

Adapting the DOTS Framework for Tuberculosis Control to the Management of Non-Communicable Diseases in Sub-Saharan Africa

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The Challenge of Managing Non-Communicable Diseases in Sub-Saharan Africa

In sub-Saharan Africa (SSA), communicable diseases, particularly HIV/AIDS, tuberculosis (TB), and malaria, are still responsible for the greatest burden of morbidity and mortality [1]. However, non-communicable diseases (NCDs) are becoming a significant burden [1]. The Global Burden of Disease Study, conducted in 2001, showed that 20% of deaths in SSA were due to NCDs [2], and this burden is predicted to rise to 40% by 2020 [3]. Obesity, hypertension, diabetes mellitus, cardiovascular disease, asthma, chronic obstructive pulmonary disease, epilepsy, and mental illness are some of the important, chronic NCDs that pose significant challenges in terms of management and follow-up.

How are NCDs currently managed in the routine health care settings of African countries? In brief, badly. Anecdotal reviews point to poorly managed health care systems with frequent stock interruptions of essential drugs [4–6]. Untreated hypertension is blamed for high rates of stroke morbidity and mortality in urban and rural Tanzania [7] and rural South Africa [8,9]. Only a small proportion of patients with epilepsy receive drug treatment at any one time, mainly due to poor health care delivery systems and unavailability of drugs [10]. Even in specialist centres, asthma patients are given sub-standard care [11] and have poor access to essential

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Summary Points

- In sub-Saharan Africa, management standards for NCDs in public health services are poor.
- With the growing burden of NCDs, now is the time to develop and implement standardised NCD management protocols and systems for diagnosis, treatment, monitoring, and reporting.
- DOTS has been the framework for tuberculosis control for over a decade, allowing structured and well-monitored services to be delivered to millions of tuberculosis patients in some of the poorest countries of the world.
- The DOTS model has been successfully adapted for the scale-up of ART in Malawi, allowing long-term, structured treatment to be given to thousands of patients.
- This paper discusses why the DOTS paradigm should be adapted for NCDs, and, with the “DOTS five-point policy package” as a template, shows how this could be implemented and rolled out in resource-poor countries, with special reference to sub-Saharan Africa.

medications [12]. There is a growing burden of diabetes mellitus and its associated complications, and many patients with type 1 diabetes mellitus have extremely short life expectancies [13].

Some of us know from personal experience of running routine diabetes and hypertension clinics in African hospitals that there are no formalised systems of recording how many patients have been diagnosed and started on therapy,

how many are retained on therapy, or what proportion have died or developed complications. We treat patients with whatever drugs are available, and consider that our mission is accomplished. In summary, unstructured and unmonitored clinical care and little information about morbidity or mortality from NCDs are mostly the norm in sub-Saharan Africa [14]. How do we begin to rectify this unsatisfactory situation? A possible solution arises out of the existing “DOTS” framework for control of TB.

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Abbreviations: ART, antiretroviral therapy; DOTS, directly observed therapy, short-course; NCD, non-communicable disease; SSA, sub-Saharan Africa; TB, tuberculosis; WHO, World Health Organization

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The DOTS Tuberculosis Control Framework

In 1994, with the estimated annual global TB incidence rate at 8 million and the annual TB death rate at 1–2 million, the World Health Organization (WHO) announced a global emergency and developed a framework for TB control. This framework, based on the pioneering work of Dr. Karel Styblo [15] and subsequently branded “DOTS” by WHO (directly observed therapy, short-course), incorporated an important five-point policy package (Box 1) [16]. Between 1995 and 2005, DOTS was successfully expanded to 190 countries, and 26 million people, most of them poor, were successfully treated with standardised anti-tuberculosis drug regimens [17]. One of the crucial components of DOTS is the registration, recording, and reporting format, which is used to determine the number of patients enrolled for treatment every quarter and, 12 months later, the quarterly cohort’s subsequent end-of-treatment outcomes. Case-finding and treatment outcome data at facility level, collected and collated at national level, provide country-level information on the burden of TB. These data also form the basis of national drug forecasting and procurement. Well-run TB control programmes prevent stock interruptions of anti-tuberculosis drugs through reliable drug forecasting and six-monthly procurement.

Applying the DOTS Paradigm to Delivering Antiretroviral Therapy in Malawi

In 2001, we advocated to adapt the DOTS model for the delivery and monitoring of antiretroviral therapy (ART) in resource-poor countries [18]. The difference between the treatment of TB and that of HIV/AIDS is that the latter is required life-long. In the past six years, this model has been developed and used successfully to deliver and monitor ART for more than 145,000 patients in Malawi, a poor country with a gross domestic product of less than US\$200 per annum [19–21]. One of the keys to the success of this ambitious programme, in a country with an under-resourced health care system and a grave shortage of skilled health care workers, has been the simplification of management protocols

Box 1. Five-Point Policy Package of the DOTS Framework for Tuberculosis Control

- Political commitment
- Passive case-finding using sputum smear microscopy in patients presenting to health care facilities as the cornerstone of diagnosis
- Standardised, short-course, combination anti-tuberculosis chemotherapy (with the rifampicin component given under direct observation by a health care worker, community, or family member)
- Standardised monitoring and evaluation system
- Uninterrupted drug supplies

to match existing infrastructure. Nationwide implementation of these protocols has been achieved through standardised training, a focus on a small number of treatment regimens, and quarterly standardised supervision and monitoring.

The principles of ART monitoring are simple and intuitive and are described in more detail in Text S1 [19,21,22]. Five standardised primary treatment outcomes have been defined (Box 2), which have proven essential for the monitoring of life-long treatment. Many ART facilities in Malawi have now registered between 1,500 and 2,500 ART patients, and health personnel cope satisfactorily with this patient load due to regular supervision, feedback of results from the HIV unit, and a system of certificates of excellence. The standard monitoring and supervision system is used across the public and the private sector in Malawi.

Should the DOTS Paradigm Be Adapted for NCDs?

In general, health systems in SSA are more oriented to managing acute problems than chronic diseases, but this will have to change if NCDs are to be properly diagnosed, treated, and prevented [23]. If life-long ART can be managed and monitored by the system described in the previous section, this paradigm could also be used for patients with NCDs.

A simple, standardised system of diagnosis and treatment has the

advantage that it can be rolled out and implemented in all parts of the country, thereby improving access and facilitating follow-up for all patients in need. A standardised monitoring and evaluation system also has several advantages. First, each facility would know, at the end of each quarter, how many new patients had been diagnosed and registered, the cumulative number of patients started on treatment, their treatment regimens, the number retained on treatment, and the number with disease-related complications. Second, experience from the ART programme has shown that well-designed master cards and registers can improve standards of care [22]. The implementation of management protocols is enforced by requiring set fields to be completed, prompting the health worker to assess and monitor patients for complications, by clinical and/or laboratory means. Third, data on the number of patients starting therapy every quarter and the total number alive and retained on therapy allow rational drug forecasting, and this would help to prevent the frequent interruptions of drug stocks that typify health service delivery in much of SSA [4–6,8]. In Malawi, such a system has allowed rapid scale-up of ART with no drug interruptions to date [24]. Strategic information generated by the system would be pivotal not only for the running of the programme, but also for advocacy and extended support for NCD programmes.

A DOTS strategy has been proposed and is being evaluated for managing patients with schizophrenia in resource-poor countries, with a focus on regular supplies of antipsychotic medication and supervision of drug administration [25]. A master card system and patient register has been developed for monitoring outcomes in asthma [11] and smoking cessation services [26]. This paradigm, providing standardised care and monitoring, could be developed for other NCDs.

Lifestyle modification is an essential part of this endeavour. As HIV prevention is crucially linked to ART delivery, if only to curb the huge numbers of patients who might otherwise become eligible each year for treatment, so too is attention to factors such as diet, exercise, smoking, and alcohol in the prevention of NCDs.

Using the DOTS Paradigm for Managing NCDs in Sub-Saharan Africa

Political commitment. Human and financial resources, and therefore political commitment, are needed to develop, implement, and supervise standardised approaches.

Passive case-finding and standardised treatment. The only feasible and affordable way of identifying patients with NCDs is to diagnose and treat those who present to health facilities. Active case-finding is too labour-intensive. Simple diagnostic and treatment protocols are needed for patients in chronic structured care to ensure that standard quality care is maintained at all levels of the health care system. With life-long NCD treatment, directly observed treatment by health workers, communities, or family members is too onerous, and self-administered therapy has to be the accepted standard.

Standardised monitoring and evaluation, and drug quantifications. At facility level, treatment master cards need to be adapted for specific NCDs (Text S2). Registers can be similarly adapted and, provided they are updated from treatment cards, can be used to provide an up-to-date cross-section of case burden and treatment outcomes. Because diabetes mellitus and hypertension often occur as comorbidities, it would be appropriate to combine medications, complications, and outcomes in one master card and register.

Primary outcomes of alive, dead, stopped therapy, lost to follow-up, and transferred-out to another treatment facility will apply to all NCDs, and quarterly collation of data would allow regular updating of the denominator (how many patients have started on therapy in a facility) and the key numerator (how many patients are retained on therapy in that facility at the end of every quarter). There would be regular updates of adverse outcomes such as death and stopping treatment. Active tracing of patients who fail to attend clinics would be needed to determine the actual primary outcome of patients who were “lost to follow-up”. For example, an operational research study in Malawi showed that 50% of ART patients who were classified as “lost to follow-up” had died [27]. Patients who transfer out to other

Box 2. Standardised Primary ART Outcomes used in Malawi

Alive and on ART: Patient who is alive and on ART at the facility where he/she is registered.

Dead: Patient who dies from any cause while on ART.

Defaulted: Patient who has not attended the ART clinic for three months or longer for no known reason.

Stopped: Patient who is known to have discontinued treatment for any reason.

Transferred-out: Patient who has been permanently transferred out to another ART treatment facility.

facilities should be balanced with those who transfer in. Typical complications that may arise from conditions such as diabetes and hypertension should be categorised and recorded on master cards and in the register; this would provide strategic information on morbidity. Regular medications should be recorded on the master card and also on the register, and with quarterly and cumulative outcome data, an inherent system is thus built to allow accurate drug forecasting.

Expanding the DOTS Paradigm for NCDs

Within a country, the DOTS paradigm for NCDs should be piloted in one or two facilities, and lessons learnt in these facilities should be used to assist national roll-out within the public sector. It will be important to get private sector participation; this has been achieved in Malawi with respect to ART (see Text S1). Regular supervision, through provincial health officers, with collection and collation of data from all facilities would provide strategic information at the national level.

As the numbers of patients with NCDs grow, it will be useful to build real-time electronic data management systems where quarterly and cumulative analyses can readily be obtained. Such electronic systems for managing and monitoring ART are already being piloted in Malawi, and a similar system is being developed for asthma care. A culture of applied research to determine how best to orientate health systems to NCDs must also be developed [28,29].

Conclusion

There is a misconception that public health is synonymous with infectious disease control [30]. NCDs are the current public health problem in the industrialised world, and will become an increasing burden on health services in the developing world. Regular, accurate, and timely data on case numbers and treatment outcomes are a *sine qua non* for proper management. At present, no such systems exist in the general health sector in sub-Saharan Africa, and the simple approach we advocate could be the first in a series of steps (which include attention to life-long adherence to medication, self-management, peer support, and patient associations [31]) designed to improve the situation.

We are proposing a system of NCD programme management and monitoring at health facility level. Such a system would not provide population-level surveillance on NCD prevalence and relevant risk factors, which is an ambitious exercise requiring huge resource inputs. NCDs are managed poorly at facility level in most African countries. It is important that ministries of health and health care facilities in SSA wake up now to the challenge of NCDs, so that by the year 2020 they are not overtaken by yet other disease burdens for which the health systems are unprepared and for which there are only unreliable estimates on which to plan appropriate action. ■

Supporting Information

Text S1. Supervising and monitoring antiretroviral therapy in Malawi

Found at doi:10.1371/journal.pmed.0050124.sd001 (196 KB DOC).

Text S2. Monitoring templates for patients with diabetes mellitus, hypertension, and epilepsy

Found at doi:10.1371/journal.pmed.0050124.sd002 (57 KB DOC).

Alternative Language Summary S3. Translation of the summary points into French by S. Bachy

Found at doi:10.1371/journal.pmed.0050124.sd003 (28 KB DOC).

Alternative Language Summary S4. Translation of the summary points into Spanish by I. Lopez

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