

Applying lessons learnt from the ‘DOTS’ Tuberculosis Model to monitoring and evaluating persons with diabetes mellitus in Blantyre, Malawi

Theresa J. Allain¹, Joep J. van Oosterhout¹, Gerald P. Douglas^{2,3}, Sabine Joukes², Oliver J. Gadabu², Christopher Darts², Anil Kapur⁴ and Anthony D. Harries^{5,6}

1 Department of Medicine, College of Medicine, Blantyre, Malawi

2 Baobab Health Trust, Lilongwe, Malawi

3 Center for Health Informatics for the Underserved, University of Pittsburgh, Pittsburgh, PA, USA

4 World Diabetes Foundation, Lyngby, Denmark

5 International Union against Tuberculosis and Lung Disease, Paris, France

6 London School of Hygiene and Tropical Medicine, London, UK

Summary

The global burden of diabetes mellitus (DM) is immense and predicted to reach 438 million by 2030, with 80% of the cases being in the developing world. The management of chronic non-communicable diseases like DM is poor in most resource-limited settings, and the ‘directly observed therapy, short course’ (DOTS) framework for tuberculosis control has been proposed as a feasible way to improve this situation. In late 2009, aspects of the DOTS model were applied to the management of persons with DM in the diabetes clinic in Queen Elizabeth Central Hospital, Blantyre, Malawi, and a point-of-care electronic medical record system was set up to support and monitor patients in care. This is the first quarterly and cumulative report of persons with DM registered for care stratified by treatment outcomes, complications and medication history up to 31 December 2010. There were 170 new patients registered between October and December 2010, with 1864 ever registered by 31 December 2010. Most patients were alive and in care; 3 died, 53 defaulted and 3 transferred out. Of those on oral hypoglycaemic agents, metformin was most commonly used. Complications were common. The monitoring and evaluation will be further refined, and at the same time, the systems developed in Blantyre will be expanded to other parts of the country.

keywords diabetes mellitus, tuberculosis, directly observed therapy, short course, Malawi, non-communicable diseases, electronic medical record systems

Introduction

The global burden of diabetes mellitus (DM) is immense and grows inexorably from year to year. In 2010, there were an estimated 285 million people living with DM, accounting for 3.5 million deaths (International Diabetes Federation 2009). Driven by changes in socio-economic conditions, diet and physical activity levels, the prevalence of DM is expected to reach 438 million by 2030, with 80% of these cases being in the developing world.

In most poor settings, particularly in sub-Saharan Africa, the management of chronic non-communicable diseases (NCDs) like DM is poor (Harries *et al.* 2008; Cohen *et al.* 2010). Sub-standard care is frequent, complications are not prevented, recognised or treated, and stock interruptions of essential drugs are all too common. Unstructured and

unmonitored clinical care is the norm, and there is little regular or reliable information about incident and prevalent cases, treatment outcomes, morbidity and mortality.

We have argued previously that this unsatisfactory situation can be rectified (Harries *et al.* 2008). WHO developed a framework for tuberculosis control in 1994, based on the pioneering work of Dr. Karel Styblo and subsequently branded this framework as ‘DOTS’ (directly observed therapy, short course) (WHO 1994). The DOTS strategy includes five key principles: sustained political and financial commitment; quality-assured diagnosis; standardised anti-tuberculosis treatment; regular, uninterrupted supply of high-quality drugs; and standardised monitoring, recording and reporting. Between 1995 and 2008, DOTS was expanded to more than 190 countries and used to deliver and monitor anti-tuberculosis treatment to

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43 million patients: during this 13-year period, 36 million patients were cured, and up to 6 million deaths were averted (Lonnroth *et al.* 2010). In 2001, we advocated to adapt the DOTS model to deliver and monitor antiretroviral therapy (ART) in resource-poor countries (Harries *et al.* 2001). This was taken up in Malawi, a resource-poor country in central-southern Africa, and between January 2004 and June 2010, the model was used to successfully deliver and monitor ART to more than 350 000 people living with HIV (Ministry of Health 2010).

The main difference between the treatment of tuberculosis and that of HIV/AIDS is that the latter is required lifelong. If lifelong ART can be managed and monitored by an adapted 'DOTS' framework, the paradigm can also be used for patients with NCDs, such as DM, where treatment is also for life. Accurate and regular monitoring in diabetes is an essential component of good care, and with the expected and ongoing increase in diabetes prevalence in Malawi (Malawi Ministry of Health and WHO 2010), it is timely to put in place a strategy now that will facilitate the scaling up of diabetes care as needed. Paper-based patient registers and treatment cards are the tools most commonly used for monitoring chronic communicable diseases such as tuberculosis and HIV/AIDS, and templates for paper-based registers and treatment cards have also been developed for use in NCDs (Harries *et al.* 2008). The registers and cards are used for cohort analysis of case numbers and treatment outcomes. However, with HIV/AIDS and NCDs, the numbers of patients on therapy in clinical sites grow steadily from year to year, making cohort analysis time-consuming and labour-intensive after several years of patient registration. For this reason, a real-time, robust, electronic medical record system is an attractive alternative, where data are entered at the time of patient contact and where quarterly and cumulative analyses can be readily and easily obtained on a regular basis without the need for manual counting and tallying of numbers.

In late 2009, a decision was made to reform the management of patients in the diabetes clinic in Queen Elizabeth Central Hospital (QECH), Blantyre, Malawi, based on the principles of DOTS. Changes included the training of dedicated nurses for diabetes, the introduction of standardised management guidelines and protocols, and improved drug supply of essential drugs, particularly metformin, through closer liaison with the hospital pharmacy, and because there was no formal established paper-based register or treatment card system in place at the time, an electronic medical record system was introduced. The objectives of this study are to report on (i) the development and use of the DOTS framework and electronic medical record system to manage and monitor persons with DM in

QECH and (ii) quarterly and cumulative case finding and treatment outcome analysis.

Methods

Setting

This was a retrospective descriptive study of the use of the DOTS framework and an electronic medical record (EMR) system to manage and monitor persons with DM in Malawi. The study was conducted in the diabetes clinic, QECH, Blantyre, Malawi. Malawi is a very poor, land-locked country in central-southern Africa with a per capita gross domestic product of less than USD\$200 per year and a population of 13 million (Population and Housing Census 2008). QECH is the largest central hospital in the country and also serves as the main hospital for the medical school.

Patients

Persons diagnosed with DM in Blantyre or elsewhere in the southern region of the country are referred to QECH for the management of their DM: investigations and treatment are provided free of charge. The diabetes clinic operates twice a week. Patients arrive early in the morning to have their fasting blood glucose levels measured and are then seen by doctors and clinical officers in the afternoon. They are checked clinically for complications of DM or comorbidities such as hypertension and asked about a previous or recent history of tuberculosis. At least once per year, urine is tested, by dipstick, for protein, and serum creatinine is measured if persistent or heavy proteinuria is found. Nephropathy is defined as the presence of proteinuria. Annual, slit lamp examination of the retina, through dilated pupils, is carried out by an ophthalmologist to assess for retinopathy. The diagnosis of neuropathy is based on subjective reports of numbness or burning of the feet, because we have previously found this has good correlation with objective sensory loss (Cohen *et al.* 2010), amputations or current foot ulcers. In keeping with the national policy on HIV testing, all patients are encouraged to go for HIV testing and counselling (HTC) if their status is unknown. This can be performed at test centres within QECH or the local area. The HIV status is only recorded if documented evidence of the result is available. Finally, the patient is prescribed medication for the next 3 months. Stable patients are seen every quarter, whereas those whose blood glucose levels are high or seen as unstable are seen more often. Patients carry health passports (van der Hoek *et al.* 1994), and all information and the dates of the next appointment are written in this patient record.

Medical record system

The touch screen EMR system for supporting and monitoring the scale up of ART in Malawi has been previously described (Douglas *et al.* 2010), and similar principles were used to set up the EMR system in the diabetes clinic. The development of software for diabetes management was an iterative process, involving close collaboration between developers and clinicians. After a pilot phase, the software was refined, and since then, the program is being monitored and further modified as needed.

Touch screen clinical workstations (TCW) were set up in the clerk's office, the nurses' area and every clinic room, connected to a central server that stores the data. Clinicians use a TCW to enter patient information during clinical encounters at the point of care (Figure 1a). Each TCW is password protected and comprises a low-power panel PC-style touch screen computer (no mouse or keyboard), augmented with a thermal label printer and barcode scanner. New patients are registered by the clerk, and a barcoded label is printed for the health passport (Figure 1b). Thereafter, clinicians can access that patient's EMR by scanning the barcoded label on the patient's health passport. This starts the application at the correct stage for that patient (Figure 2). Vital signs, recorded by the nurses, are available, on the screen, when the patient sees the clinician. In addition to being an electronic tool to facilitate good clinical care, the EMR allows cohort data to be collected as a by-product of system use. Touch screen-friendly screens are generated from standard HTML Web forms using the Touchscreen Toolkit (Douglas *et al.* 2010). The system also performs clinical calculations (such as body mass index) and facilitates medication prescribing (Figure 2c). Once the clinical encounter is finished, a summary of the patient's visit and electronic prescription is printed on an adhesive label and affixed in the patient's health passport.

The system provides a complete set of automated reports for monitoring and evaluation based on the requirements of the diabetes clinic. On screen, reports are 'active', allowing the user to tunnel down to a patient list from any indicator.

Data analysis

The main data entered and stored in the EMR system at the first and subsequent patient visits include age, sex, current outcome status [alive, dead, defaulted (not seen in the clinic for 6 months), transferred out], current treatment (diet, oral hypoglycaemic drugs, insulin), presence of complications such as retinopathy, neuropathy, amputations, foot ulcers, nephropathy (identified by protein in the urine



Figure 1 (a) Patient and clinician with touch screen clinical work station (TCW) and label printer. These are wall mounted to conserve space and improve security. The bar code scanner can be seen lying on the desk. (b) Patients' health passport with barcoded label and clinicians log in card.

which precipitates further investigation by serum creatinine), previous or current tuberculosis and HIV-serostatus (tested, positive and negative and whether on ART). For the purpose of this report, data were aggregated into new patients registered in quarter 3 (1 July to 30 September 2010) with cumulative numbers and outcomes up to 30 September 2010 and new patients registered in quarter 4 (1 October to 31 December 2010) with cumulative numbers and outcomes up to 31 December 2010. In this way, the report illustrates how continuity is maintained from one quarter to the next.

Results

The new DM clinic at QECH started in December 2009. All new patients registering after this time were entered

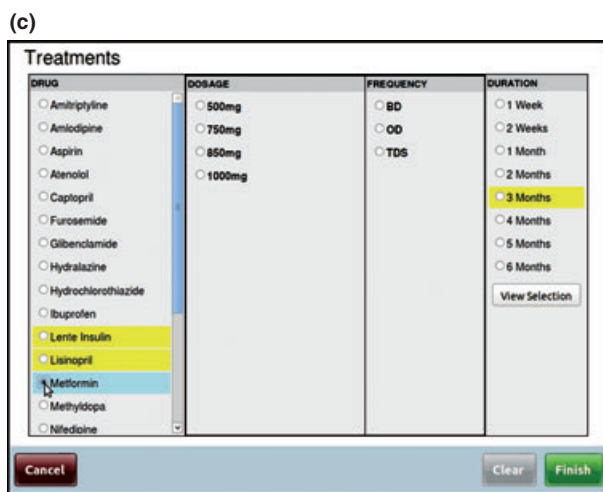
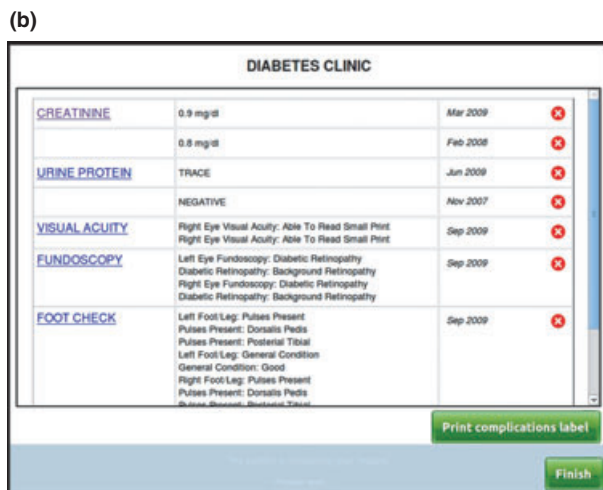
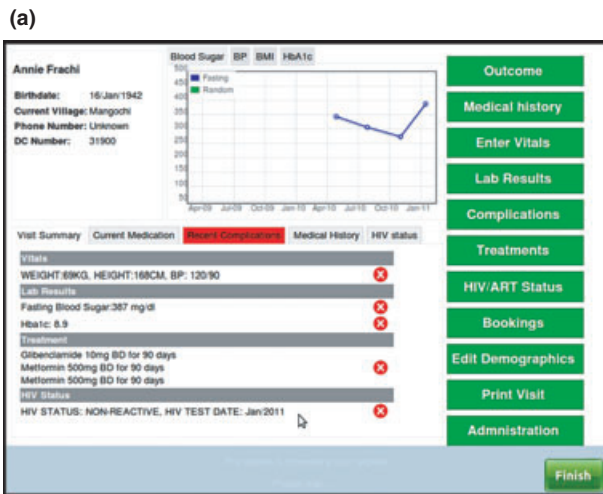


Figure 2 Screen shots of the electronic medical record (EMR): (a) The ‘patient dashboard’. This is the first screen encountered after accessing the patient’s EMR. The graphical display at the top of the screen can be switched between the measured variables (blood pressure, fasting blood glucose etc) by touching the grey ‘buttons’ above. Touching the green ‘buttons’ on the right of the screen leads to second level screens where new data can be entered and prescriptions can be made. New data entered during the consultation appears on the dashboard as text and is printed on a label that can be stuck in the health passport at the end of the consultation. (b) Complications record screen. (c) Electronic prescribing. The electronic formulary is limited to drugs relevant for diabetes and hypertension management. On this screen insulin and lisinopril have already been prescribed and metformin is being added.

into the database at their first visit, and most patients who had previously been seen in the clinic were registered during the first quarter of 2010. The cumulative number registered on 31 March 2010 was 1305. The second quarter started on 1 April 2010, and the number of new patients registered from 1 April to 30 June was 220. In the third quarter, 193 and in the fourth quarter 170 new patients were registered. The cumulative number ever registered by 31 December 2010 was 1864. Cohort output reports with quarterly and cumulative cohort analyses of DM patients, censored on 30 September and 31 December 2010, with treatment outcomes, are presented in Figure 3. At present, because of overcrowding in the clinic, not all clinicians have access to a TCW so data for some outcomes are, as yet, incomplete. Complications were common. A small number of patients particularly in the fourth quarter had a history of tuberculosis. Data on HIV and ART use are also captured.

Discussion

This is the first report to show how the DOTS monitoring system with quarterly and cumulative cohort analysis can be used to monitor and report on persons with DM in an African clinic. The number of new patients registered in the diabetes clinic for each quarter provides informative data on ‘new incident cases’ and over time reflects incident disease in the population served by the clinic as well as ease of patient access. The number of patients alive and registered in the clinic by 31 December 2010 provides informative data on ‘prevalent cases’. This is a vital piece of strategic information, indicating the current burden of disease as well as providing necessary data for rational drug forecasting and planning of logistics and staffing. These outcomes will become more reliable indicators of true incidence and prevalence once other, accessible diabetic clinics are established in the region and reporting is rolled out to these clinics. At present, the

(a)

Queen Elizabeth Central Hospital

Start Date: Thursday 01 July, 2010 End Date: Thursday 30 September, 2010

Patient Details	Quarterly Cohort (Jul - Sep, 2010)	Cumulative Cohort up to 30 Sep, 2010
Total Registered	193	1694
<i>Males</i>	81	656
<i>Females</i>	112	1038
<i>Outcome</i>		
Alive and on treatment	192	1635
Dead	0	3
Defaulters	0	53
Transfer Out	1	3
Stop Treatment	0	0
<i>Treatment Of Those Who Are Alive And On Treatment</i>		
Diet only	81	839
Oral hypoglycaemic agents only	73	516
Insulin only	19	170
Insulin and oral hypoglycaemic agents	19	110
Metformin	74	528
Glibenclamide	61	448
Lente Insulin	37	277
Soluble Insulin	4	19
<i>Complications Of Those Who Are Alive And On Treatment</i>		
Diabetic Retinopathy	11	121
Cataracts	0	38
Nephropathy	14	561
Neuropathy	32	260
Macrovascular	0	0
No recorded complications	153	1057
<i>TB Status Of All Patients Registered</i>		
TB Status Known	0	7
TB Ever	0	5
TB Since Diabetes Diagnosis	0	2
TB Status Unknown	193	1687
<i>HIV Status Of All Patients Registered</i>		
Reactive Not on ART	1	8
Reactive on ART	9	51
Non Reactive	0	0
Unknown	183	1635

Figure 3 Quarterly and cumulative cohort analyses of diabetes mellitus (DM) patients, censored on September 30th (Quarter 3 – Figure 3a) and December 31st 2010 (Quarter 4 – Figure 3b), with treatment outcomes, medication use and complications shown. Data entry for complications, TB and HIV status is ongoing and do not yet reflect the true prevalence of these conditions.

QECH clinic has a high number of self-referrals from a wide area, which confounds their interpretation. The total number of patients alive and in care combined with the new cases registered over each quarter, stratified in turn by type of oral hypoglycaemic drug and type of insulin, add precision to the complicated task of drug forecasting, which is critical to prevent drug stock-outs. The numbers

alive and in care with complications also allow rational planning for the referral and management of eye disease and surgical care (amputations and foot ulcers).

As this is a new clinic, deaths, defaults and patients who have stopped treatment or transfer-outs are few. The adverse outcomes of death, default and stopped treatment are a gauge for clinic performance as they indicate

(b)

Queen Elizabeth Central Hospital

Start Date: Friday 01 October, 2010 End Date: Friday 31 December, 2010

Patient Details	Quarterly Cohort (Oct - Dec, 2010)	Cumulative Cohort up to 31 Dec, 2010
Total Registered	170	1864
<i>Males</i>	80	736
<i>Females</i>	90	1128
<i>Outcome</i>		
Alive and on treatment	170	1805
Dead	0	3
Defaulters	0	53
Transfer Out	0	3
Stop Treatment	0	0
<i>Treatment Of Those Who Are Alive And On Treatment</i>		
Diet only	94	933
Oral hypoglycaemic agents only	56	572
Insulin only	14	184
Insulin and oral hypoglycaemic agents	6	116
Metformin	54	582
Glibenclamide	39	487
Lente Insulin	20	297
Soluble Insulin	2	21
<i>Complications Of Those Who Are Alive And On Treatment</i>		
Diabetic Retinopathy	9	122
Cataracts	0	38
Nephropathy	13	574
Neuropathy	7	267
Macrovascular	0	0
No recorded complications	151	1208
<i>TB Status Of All Patients Registered</i>		
TB Status Known	2	9
TB Ever	1	6
TB Since Diabetes Diagnosis	1	3
TB Status Unknown	168	1855
<i>HIV Status Of All Patients Registered</i>		
Reactive Not on ART	1	9
Reactive on ART	6	57
Non Reactive	0	0
Unknown	163	1798

Figure 3 (Continued).

'attrition' from care (Harries *et al.* 2009). Although compounded by considerable comorbidities in a setting such as Malawi, high death rates may indicate poor effectiveness of therapy and may be related to poor clinical access or late presentation for diagnosis and treatment. High rates of default or of patients stopping therapy indicate insufficient patient education about the disease including the necessity of continued treatment as well as practical and financial issues in accessing the clinic such as

lack of transport. The district hospitals in the region are in the process of setting up diabetes clinics based on the QECH model, and once these are established should improve access and reduce defaults. Patients do transfer out from one clinic to another for personal, family and occupational reasons, and this is not in itself an adverse outcome. However, if this treatment outcome is not taken into account, transfer-out and transfer-in can lead to double counting of patients at the national level.

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In addition to providing operational outcomes, we believe that the EMR facilitates better clinical care (Tierney *et al.* 2010). For some patients, the graphic feedback of parameters such as weight, fasting blood glucose and blood pressure can enhance the consultation and help promote disease understanding, diet and medication adherence. The system prompts clinicians for complication screening and stores information on complications in an accessible format. Knowledge about patients' HIV status is now considered to be an essential component of care in our clinic. Malawi is suffering from a dire HIV epidemic (National AIDS Commission 2005), and we recently demonstrated a HIV seroprevalence of 13% in adults attending our diabetes clinic (Cohen *et al.* 2010). There are many potential interactions between HIV infection and diabetes, including common presentations (e.g. weight loss and increased susceptibility to infection), possible worsening of microvascular complications (Cohen *et al.* 2010), and HIV-infected patients on ART might, over time, develop DM because of the recognised association between medication and the development of metabolic syndrome and type 2 DM, or patients with prior DM may experience worsening of control after starting ART (Mutimara *et al.* 2007; Wand *et al.* 2007). The 'HIV status' button on the electronic dashboard allows the clinician to rapidly see whether the HIV status of the patient is known and can promote discussion about HIV testing if needed.

Most clinicians have taken to using the system enthusiastically. When clinician numbers exceed the number of TCWs, there is competition in who will have access to a TCW. Similar enthusiasm by clinicians, for a point-of-care EMR, has been described in Kenya (Were *et al.* 2010). The training requirement when first using the system is less than half an hour, and once the baseline data fields are filled, updating the EMR at subsequent clinic visits is relatively quick. The EMR has also improved the ease and accuracy of prescribing. This can potentially reduce drug errors and allows us to instantaneously ascertain usage of the main essential drugs: glibenclamide, metformin, lente insulin and soluble insulin, which can be fed back to pharmacy for stock forecasting. Diabetes is now recognised to increase the risk of tuberculosis (Jeon & Murray 2008; Dooley & Chaisson 2009), and it is recommended that persons with diabetes are screened for tuberculosis on a regular basis. This information is captured in the EMR. Finally, by providing a database of all diabetic patients, the EMR has provided an infrastructural platform for audit and clinical research. During the use of the system, we have inevitably encountered areas that could be improved, and there is an ongoing process of refining the software, through working closely with the software team. The hardware has been described previously (Douglas *et al.*

2010) and is very reliable. Spare hardware is kept on-site, and data from the server are automatically backed up daily. We have not, to date, experienced any disruptions to the use of the system.

The EMR system performed well, allowing these cohort analyses to be performed at the touch of a button. The advantage of starting straight away with an electronic medical record is that no laborious and costly back entry of data is required from registers and treatment cards, as has been the case with antiretroviral therapy scale up in Malawi (Douglas *et al.* 2010), and clinical staff will also not be confronted in the future with the difficult decision of whether to use paper-based or electronic-based systems as it is additional work to keep both running simultaneously. A limitation of the cohort report presented in Figure 3 is that although registration and outcome data are complete, because of growing patient numbers and limited examination rooms, some patients are seen in 'ad hoc' locations without access to a TCW. Consequently, not all patient visits are documented in the system, resulting in an incomplete cohort report for medication use, complications, TB and HIV status. We are in the process of acquiring mobile TCWs that can be used in these ad hoc locations to overcome this challenge.

The diabetes clinic will now continue to register new patients and see established patients using the electronic medical record system, and quarterly and cumulative reports will be generated at the beginning of each quarter for the previous 3-month period. In due course, cohort survival outcome data can be generated from these reports, in the same way as for the antiretroviral clinics (Libamba *et al.* 2006), and this will allow clinicians and officers in charge of services to assess whether there has been improvement or deterioration over time. Before the DOTS model can be said to be truly applied to diabetes care, and for the model to become sustainable, it is important that other key principles are addressed, especially sustained political and financial commitment. We are involved in discussions with the Ministry of Health which we hope will make this possible. Plans are to expand the DOTS model to other district and mission hospitals in the southern region of the country and to the other main central hospital in Lilongwe, the capital city, and in this way develop a national health facility monitoring system that captures thorough clinical data on patients with diabetes.

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Corresponding Author AD Harries, Old Inn Cottage, Vears Lane, Colden Common, Winchester SO21 1TQ, UK.
Tel.: +44 (0) 1962 714 297; Fax: +44 (0) 1962 714 297; E-mail: adharries@theunion.org