legislative process. *HIV Nursing* 2010;1(2):28-31.
15. South African Pharmacy Council. Rules Relating to Good Pharmacy Practice. Board Notice No. 49 of 2015. Government Gazette No. 38511 (27 February 2015).
16. South African Pharmacy Council. Rules Relating to Good Pharmacy Practice. Board Notice No. 50 of 2015. Government Gazette No. 38511 (27 February 2015).
17. Bemelmans M, Baert S, Goemaere E, et al. Community-supported models of care for people on HIV treatment in sub-Saharan Africa. *Trop Med Int Health* 2014;19(8):968-977 [http://dx.doi.org/10.1111/tmi.12332]

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