Operational research on implementation of tuberculosis guidelines in Mozambique
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Citation for published version (APA):
Brouwer, M. A. (2015). Operational research on implementation of tuberculosis guidelines in Mozambique

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1. General introduction
Tuberculosis (TB) and Human Immunodeficiency virus (HIV) infections remain considerable public health challenges for many countries. Worldwide, the number of new HIV infections is declining.\(^1\) This also applies to sub-Saharan Africa though in 2012 still 70% of the world’s new infections occurred in this region. Of all new infections in sub-Saharan Africa, almost 50% occur in Southern Africa. In Mozambique alone, an estimated 120,000 new HIV infections occurred in 2012.

For TB, twenty-two high burden countries represent 80% of the world’s TB cases.\(^2\) In terms of estimated incidence and prevalence, Southern Africa bears the heaviest TB burden: of the five countries with the highest estimated TB incidence, four are in Southern Africa. According to the 2014 Global TB report, the incidence ranges from 552 per 100,000 population in Mozambique and Zimbabwe to 1,382 in Swaziland.\(^2\) HIV is one of the strongest risk factors for developing TB and has been the driving force for the TB incidence in the region.\(^3\)

The Directly Observed Treatment, Short course (DOTS) strategy has guided global TB control efforts since 1993.\(^4\) The strategy consist of several pillars including short course chemotherapy, direct observation of the intake of the medication during the first two months, notification and evaluation of reported patients, and ensuring the availability of medicines at all times. It became part of the Stop TB Strategy in 2006, which also included components to address the TB/HIV challenge.\(^5\) Policies and guidelines describe in more detail the interventions and activities to carry out the strategy. The purpose of guidelines in general is to improve patient care and assist in medical decision-making.\(^6\) Since 2009, the World Health Organization (WHO) uses an elaborate guideline development process, which includes a systematic review of the available evidence and an assessment of the quality of that evidence.\(^7\) The review and quality assessment result in recommendations. To finalize the formal guideline process, there is a need to disseminate, implement and evaluate these recommendations.

Most countries’ strategic TB plans to guide TB control at country level reflect the Stop TB Strategy. The TB national strategic plan 2008-2012 for Mozambique included most of its elements.\(^8\) TB manuals of countries present the translation and adaptation of these global strategies and guidelines to the local setting. It is mainly these TB manuals that guide the implementation and use of TB control interventions at the various levels of the health care system.

The translation of international policy and guidelines into national practice constitutes a major challenge.\(^9\) Reasons may be that relevant factors for effective guideline production as described by Thomson et al are not taken into account.\(^6\) These relevant factors are: the development group, the development itself and the presentation of the guidelines, dissemination, implementation and evaluation.

**Guideline development group**

The development of guidelines is usually a team effort. Key affected groups, including representatives from users, should participate in the development process.\(^10\) The team should have the necessary skills, such as scientific and group leadership, to develop the guideline.\(^6\) The team composition may influence implementation and adherence to the guidelines. A study evaluating adherence to TB contact tracing guidelines, concluded that representation of the end-users in the guideline development process could improve adherence to these guidelines.\(^11\)
Guideline development and presentation

The WHO handbook for guidelines development prescribes a format for WHO guidelines: an executive summary, a main body and appendices.\(^7\) The handbook recommends 1, 3 and 25 pages respectively as lengths for these sections. Thomson et al suggest that the proposed use determines the guideline format.\(^6\)

A study in Uganda evaluated how factors related to the guideline development process influenced health care service delivery.\(^12\) Presentation of the evaluated guidelines was mostly in the form of booklets, even though staff at the service delivery level often preferred charts because of the easy language and illustrative diagrams.

Dissemination

Dissemination of guidelines means making the guidelines available to those that should use them. This implies that the intended users are clear. In the Uganda study, many guidelines were for health care workers without specifying the level and the qualification of these workers.\(^12\) Also, dissemination did not occur systematically to all relevant levels. Dissemination approaches include through professional bodies, continuing medical education efforts, and relevant journals.\(^13\) The most common approach in sub-Saharan Africa is training of health care workers. Health care workers attend workshops where they receive a copy of the guidelines\(^14\) which they perceive as their personal copies. This limits availability to other health care workers and at the facility if the health care worker transfers to another facility.

Implementation

Implementation often involves a change in practice which could be achieved through addressing the knowledge, attitudes and practices of the professionals involved.\(^6\) This may not be sufficient. A variety of organisational aspects such as revision of professional roles, multidisciplinary teams, integrated care, knowledge and quality management contribute to achieve the desired change.\(^15\) Shifting tasks from medical doctors to non-doctor clinicians is an example of the revision of professional roles. Due to the shortage of medical doctors, Mozambique evaluated the quality of care of non-doctor clinicians for HIV-infected patients.\(^16\) The non-doctor clinicians received a 14-day training course on care for HIV-infected patients. The study found that in most clinical encounters with patients they did not adhere to the guidelines as taught in the course.

Another example where the organisation of an intervention did not lead to the desired improvements comes from Malawi in the early days of TB/HIV collaboration. Initiation of antiretroviral therapy (ART) in co-infected TB patients was postponed until they completed two months of TB treatment.\(^17\) This resulted in more difficulties to achieve the required change in practice, which was the provision of ART. The reason was that most patients had returned to their communities where few if any HIV treatment services were available. After returning to their communities and feeling better on TB treatment, patients were less likely to return to the hospital for ART. Had initiation of ART been integrated in the first two months of TB treatment while the patients still attended the hospital and felt more ill, ART coverage may have been higher.

Other factors relevant for implementation are support and leadership, and alignment with existing roles and tasks.\(^18\) Despite the embracing of operational or implementation research, there seems to be inadequate attention for implementation.\(^19\)
Evaluation

Newly emerging evidence necessitates the revision of guidelines periodically. The guideline development process includes evaluation that should also inform the revision of the guidelines. This does not seem to happen systematically, nor is it clear who should do the evaluation and how. The WHO handbook for guideline development includes only half a page on evaluation and monitoring compared to 7 pages on the assessment of the evidence. The half page provides very little practical information on carrying out an evaluation.

Recommendations made in guidelines should have an effect or outcome. Therefore guidelines should include measurable indicators to monitor the outcome of the guideline. However, measuring outcomes alone is not sufficient and it is necessary to take into account all parts of the development process. If the dissemination process occurred inadequately, one would not expect improved outcomes. To interpret the outcome indicators, baseline information or a reference value for the indicator is needed.

Research questions

The overall objective of this thesis is to assess how guideline implementation and evaluation contribute to health care decision-making and to assess what critical factors contribute to successful or unsuccessful implementation of TB control guidelines through case studies mainly conducted in Mozambique. We specifically evaluate two components of the guideline development process as outlined above, i.e. implementing guidelines and evaluation of guidelines.

The central research questions of this thesis are:

1. How can assessment of guideline implementation and its evaluation contribute to health care decision-making?

Guidelines support health care decision-making at both patient and health care service delivery level. To do so effectively, health care workers and decision-makers should use guidelines and monitor their outcomes. If this occurs either not or incompletely, the decision-making process lacks crucial information. This could lead to poor or no decision-making. In this thesis we evaluate outcomes described in guidelines with the aim to inform health care decision-making.

2. Which factors are critical for failure or success in guideline implementation?

Improved health care is one of the objectives of guidelines, however, implementation of these is often challenging. If the desired outcomes of guidelines are not achieved, assessment of the reasons for this need exploration. It seems logical to evaluate guideline implementation or the guideline itself, though this does not happen systematically. In this thesis we assess various aspects of guideline implementation to identify factors that contribute to failure and success of the implementation.

Guidelines assessed

To address these questions, the thesis focuses on guideline implementation and evaluation in a local context. It looks at several guidelines developed in the first decade of the 21st century when it became clear that the prevailing strategy for TB control, the DOTS strategy, was insufficient in the context of HIV. The HIV epidemic in many countries led to an increase in these countries’ TB case notifications. The global
willingness to provide care to HIV-infected individuals together with availability of funding created opportunities that did not exist before.

Studies had found that many HIV-infected patients died of TB and that provision of co-trimoxazole preventive therapy reduced the mortality for co-infected TB patients.\textsuperscript{22} Other studies identified TB clinics as a good entry point for testing for and diagnosing HIV infection.\textsuperscript{23} Centres for voluntary HIV testing proved good places to screen for TB.\textsuperscript{24} Isoniazid preventive therapy proved to protect HIV-infected individuals from TB although the effect was limited to a few years.\textsuperscript{25}

HIV and multi-drug resistant TB (MDR-TB) placed infection control back on the agenda.\textsuperscript{26} HIV-infected people have a vulnerability to develop TB disease soon after they acquire infection with HIV.\textsuperscript{27} MDR-TB has poorer treatment outcomes compared to drug-sensitive TB, and is much more costly to treat. An outbreak of MDR- and extensively drug resistant (XDR) TB in South Africa identified nosocomial transmission as the most important cause for the outbreak that had a high mortality in the mainly HIV-infected patients.\textsuperscript{28} Mozambique has the combined challenge of an high HIV prevalence\textsuperscript{29} and a relatively high percentage of new TB patients having MDR-TB (3.5%).\textsuperscript{30} MDR-TB is more frequent in HIV-infected people.\textsuperscript{30,31}

Several of these developments contributed to the development of the interim policy for TB/HIV collaborative activities in 2004.\textsuperscript{32} The policy recommends sets of activities for collaboration in health care facilities to decrease the burden of TB in people living with HIV (PLHIV), and to decrease the burden of HIV in TB patients. Intensified case finding, the provision of isoniazid preventive therapy and infection control in health care and congregate settings are the activities to decrease the burden of TB in PLHIV. HIV testing and counselling, HIV prevention methods, co-trimoxazole preventive therapy, HIV care and support, and provision of anti-retroviral therapy (ART) are the activities to reduce to burden of HIV in TB patients.

The WHO also published guidelines on the diagnosis of smear-negative and extrapulmonary TB,\textsuperscript{33} and on infection control in health care facilities.\textsuperscript{34} Smear-negative and extrapulmonary TB occur more frequently in HIV-infected people and are a diagnostic challenge in settings depending mainly on smear microscopy.\textsuperscript{35} Several studies found substantially higher notification rates of TB among health care workers in comparison with the general population. Nursing students in Zimbabwe had a much higher prevalence of TB infection compared to polytechnic school students.\textsuperscript{36} Hospital staff in Kenya had high TB notification rates and the risk for TB disease was higher for staff members that spend more hours with patients.\textsuperscript{37} These studies illustrated clearly that infection control needs strengthening.

Research setting

The studies of this thesis took place in Mozambique. The country notified an increasing number of TB patients since 1990 and reached almost 50,000 cases in 2012 (Figure 1).\textsuperscript{38} The estimated incidence in 2011 of 551 per 100,000 would result in almost 139,000 cases, suggesting that many TB cases remain undiagnosed.\textsuperscript{38}

Mozambique also faces a substantial HIV epidemic. A national population prevalence survey in 2009 showed that nationwide 11.5% of the adult population was infected with HIV.\textsuperscript{29} Prevalence within the country showed a large variation from 3.7% in Niassa province to 25.1% in Gaza province. Furthermore, prevalence was higher in women compared to men, and in urban areas compared to rural areas. Many TB patients in Mozambique are co-infected with HIV: in 2013, 91% of notified TB patients knew their HIV-status and 56% were HIV positive.\textsuperscript{2}
Mozambique became independent from Portugal in 1975. Soon thereafter the country entered into a civil war that lasted until the Peace Agreement in 1992. Conflict situations contribute to (re) emergence of infectious diseases through various mechanisms. Conflict situations may lead to a breakdown of the health care infrastructure including disruption of disease control programmes and reduced practice of infection control. It also leads to inadequate disease surveillance and increased movement of the population. Access of the population to health care services and of the health care services to reach out to the population for interventions may be reduced. In the prolonged civil war, many of these mechanisms also affected Mozambique’s infrastructure. Roads, schools and health care facilities were destructed and became dysfunctional.

The National TB Control Programme (Programa Nacional de Controlo de TB) has directed TB control in Mozambique since the 1980s. Mozambique practised the DOTS strategy already before it became the global policy because of the international support advising implementation of short course chemotherapy, direct observation of the intake of the medication during the first two months, evaluation, notification and ensuring availability of medicines. The country succeeded full implementation of the strategy only in 2000 because the war limited geographical expansion.

Mozambique adopted the interim policy for TB/HIV collaborative activities, the guidelines on the diagnosis of smear-negative and extrapulmonary TB and on infection control in health care facilities mainly through translation into Portuguese. Routine supervisory visits to districts and health care facilities in Mozambique identified several gaps and challenges related to the use of these guidelines. Health care workers in health care facilities and at district level did not always know how to use the guidelines. There was no system in place to assess their implementation. Although health care facilities and districts collect a substantial amount of data on a monthly or quarterly basis, they did not use the data to evaluate their performance. Also, countries including Mozambique spend a substantial amount of resources on the process of guideline development and implementation. Therefore an evaluation of guideline implementation at health care facility and district level seemed warranted.

Figure 1 Incident TB notifications in Mozambique 1990-2012
The studies took place in three provinces in central Mozambique: Manica, Sofala and Tete (Figure 2).

At the start of the studies in 2007, these three provinces had a population of 4.7 million, representing 23% of the country’s population. They notified 4,399 sputum smear-positive TB cases and 9,399 all forms of TB cases (National TB Programme data). This was 24 and 25% of the country’s total notification, respectively. The HIV prevalence in the provinces was 15.3% in Manica, 15.5% in Sofala and 7% in Tete Province.

The Ministry of Health provides guidelines for TB and HIV control activities in the country through the National TB Programme and the National Aids Control Programme (Programa Nacional de Controlo das IST/HIV/SIDA). The National TB Programme and the National Aids Control Programme distribute the guidelines through the provincial and district health offices to the health care facilities. Supervision occurs from one level to the next. Data flow moves the other direction: from health care facilities to the district that prepares an aggregated report for the province. Similarly, the provinces prepare an aggregated report for the national level. Review meetings take place at the various levels to discuss progress.

All districts keep a TB register with nominal TB notifications. Larger health care facilities also maintain a TB register, but smaller ones do report the TB notifications to the district where these enter into the district register.

Legend:
- Sm+ = smear-positive pulmonary tuberculosis
- AF = all forms of tuberculosis
- TB data concern number of notifications of the year 2007 and are from the national TB control programme. The population data come from the same source.

Figure 2 The three provinces of Mozambique where the research took place
Specific research questions

In order to answer the central research questions of 1) How can assessment of guideline implementation and its evaluation contribute to health care decision-making? and 2) Which factors are critical for failure or success in guideline implementation?, we formulated specific research questions.

The specific research questions are:

1. How can routinely available TB and HIV programme data facilitate evaluation of guideline implementation and assist in decision-making?

The evaluation of the guideline on ART use in chapter 2 investigates whether the TB programme misses opportunities for ART initiation because of non-availability of laboratory results. In chapter 3 we assess whether routinely available data are a good source for evaluating implementation of the use of ART in co-infected TB patients using completeness and correctness of data as the outcome measure. Chapter 4 evaluates the possibility to assess potential under-diagnosis of some forms of tuberculosis with routinely available data on TB cases and HIV prevalence.

2. What can we learn from users about the implementation of guidelines?

Chapter 5 describes how health care workers use the guideline on TB infection prevention and control. We evaluate how they use the measures as outlined in this guideline to reduce their occupational TB infection risk. Furthermore, it describes the challenges health care workers face in their work practice while using these guidelines.

3. What is the implementation status of current tuberculosis guidelines in Mozambique?

In chapter 6 we evaluate the level of implementation of selected TB infection prevention and control measures in health care facilities. In chapter 7 we assess a specific part of the guideline on TB infection prevention and control: the assessment of ventilation in rooms in health care facilities. We assess how to conduct measurement of air velocity, an essential component in ventilation assessment.
References